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RESERVATIONS: (202) 741–6008

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Presidential Documents

Title 3—

The President

Memorandum of July 22, 2010

Designation of the National Science and Technology Council to Coordinate Certain Activities Under the Arctic Research and Policy Act of 1984

Memorandum for the Director of the Office of Science and Technology Policy

By the authority vested in me as President by the Constitution and the laws of the United States, including the Arctic Research and Policy Act of 1984 (Title I of Public Law 98–373) (the "Act"), I hereby assign to the National Science and Technology Council (NSTC) responsibility to coordinate activities assigned in sections 107 and 108 of the Act to the Interagency Arctic Research Policy Committee, including through committees of the NSTC.

The Director of the Office of Science and Technology Policy is authorized and directed to publish this memorandum in the *Federal Register*.

THE WHITE HOUSE,
Washington, July 22, 2010.

[FR Doc. 2010–18642
Filed 7–27–10; 8:45 am]
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Rules and Regulations

Federal Register
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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.

FEDERAL RETIREMENT THRIFT INVESTMENT BOARD

5 CFR Parts 1604 and 1651

Uniformed Services Accounts and Death Benefits

AGENCY: Federal Retirement Thrift Investment Board.

ACTION: Final rule.

SUMMARY: The Federal Retirement Thrift Investment Board (Agency) is making several changes to its death benefits regulations. In particular, it is expanding the requirements necessary in order for a designation of beneficiary form to be valid. This change will also allow participants holding both a uniformed services and civilian account to submit a single designation of beneficiary form which can be used to designate beneficiaries for both accounts. The Agency is also amending its death benefit regulations to allow participants to designate a custodian under the Uniform Transfers to Minors Act as a beneficiary, permit the Agency to defer to state law when a potential beneficiary is implicated in the death of a participant and is subsequently found not guilty by reason of insanity, and require a notary to witness disclaimers of death benefits.

DATES: This rule is effective August 1, 2010.

FOR FURTHER INFORMATION CONTACT: Megan G. Grumbine at (202) 942–1644 or Laurissa Stokes at (202) 942–1645.

SUPPLEMENTARY INFORMATION: The Agency administers the TSP, which was established by the Federal Employees' Retirement System Act of 1986 (FERSA), Public Law 99–335, 100 Stat. 514. The TSP provisions of FERSA are codified, as amended, largely at 5 U.S.C. 8351 and 8401–79. The TSP is a tax-deferred retirement savings plan for Federal civilian employees and members of the uniformed services. The TSP is similar to cash or deferred arrangements established for private-sector employees under section 401(k) of the Internal Revenue Code (26 U.S.C. 401(k)).

On June 18, 2010, the Agency published a proposed rule with request for comments in the **Federal Register** (75 FR 34654, June 18, 2010). The Agency received comments from one Federal employees' union, two participants, and three other parties.

The Federal employees' union endorsed the proposed changes. The union expressed concern that the complexity of the Form TSP–3, Beneficiary Designation, and the multiplicity of its requirements will cause a large number of forms to be rejected as invalid. The union, however, noted with approval that the Agency stated in its proposed regulation that Agency staff will act quickly to review beneficiary designation forms and to alert participants of the need to correct any omissions or errors. The Agency intends to keep this commitment by assigning sufficient staff to this task.

The Federal employees' union also specifically noted its approval of the Agency's proposal to permit a participant to designate a custodian under the Uniform Transfers to Minors Act (UTMA) as the beneficiary of his or her TSP account. With respect to the requirement that the UTMA custodianship be established under the laws of the District of Columbia, the union asked the TSP to provide guidance to assure compliance with District of Columbia laws. Finally, the union suggested that the Form TSP–3 instructions be revised to explain the designation of a custodian under the UTMA and include an example to illustrate this fact pattern.

The Agency considered including an explanation of the designation of a custodian under the UTMA in the instructions to the Form TSP–3. But due to the complex financial and tax consequences of designating a custodian under the UTMA, the Agency wishes to discourage participants from making this decision without first obtaining expert advice. Moreover, the process of designating a custodian under UTMA requires a lengthy explanation, which the Agency believes would make the Form TSP–3 overly complex. Therefore, in response to this comment, the Agency created a special form for designating an UTMA custodian. This form will be made available on the TSP website and will include instructions to ensure that the designation is valid under the District of Columbia Uniform Transfers to Minors Act.

One participant commented simply to express his support for the proposed changes. Another participant commented to express frustration with unspecified aspects of the current rules for designating beneficiaries, as well as his hope that the revised rules will be less frustrating.

One commenter objected to the requirement to link the contingent beneficiary to a primary beneficiary because he believes the requirement is not clear. In response to this comment, the Agency is clarifying the language proposed for 5 CFR 1651.3(c)(7). The language in the proposed rule required a participant to "Match each contingent beneficiary to a primary beneficiary." This final rule replaces that language with the following: "For each contingent beneficiary, identify the primary beneficiary whose share the contingent beneficiary is to receive in the event the primary beneficiary dies before payment is made."

One commenter suggested that the proposed rule be changed to allow participants to designate one or more charities as a primary or contingent beneficiary. The Agency's regulations currently allow participants to designate one or more charities as a primary or contingent beneficiary. 5 CFR 1651.3(b). This proposed rule does not affect the participant's ability to designate a charity as a beneficiary.

Two of the commenters also objected to including the beneficiary's date of birth or social security number on the Form TSP–3. The proposed rule does not specifically require the participant to include the beneficiary's date of birth or social security number on the Form TSP–3. It does, however, require the participant to designate each primary and each contingent beneficiary in a manner so that the Agency can identify the individual or entity. The preamble to the proposed rule gave the date of birth or social security number as examples of information that would allow the TSP to identify the participant's beneficiary. The TSP needs sufficient information to identify the participant's beneficiary to ensure accurate processing and payment and to

reduce the processing time and resources necessary to identify beneficiaries.

One commenter requested clarification on whether the TSP will accept the designation of a testamentary trust. This commenter also requested that the TSP permit a per stirpital designation. These comments are outside the scope of the proposed rule under consideration.

The Agency appreciates the opportunity to review and respond to comments from participants who take an active interest in the TSP and offer suggestions. The comment process allowed the Agency to address any potential misunderstandings about the proposed changes, to consider unanticipated legal or policy impediments to the proposed changes, and to hear suggestions about how better to implement the proposed changes. Although the comments caused the Executive Director to make only one change to the text of the proposed rule, he did carefully consider each comment and addressed some of the concerns through other Agency guidance. Therefore, the Agency is publishing the proposed rule as final with a modification to the language proposed for 5 CFR 1651.3(c)(7).

Regulatory Flexibility Act

I certify that these regulations will not have a significant economic impact on a substantial number of small entities. They will affect only employees of the Federal Government.

Paperwork Reduction Act

I certify that these regulations do not require additional reporting under the criteria of the Paperwork Reduction Act.

Unfunded Mandates Reform Act of 1995

Pursuant to the Unfunded Mandates Reform Act of 1995, 2 U.S.C. 602, 632, 653, 1501 1571, the effects of this regulation on state, local, and tribal governments and the private sector have been assessed. This regulation will not compel the expenditure in any one year of $100 million or more by state, local, and tribal governments, in the aggregate, or by the private sector. Therefore, a statement under § 1532 is not required.

Submission to Congress and the Government Accountability Office

Pursuant to 5 U.S.C. 810(a)(1)(A), the Agency submitted 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 before publication of this rule in the **Federal Register**. This rule is not a major rule as defined at 5 U.S.C. 814(2).

List of Subjects

5 CFR Part 1604

Military personnel, Pensions, Retirement.

5 CFR Part 1651

Claims, Government employees, Pensions, Retirement.

Gregory T. Long,

Executive Director, Federal Retirement Thrift Investment Board.

■ For the reasons set forth in the preamble, the Agency amends 5 CFR chapter VI as follows:

PART 1604—UNIFORMED SERVICES ACCOUNTS

■ 1. The authority citation for part 1604 continues to read as follows:

Authority: 5 U.S.C. 8440e, 8474(b)(5) and (c)(1).

§ 1604.8 [Amended]

■ 2. Amend § 1604.8, by removing the second sentence of paragraph (a).

PART 1651—DEATH BENEFITS

■ 3. The authority citation for part 1651 continues to read as follows:

Authority: 5 U.S.C. 8424(d), 8432(j), 8433(e), 8435(c)(2), 8474(b)(5) and 8474(c)(1).

■ 4. Amend § 1651.3, by adding a fourth sentence to paragraph (b), and revising paragraph (c) to read as follows:

§ 1651.3 Designation of beneficiary.

* * * * *

(b)* * * A participant may designate a custodian under the Uniform Transfers to Minors Act provided that the custodianship is established under the laws of the District of Columbia and that the participant designates the custodianship using the Agency's designation of custodian form.

(c) *Validity requirements.* To be valid and accepted by the TSP record keeper, a TSP designation of beneficiary form must:

(1) Be received by the TSP record keeper on or before the date of the participant's death;

(2) Identify the participant in such a manner so that the Agency can locate his or her TSP account;

(3) Be signed and properly dated by the participant and signed and properly dated by two witnesses;

(i) The participant must either sign the form in the presence of the witnesses or acknowledge his or her signature on the form to the witnesses;

(ii) All submitted and attached pages must be signed by the participant, dated by the participant, and witnessed in the same manner (by the same witnesses) as the form itself and must follow the format of the TSP designation of beneficiary form;

(iii) A witness must be age 21 or older; and

(iv) A witness designated as a beneficiary will not be entitled to receive a death benefit payment; if a witness is the only named beneficiary, the designation of the beneficiary is invalid. If more than one beneficiary is named, the share of the witness beneficiary will be allocated among the remaining beneficiaries pro rata.

(4) Designate primary beneficiary shares which when summed equal 100%;

(5) Contain no substantive alterations (e.g., struck-through shares or scratched-out names of beneficiaries);

(6) Designate each primary and each contingent beneficiary in such a manner so that the Agency can identify the individual or entity; and

(7) For each contingent beneficiary, identify the primary beneficiary whose share the contingent beneficiary is to receive in the event the primary beneficiary dies before payment is made.

* * * * *

■ 5. Amend § 1651.12, by revising the second sentence to read as follows:

§ 1651.12 Homicide.

* * * If the beneficiary is implicated in the death of the participant and the beneficiary would be precluded from inheriting under state law, the beneficiary will not be entitled to receive any portion of the participant's account. * * *

■ 6. Amend § 1651.17, by revising paragraph (b)(2) to read as follows:

§ 1651.17 Disclaimer of benefits.

* * * * *

(b) * * *

(2) Signed or acknowledged, in the presence of a notary, by the person (or legal representative) disclaiming the benefit; and

* * * * *

[FR Doc. 2010–18436 Filed 7–27–10; 8:45 am]

BILLING CODE 6760–01–P

DEPARTMENT OF AGRICULTURE

Commodity Credit Corporation

7 CFR Part 1410

RIN 0560–AH80

Conservation Reserve Program

AGENCY: Commodity Credit Corporation, USDA.

ACTION: Interim rule.

SUMMARY: The Commodity Credit Corporation (CCC) is amending the Conservation Reserve Program (CRP) regulations to implement provisions of the Food, Conservation, and Energy Act of 2008 (the 2008 Farm Bill). The 2008 Farm Bill generally extends the existing CRP through 2012 with some changes in eligibility requirements. The changes in this rule include adding alfalfa to the definition of agricultural commodity for the purposes of determining cropping history, adding incentives for limited resource farmers and Indian tribes, adding pollinator habitat incentives, adding a provision allowing preference for local residents in accepting competitive offers, adding an additional waiver provision to exclude certain acreage for CRP county acreage maximums, and clarifying the limited harvesting and grazing activities that may be allowed on CRP land. The purpose of CRP is to cost-effectively assist producers in conserving and improving soil, water, wildlife, and other natural resources by converting environmentally-sensitive acreage from the production of agricultural commodities to a long-term vegetative cover and to address issues raised by State, regional and national conservation initiatives.

DATES: *Effective Date:* This rule is effective July 28, 2010.

Comment Date: We will consider comments that we receive by September 27, 2010.

ADDRESSES: We invite you to submit comments on this interim rule. In your comment, include the volume, date, and page number of this issue of the **Federal Register**. You may submit comments by any of the following methods:

- *Federal eRulemaking Portal:* Go to *http://www.regulations.gov.* Follow the online instructions for submitting comments.
- *Mail:* Director, Conservation and Environmental Programs Division (CEPD), USDA FSA CEPD, Mail Stop 0513, 1400 Independence Ave, SW., Washington, DC 20250–0513.
- *Hand Delivery or Courier:* Deliver comments to the above address.

Comments may be inspected at the mail address listed above between 8:00 a.m. and 4:30 p.m., Monday through Friday, except holidays. A copy of this interim rule is available through the U.S. Department of Agriculture (USDA) Farm Service Agency (FSA) home page at *http://www.fsa.usda.gov/.*

FOR FURTHER INFORMATION CONTACT: Beverly J. Preston, CRP Program Manager, USDA FSA CEPD, Mail Stop 0513, 1400 Independence Ave, SW., Washington, DC 20250–0513 at, 1400 Independence Avenue, SW., Washington, DC 20250–0513; telephone: (202) 720–9563; e-mail: *beverly.preston@wdc.usda.gov.* Persons with disabilities who require alternative means for communication (Braille, large print, audiotape, etc.) should contact the USDA Target Center at 202–720–2600 (voice and TDD).

SUPPLEMENTARY INFORMATION:

Background

This rule amends CRP regulations in 7 CFR part 1410 to implement certain changes to CRP as required by the 2008 Farm Bill (Pub. L. 110–246). This is the third of three interim rules that CCC has published to implement 2008 Farm Bill changes to CRP. On June 29, 2009, (74 FR 30907–30912) CCC published an interim rule to implement CRP provisions in the 2008 Farm Bill regarding farmable wetlands, thinning of trees to improve the condition of resources, income and payment limitations, and address issues raised by State, regional, and National conservation initiatives.

On May 14, 2010, (75 FR 27165–69) CCC published an interim rule to implement provisions in the 2008 Farm Bill regarding transition incentives for CRP participants with expiring contracts to sell or lease the land to a beginning or socially disadvantaged farmer or rancher.

This interim rule implements the remaining 2008 Farm Bill CRP provisions, which include updating cropping history requirements, adding an additional waiver provision as an exclusion to exceed the 25 percent of the county cropland CRP acreage maximum, adding an acceptability-of-offer provision to allow local resident preference, and clarifying permissive uses of CRP land. It also adds provisions for pollinator habitat incentives and incentives for limited resource farmers and ranchers and Indian tribes. This rule also updates dates and makes minor plain language improvements. This interim rule is effective on publication, but is subject to modification after the consideration of comments. After the comment period closes, CCC expects to publish a final rule that will discuss the comments and implement any amendments determined to be justified based on a review of the comments.

CRP participants enroll land under contracts for 10 to 15 years in exchange for annual rental payments and financial assistance to install certain conservation practices and to maintain approved vegetative, tree, or other appropriate covers. A wide range of conservation practices may be enrolled under CRP including, for example, introduced and native grasses and legumes, hardwood trees, wildlife habitat, grass waterways, filter strips, riparian buffers, wetlands, rare and declining habitat, upland bird habitat, longleaf pine, and duck nesting habitat. The basic structure and nature of CRP remains the same.

Definitions

This rule amends § 1410.2, "Definitions," to add a definition for "pollinator." The 2008 Farm Bill allows the Secretary to add the development of pollinator habitat and practices to encourage native and managed pollinators to any of the USDA conservation programs. The 2008 Farm Bill does not define "native or managed pollinator." This rule adds a definition of "pollinator" to mean "an insect or other animal that carries pollen from one flower to another." Other animals would include birds and bats.

Consistent with section 2105 of the 2008 Farm Bill, this rule also adds alfalfa, other multi-year grasses, and legumes grown in rotation to the definition of "agricultural commodity." This will permit, for example, land with alfalfa grown under a long-term rotation with another agricultural commodity to meet the cropping history requirement for eligible land.

This rule adds definitions for "limited resource farmer or rancher" and "Indian tribe" that are consistent with the definitions used for other USDA programs and with the 2008 Farm Bill. The 2008 Farm Bill gives the term "Indian tribe" the definition given under section 4(e) of the Indian Self-Determination and Education Assistance Act (25 U.S.C. 450b(e)). In implementing the Indian Self-Determination and Education Assistance Act, the Department of the Interior, Bureau of Indian Affairs, and the Department of Health and Human Services, Indian Health Service, established the definition of "Indian tribe" in 25 CFR 900.6. This rule adds that definition to 7 CFR 1410.2. The definition of "limited resource farmer or

rancher" in this rule is consistent with the definition that applies under the regulations for the Environmental Quality Incentives Program (EQIP) at 7 CFR 1466.3. These definitions are needed because this rule adds authority to provide additional incentives for enrollment of Indian tribes and limited resource farmers and ranchers.

This rule amends the definitions for "conserving use" and "considered planted" to update the period of time—to the period 2002 through 2007—that is considered for land use history. This change is consistent with other updates to the cropping history requirement for eligible land, as described below, required by the 2008 Farm Bill.

Maximum County Acreage

This rule amends § 1410.4, "Maximum County Acreage," to add an additional waiver provision as an exclusion of certain acreage enrolled under CRP. Under the current regulations, the amount of cropland that may be enrolled under CRP and the Wetlands Reserve Program, as specified in § 1410.4, may not exceed 25 percent of a county's total cropland unless CCC waives this cap. To implement a waiver, CCC must determine that enrolling additional land would not adversely affect the local economy of the county and that operators in the county are having difficulties complying with conservation plans implemented under 7 CFR part 12. The existing waiver provisions are not changed with this rule. This rule adds an additional waiver provision specifying that CCC may exclude high-priority continuous signup acreage, including acreage in the Conservation Reserve Enhancement Program (CREP), Farmable Wetlands Program (FWP), or State Acreage for Wildlife Enhancement (SAFE) Program, from the 25 percent cropland limitation, if the county government agrees. The 2008 Farm Bill specifies that the Secretary may implement the waiver to exclude for high-priority acreage; it does not require CCC to do so.

Under CRP, eligible land may be enrolled competitively during publicly announced general signups. An environmental benefits index (EBI) to optimize costs and benefits is used for competitive enrollment. When an offer is made, FSA collects data for a number of factors for each piece of ground offered into CRP. Each offer is assigned a point score based on its relative environmental factors and competes with all other offers. Offer acceptability is determined based on the ranking results. Generally, FSA has used these EBI factors to assess the environmental benefits for the land offered:

- Wildlife habitat benefits;
- Water quality benefits from reduced erosion, runoff, and leaching;
- On-farm benefits from reduced erosion;
- Benefits that will likely endure beyond the contract period;
- Air quality benefits from reduced wind erosion; and
- Cost.

Land may also be enrolled non-competitively on a continuous basis if the land meets certain criteria. That is not changing with this rule. Non-competitive continuous enrollment is available for certain high-priority practices including, but not limited to, filter strips, wetlands, buffers, grass waterways, land enrolled under CREP, FWP, and for certain initiatives such as wetland restoration, longleaf pine restoration, quail habitat, and SAFE. This rule amends the regulations to allow the special high-priority land including acreage in CREP, FWP, or SAFE Program to be excluded from the 25 percent maximum county acreage limit if the county government agrees.

Eligible Land

As provided for in the existing CRP regulations in § 1401.6, "Eligible Land," eligible land for CRP must be cropland with a history of production of tillable crops or marginal pastureland. The purpose of this eligibility requirement, which is not changing with this rule, is to ensure CRP is used to convert environmentally-sensitive land to a long-term environmentally-beneficial cover crop.

As provided in the 2008 Farm Bill, this rule amends § 1410.6, "Eligible Land," to change the dates of the cropping history required for certain cropland to be eligible. In the current regulation, eligible cropland must have been planted or considered planted for four of the six years during the period of 1996 through 2001. This rule amends that section to modify the cropping history dates to the four of the six years during 2002 through 2007. This rule also updates this section to refer to CCC rather than the Deputy Administrator to reflect more consistently that the program is a CCC program. References to the dates for expiring Water Bank Program contracts are removed from the eligibility requirements for marginal pastureland because all such contracts have already expired.

Acceptability of Offers

This rule amends § 1410.31, "Acceptability of Offers," to add the 2008 Farm Bill specified "local preference" as a factor in offer acceptability. This means that CCC may preferentially accept offers from residents of the county or a contiguous county where the land is offered for enrollment, provided that offer has at least equal expected benefits to offers from non-resident landowners. Section 2110 of the 2008 Farm Bill requires the Secretary to give preference to such offers.

Permissive Uses of CRP Land

The CRP regulations limit the uses of CRP land to a list of uses specified in § 1410.63 "Permissive Uses." The intent is to ensure that CRP land is not used for activities that would tend to defeat the conservation purposes of the program. Permissive uses must be consistent with the conservation of soil, water quality and wildlife habitat, including habitat during nesting season for birds in the area. To achieve this goal, section 2108 of the 2008 Farm Bill clarifies the specific restrictions on managed harvesting, grazing, other commercial uses of forage on CRP land, and installation of wind turbines. Therefore, § 1410.63 is amended to implement the specific permissive uses, and permissive use restrictions, as specified in the 2008 Farm Bill. The amendments to permissive uses are as follows:

- Provisions for managed harvesting and grazing uses are revised and clarified, as specified in the 2008 Farm Bill. Specific types of harvesting and grazing are allowed, in exchange for a payment reduction as determined by CCC. The provision for "haying" is removed, but haying is understood to be a type of harvesting. Managed harvesting provisions are expanded to include uses in addition to biomass harvest, in exchange for a payment reduction as determined by CCC. The specific requirement for harvesting biomass not more than once every three years is removed, but CCC will continue to require that biomass harvesting and any other harvesting not defeat the conservation purposes of the contract. Appropriate vegetation management requirements for the land will apply including the timing, frequency, and duration that is consistent with the purposes of CRP. Managed harvesting will be conducted according to an approved CRP conservation plan.
- Routine grazing, in exchange for a payment reduction, is added as a permissive use, as specified in the 2008 Farm Bill. Appropriate vegetation management requirements and stocking rates for the land will apply, as appropriate, consistent with the Natural Resources Conservation Service (NRCS) Field Office Technical Guide (FOTG) grazing standards that are suitable for

continued routine grazing. The allowed frequency and timing of routine grazing will take into account regional differences that are consistent with the purposes of CRP according to an approved CRP conservation plan. The provision for managed grazing that is incidental to the gleaning of crop residue is removed, but this practice is understood to be a type of routine grazing.

• Prescribed grazing to control invasive species, in exchange for a payment reduction, is added as a permissive use, as specified in the 2008 Farm Bill. Appropriate vegetation management requirements and stocking rates for the land will apply. The allowed frequency of prescribed grazing will take into account regional differences that are consistent with the purposes of CRP according to an approved CRP conservation plan. Invasive species such as kudzu and leafy spurge will be targeted.

• Harvesting, grazing, or other commercial use of forage allowed in response to a drought or other emergency, is added as a permissive use in exchange for a payment reduction. Emergency haying and grazing has been allowed in the past, in response to droughts and other emergencies, but was not specified as a permitted use in the CFR.

• Wind turbine installation provisions are revised; the 2008 Farm Bill requires a payment reduction for this use.

The following permissive use provisions in § 1410.63 remain unchanged:

• The general provision that the permissive uses in this section may be allowed, but are not automatically allowed, is unchanged.

• Commercial shooting preserve use provisions are unchanged.

• Spot grazing use provisions are unchanged.

• Forestry maintenance use provisions are unchanged.

• Sale of carbon, water quality, or other environmental credits provisions are unchanged.

As noted above, in § 1410.63, there is the general provision that the permissive uses may be allowed, but are not automatically allowed. All of the permissive uses in § 1410.63 require approval by CCC, which also means that they may not be approved for use in a particular region or for a specific CRP contract. CCC will exercise the discretionary authority provided in section 2108 of the 2008 Farm Bill to determine which activities will be approved for specific CRP contracts.

As noted above, the 2008 Farm Bill requires a payment reduction for the permissive use for wind turbine installation. All of the permissive uses except commercial shooting preserves and sale of carbon, water quality, or other environmental credits will, as in the past, require a payment reduction as determined by CCC. The reduction for the installation of wind turbines is new. The 2008 Farm Bill requires the payment reduction, but gives CCC discretionary authority as to the amount of the reduction.

Incentives for Native and Managed Pollinator Habitat, Limited Resource Farmers and Ranchers, and Indian Tribes

Section 2708 of the 2008 Farm Bill allows, but does not require, the Secretary to add provisions to encourage the development of habitat for, and use of conservation practices to benefit, native and managed pollinators. Accordingly, this rule adds a new paragraph to § 1410.62 "Miscellaneous," to add a provision that will allow approval of practices to encourage the development of habitat for, and use of conservation practices to benefit, native and managed pollinators. FSA, working with NRCS and State technical committees, will develop and define conservation practice standards that provide habitats for pollinators. The requirements in those practices for acreage and other characteristics of habitat will take into account appropriate habitat needs relevant to specific geographical areas and species.

Section 2708 of the 2008 Farm Bill also allows the Secretary to provide special incentives for certain categories of participants, including Indian tribes and limited resource farmers and ranchers. This rule therefore amends § 1410.62, "Miscellaneous," to add incentives for Indian tribes and for limited resource farmers and ranchers. Implementation of the incentives will be coordinated with other USDA programs that provide assistance, including CRP technical assistance, to these farmers and ranchers. Implementation will be subject to funding availability and acreage limits that apply to CRP as a whole.

Notice and Comment

CCC is not required by 5 U.S.C. 553 or any other provision of law to publish a notice of proposed rulemaking with respect to the subject matter of this rule. CCC is authorized by section 2904 of the 2008 Farm Bill to issue an interim rule effective on publication with an opportunity for comment.

Executive Order 12866

This rule has been determined to be economically significant and was reviewed by the Office of Management and Budget (OMB) under Executive Order 12866. A Cost Benefit Analysis is summarized below and is available from the contact information listed above.

Cost Benefit Analysis

The changes to CRP in this rule are expected to cost about $6.7 million per year over ten years (2011–2020). This is a net cost that reflects roughly $77 million in additional CRP payments to participants over the next ten years for additional land enrolled through the county maximum acreage waivers to exclude certain acreage and revised cropping history requirements and payments for pollinator habitat practices, minus roughly $10 million in reduced payments for the revised permissive uses. The benefits to participants will be the net additional $6.7 million per year over the next ten years. There are expected to be additional non-quantifiable environmental benefits from the waivers to exclude that will allow more environmentally sensitive acres to be enrolled through continuous signup, from additional highly erodible land enrollment that could result from making land in long-term hay rotations eligible, and from the incentives for pollinator habitat.

The other provisions in this rule, such as local preference, are expected to have little to no cost. These provisions will largely substitute one CRP participant for another, or one practice for another, leading in a shift in costs and benefits to different participants and practices, but little net cost or benefit for CRP as a whole.

Regulatory Flexibility Act

It has been determined that the Regulatory Flexibility Act is not applicable to this interim rule because CCC is not required by 5 U.S.C. 553 or any other provision of law to publish a notice of proposed rulemaking for this rule. CCC is authorized by section 2904 of the 2008 Farm Bill to issue an interim rule effective on publication with an opportunity for comment.

Environmental Evaluation

In 2003, FSA, on behalf of CCC, finalized a Programmatic Environmental Impact Statement (PEIS) for the reauthorization of the CRP in Title II of the Farm Security and Rural Investment Act of 2002 (2002 Farm Bill) and published a Record of Decision (ROD). Consistent with provisions in 40 CFR 1508.28, in order to focus primarily on

the issues relevant to this specific rule and not duplicate material found in the 2003 EIS, FSA tiered a Programmatic Environmental Assessment (PEA) on select provisions of the 2008 Farm Bill for CRP to the 2003 PEIS; tiering is appropriate when the sequence of analysis is lesser in scope than the initial programmatic statement.

The PEA incorporated by reference general discussions and analysis from the 2003 PEIS to assess potential environmental impacts associated with implementation of only those non-discretionary provisions identified in this rule for CRP consistent with the 2008 Farm Bill. The Final PEA and Finding of No Significant Impact (FONSI) on select provisions of the 2008 Farm Bill for CRP was published in the **Federal Register** on December 16, 2008 (73 FR 76331–76332) for public review and comment. The proposed changes analyzed in the PEA were separate and distinct from the proposals for discretionary changes examined in the 2010 Final Supplemental Environmental Impact Statement (Final SEIS). For those 2008 Farm Bill changes not examined in the PEA where discretion was exercised, FSA published a Final SEIS to the 2003 Programmatic Environmental Impact Statement (PEIS) on CRP on February 19, 2010, (75 FR 7438–7440) for public comment and review.

On behalf of the Commodity Credit Corporation, FSA prepared a Final Supplemental Environmental Impact Statement (SEIS) for CRP and the Notice of Availability (NOA) was published in the **Federal Register** (FR) on June 18, 2010 (75 FR 34737–34738). Based on a thorough evaluation of the resource areas affected by CRP, a detailed analysis of the Alternatives, and a comprehensive review of public comments, FSA has issued a Record of Decision (ROD). This decision was made after comparing overall environmental impacts and other relevant information with regard to the reasonable alternatives considered in the Final SEIS. The ROD can be found on FSA's Web site: *http://www.fsa.usda.gov/FSA/webapp?area=home&subject=ecrc&topic=nep-cd.*

Executive Order 12372

This program is not subject to Executive Order 12372, which requires consultation with State and local officials. See the notice related to 7 CFR part 3015, subpart V, published in the **Federal Register** on June 24, 1983 (48 FR 29115).

Executive Order 12988

This rule has been reviewed under Executive Order 12988, Civil Justice Reform. This final rule is not retroactive and does not preempt State or local laws, regulations, or policies unless they represent an irreconcilable conflict with this rule. Before any judicial action may be brought regarding provisions of this rule, the administrative appeal provisions of 7 CFR parts 11, 624, and 780 must be exhausted.

Executive Order 13132

The policies contained in this rule do not have any substantial direct effect on States, on the relationship between the Federal government and the States, or on the distribution of power and responsibilities among the various levels of government. Nor does this rule impose substantial direct compliance costs on State and local governments. Therefore, consultation with the States is not required.

Executive Order 13175

The policies contained in this rule do not have tribal implications that preempt tribal law.

USDA will undertake, within 6 months after this rule becomes effective, a series of regulation Tribal consultation sessions to gain input by Tribal officials concerning the impact of this rule on Tribal governments, communities, and individuals. These sessions will establish a baseline of consultation for future actions, should any become necessary, regarding this rule. Reports from these sessions for consultation will be made part of the USDA annual reporting on Tribal Consultation and Collaboration. USDA will respond in a timely and meaningful manner to all Tribal government requests for consultation concerning this rule and will provide additional venues, such as webinars and teleconferences, to periodically host collaborative conversations with Tribal leaders and their representatives concerning ways to improve this rule in Indian country.

Unfunded Mandates

This rule contains no Federal mandates under the regulatory provisions of Title II of the Unfunded Mandate Reform Act of 1995 (UMRA, Pub. L. 104–4) for State, local, or tribal governments, or the private sector. In addition, CCC is not required to publish a notice of proposed rulemaking for this rule. Therefore, this rule is not subject to the requirements of sections 202 and 205 of UMRA.

Small Business Regulatory Enforcement Fairness Act of 1996

This rule has been determined to be Major under the Small Business Regulatory Enforcement Fairness Act of 1996, (Pub. L. 104–121) (SBREFA). SBREFA normally requires that an agency delay the effective date of a major rule for 60 days from the date of publication to allow for Congressional review. Section 808 of SBREFA allows an agency to make a major regulation effective immediately if the agency finds there is good cause to do so. Section 2904(c) provides that the authority in Section 808 of SBREFA will be used in implementing the 2008 Farm bill changes to the CRP. Consistent with section 2904(c) of the 2008 Farm Bill, FSA finds that it would be contrary to the public interest to delay implementation of this rule because it would significantly delay implementation of the program changes required by the 2008 Farm Bill by impeding the conduct of future general signups without having these additional changes to the program regulations in place. Therefore, this rule is effective on the date of its publication in the **Federal Register**.

Federal Domestic Assistance Program

The title and number of the Federal Domestic Assistance Program in the Catalog of Federal Domestic Assistance to which this rule applies is the Conservation Reserve Program—10.069.

Paperwork Reduction Act

The regulations in this rule are exempt from the requirements of the Paperwork Reduction Act (44 U.S.C. Chapter 35), as specified in section 2904 of the 2008 Farm Bill, which provides that these regulations be promulgated and the programs administered without regard to the Paperwork Reduction Act.

E-Government Act Compliance

CCC 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.

List of Subjects in 7 CFR Part 1410

Administrative practice and procedure, Agriculture, Environmental protection, Grant programs—Agriculture, Natural resources, Reporting and recordkeeping requirements, Soil conservation, Technical assistance, Water resources, Wildlife.

■ For the reasons explained above, this rule amends 7 CFR part 1410 as follows:

PART 1410—CONSERVATION RESERVE PROGRAM

■ 1. The authority citation for 7 CFR part 1410 continues to read as follows:

Authority: 15 U.S.C. 714b and 714c; 16 U.S.C. 3801–3847.

■ 2. Amend § 1410.2 as follows:
■ a. Revise the definition in paragraph (b) for "Agricultural commodity" to read as set forth below;
■ b. Add definitions in paragraph (b), in alphabetical order, for "Indian tribe," "Limited resource farmer or rancher," and "Pollinator" to read as set forth below;
■ c. Amend the definition of "Conserving use" by removing the words "1996 through 2001" each time they appear and adding, in their place, the words "2002 through 2007"; and
■ d. Amend the definition of "Considered planted" by removing the words "or will expire during calendar year 2000, 2001, or 2002".

§ 1410.2 Definitions.

* * * * *

(b) * * *

Agricultural commodity means:

(1) Any crop planted and produced by annual tilling of the soil or on an annual basis by one-trip planters,

(2) Sugarcane planted or produced in a State, or

(3) Alfalfa and other multi-year grasses and legumes grown in a rotation practice as approved by CCC.

* * * * *

Indian tribe means any Indian tribe, band, nation, or other organized group, or community, including pueblos, rancherias, colonies and any Alaska Native Village, or regional or village corporation as defined in or established pursuant to the Alaska Native Claims Settlement Act (43 U.S.C. 1601–1629h), which is recognized as eligible for the special programs and services provided by the United States to Indians because of their status as Indians.

* * * * *

Limited resource farmer or rancher means:

(1) A person with direct or indirect gross farm sales of not more than $155,200 in each of the previous two calendar years preceding the year of enrollment (adjusted for inflation using Prices Paid by Farmer Index as compiled by the USDA National Agricultural Statistics Service), and

(2) A total household income at or below the national poverty level for a family of four, or less than 50 percent of county median household income in each of the previous two years (to be determined annually using U.S. Department of Commerce data).

* * * * *

Pollinator means an insect or other animal that carries pollen from one flower to another.

* * * * *

■ 3. Revise § 1410.4(b) to read as follows:

§ 1410.4 Maximum county acreage.

* * * * *

(b) The restrictions in paragraph (a) of this section may be waived by CCC as follows:

(1) If CCC determines that such action would not adversely affect the local economy of the county and that operators in the county are having difficulties complying with conservation plans implemented under part 12 of this title; or

(2) Cropland in a county enrolled under continuous signup provisions as specified in § 1410.30 or § 1410.50 may be excluded from the restrictions in paragraph (a) of this section, as determined by CCC, provided that the county government concurs.

* * * * *

§ 1410.6 [Amended]

■ 4. Amend § 1410.6 as follows:
■ a. In paragraphs (a)(1), (a)(2) introductory text, (a)(2)(i)(B), (a)(2)(i)(C), (a)(2)(ii) introductory text, (a)(2)(ii))B), (a)(3), (b)(1) introductory text, (b)(2)(iii), (b)(6), (b)(7), (b)(11), (b)(12), (c) introductory text and (c)(3), remove the words "the Deputy Administrator" each time they appear and add, in their place, the word "CCC",
■ b. In paragraph (a)(1), remove the words "1996 through 2001" and add, in their place, the words "2002 through 2007",
■ c. Remove paragraph (a)(2)(i),
■ d. Redesignate paragraph (a)(2)(ii) as paragraph (a)(2)(i) and reserve paragraph (a)(2)(ii), and
■ e. In newly redesignated paragraph (a)(2)(i), introductory text, second sentence, add the word "by" before the word "CCC".

■ 5. Amend § 1410.31 to redesignate paragraph (c) as paragraph (d) and to add new paragraph (c) to read as follows:

§ 1410.31 Acceptability of offers.

* * * * *

(c) Notwithstanding paragraph (b) of this section, when all other appropriate factors are equivalent, CCC may give preference to offers from residents of the county or contiguous county where the offered land is located.

* * * * *

■ 6. Amend § 1410.62 as follows:
■ a. In paragraph (g), remove the words "beginning and socially disadvantaged" and add, in their place, the words "Indian tribes and beginning, limited resource, and socially disadvantaged" and
■ b. Add paragraph (h) to read as follows:

§ 1410.62 Miscellaneous.

* * * * *

(h) As determined by CCC, consistent with the purposes of CRP, the development of habitat for, and use of conservation practices for, native and managed pollinators may be authorized.

■ 7. Amend § 1410.63 by revising paragraph (c) to read as follows:

§ 1410.63 Permissive uses.

* * * * *

(c) The following activities may be permitted, as determined by CCC, on CRP enrolled land insofar as they are consistent with the conservation purposes of the program including timing, frequency, and duration as provided in an approved CRP conservation plan that identifies appropriate vegetative management requirements:

(1) Managed harvesting, including harvest of biomass, but only in exchange for a payment reduction as determined by CCC and in accordance with harvest frequency and timing of harvesting activities outside the official nesting and broodrearing season only as identified in an approved CRP conservation plan;

(2) Routine grazing, but only in exchange for a payment reduction as determined by CCC and in accordance with appropriate vegetative management requirements and stocking rates for the land, grazing frequency, and grazing periods outside the official nesting and broodrearing season only as identified in an approved CRP conservation plan;

(3) Prescribed grazing to control invasive species, but only in exchange for a payment reduction as determined by CCC and in accordance with appropriate vegetative management requirements and stocking rates for the land, grazing frequency, and grazing periods outside the official nesting and broodrearing season only as identified in an approved CRP conservation plan;

(4) Harvesting, grazing, or other commercial use of the forage on the land in response to a drought or other emergency, but only in exchange for a payment reduction as determined by CCC;

(5) Wind turbines on CRP land installed in numbers and locations as determined appropriate by CCC

considering the location, size, and other physical characteristics of the land, the extent to which the land contains wildlife and wildlife habitat, and the purposes of CRP, but only in exchange for a payment reduction as determined by CCC;

(6) Spot grazing, if necessary for control of weed infestation, and not to exceed a 30-day period according to an approved conservation plan, but only in exchange for a payment reduction as determined by CCC;

(7) Forestry maintenance such as pruning, thinning, and timber stand improvement on lands converted to forestry use, but only in accordance with a conservation plan, and only in exchange for a payment reduction as determined by CCC; and

(8) The sale of carbon, water quality, or other environmental credits, as determined appropriate by CCC.

Signed at Washington, DC, on July 21, 2010.

Jonathan W. Coppess,

Executive Vice President, Commodity Credit Corporation.

[FR Doc. 2010–18473 Filed 7–27–10; 8:45 am]

BILLING CODE 3410–05–P

NUCLEAR REGULATORY COMMISSION

10 CFR Part 110

[NRC–2008–0567]

RIN 3150–AI16

Export and Import of Nuclear Equipment and Material; Updates and Clarifications

AGENCY: Nuclear Regulatory Commission.

ACTION: Final rule.

SUMMARY: The United States Nuclear Regulatory Commission (NRC) is amending its regulations that govern the export and import of nuclear equipment and material. This rule allows International Atomic Energy Agency Code of Conduct on the Safety and Security of Radioactive Sources Category 1 and 2 quantities of radioactive materials to be imported under a general license. This rule also revises the definition of "radioactive waste" and removes the definition of "incidental radioactive material." In addition, this rule updates, clarifies, and corrects several provisions.

DATES: The rule is effective on August 27, 2010.

ADDRESSES: You can access publicly available documents related to this document using the following methods:

Federal e-Rulemaking Portal: Go to *http://www.regulations.gov* and search for documents filed under Docket ID [NRC–2008–0567]. Address questions about NRC dockets to Ms. Carol Gallagher at 301–492–3668; e-mail *Carol.Gallagher@nrc.gov.*

NRC's Public Document Room (PDR): The public may examine and have copied for a fee publicly available documents at the NRC's PDR, Room O1 F21, One White Flint North, 11555 Rockville Pike, Rockville, Maryland.

NRC's Agencywide Documents Access and Management System (ADAMS): Publicly available documents created or received at the NRC are available electronically at the NRC's electronic Reading Room at *http://www.nrc.gov/reading-rm/adams.html.* From this page, the public can gain entry into ADAMS, which provides text and image files of NRC's public documents. If you do not have access to ADAMS or if there are problems in accessing the documents located in ADAMS, contact the NRC's PDR reference staff at 1–800–397–4209, 301–415–4737, or by e-mail to *pdr.resource@nrc.gov.*

FOR FURTHER INFORMATION CONTACT: Brooke G. Smith, Senior International Policy Analyst, Office of International Programs, U.S. Nuclear Regulatory Commission, MS–O4E21, Washington, DC 20555–0001; telephone: (301) 415–2347; e-mail: *brooke.smith@nrc.gov,* or Jill Shepherd, Licensing Officer, Office of International Programs, U.S. Nuclear Regulatory Commission, MS–O4E21, Washington, DC 20555–0001; telephone: (301) 415–3635; email: *jill.shepherd@nrc.gov.*

SUPPLEMENTARY INFORMATION:

I. Background
II. Analysis of Public Comments on Proposed Rule
III. Section-by-Section Analysis

I. Background

On June 23, 2009, the NRC published a proposed rule that requested comments on the proposed changes to 10 CFR part 110, Export and Import of Nuclear Equipment and Material (74 FR 29614). This final rule updates, clarifies, and corrects several provisions in 10 CFR part 110 to improve NRC's regulatory framework for the export and import of nuclear equipment, material, and radioactive waste. It also clarifies and corrects the regulations addressing the general license for the export of byproduct material. In addition, changes are made to the regulations governing the export and import of International Atomic Energy Agency (IAEA) Code of Conduct on the Safety and Security of Radioactive Sources Category 1 and Category 2 quantities of radioactive materials listed in appendix P to 10 CFR part 110 and the definition of "radioactive waste" in 10 CFR part 110. A discussion of the most significant changes follows.

A. Category 1 and 2 Quantities of Radioactive Material Listed in Appendix P to 10 CFR Part 110

The NRC reevaluated the need for a specific license for the import of Category 1 and 2 quantities of radioactive material to a U.S.-licensed user in light of enhancements made to the NRC's domestic regulatory framework. As a result, the NRC is amending 10 CFR part 110 to allow imports of Category 1 and 2 quantities of materials listed in Appendix P under a general license.

After the attacks of September 11, 2001, the Commission determined that certain licensed material should be subject to enhanced security requirements and safeguarded during transport, and that individuals with unescorted access to risk-significant quantities of radioactive material should be subject to background investigations. The results of vulnerability assessments performed by the NRC were used in the development of security enhancement orders that were issued to licensees using a graded approach based on the relative risk and quantity of material possessed by the licensee. (70 FR 72128; December 1, 2005) These security orders specifically address the security of byproduct material possessed in quantities greater than, or equal to, Category 1 and 2 quantities. The orders provide for enhanced security measures for such things as license verification before transfer, intrusion detection and response, access control, and coordination with local law enforcement authorities. The orders also contain requirements for the licensee to determine the trustworthiness and reliability of individuals permitted unescorted access to risk-significant radioactive materials. The determination involves a background investigation of the individual.

With the passage of the Energy Policy Act of 2005 giving the NRC new fingerprinting authority, the Commission determined that individuals with access to Category 1 and 2 quantities of radioactive material warrant fingerprinting and FBI criminal history records checks.

By the end of 2007, the NRC had issued orders to all NRC licensees that possessed Category 1 or 2 quantities of radioactive material (72 FR 70901; December 13, 2007) to require fingerprinting and FBI criminal history

records checks for unescorted access to Category 1 or 2 quantities of radioactive material.

For all these requirements, NRC Agreement States have also imposed legally-binding measures on their licensees possessing Category 1 and 2 quantities of radioactive material.

During the same time period, the NRC issued two sets of orders to licensees transporting radioactive material in quantities greater than, or equal to, Category 2. The additional security measures contained in the orders provide for enhanced security measures during transportation that are beyond the current regulations, including enhanced security in preplanning and coordinating shipments, advance notification of shipments to the NRC and States through which the shipment will pass, control and monitoring of shipments that are underway, trustworthiness and reliability of personnel, information security considerations, and control of mobile or portable devices.

The security requirements put in place by the orders supplement the existing domestic regulatory requirements. A rulemaking is currently underway that, if promulgated, would incorporate security requirements for Category 1 and 2 quantities of radioactive material into the domestic regulations. (SECY–09–0181; December 14, 2009 (ML0928201950)).

Another significant enhancement pertinent to these materials is the establishment of the National Source Tracking System (NSTS) that tracks from "cradle to grave" transactions involving Category 1 and 2 radioactive sources (71 FR 65686; November 8, 2006). Licensees are responsible for recording the manufacture, shipment, arrival, and disposal of all licensed and tracked Category 1 and 2 sources. For every nationally tracked source that is imported, the facility obtaining the source is required to report the information to the NSTS by the close of the next business day after receipt of the imported source. With the NSTS in place, there is much more information about imported sources available to the staff.

In light of the many security enhancements, the Commission had decided to eliminate the specific license requirement in § 110.27(f) for imports of radioactive material listed in Table 1 of Appendix P to 10 CFR part 110. Conforming changes have been made to §§ 110.32, 110.43, and 110.50. Imports of radioactive material into the United States under a general license continue to be contingent on the consignee being authorized to receive and possess the material under a general or specific NRC or Agreement State license. *See* § 110.27(a). Moreover, importers of Category 1 and 2 materials under a general license are still subject to the notification requirements prior to shipment as required by § 110.50. The advance notification of imports of Category 1 and 2 quantities of material, § 110.50 (c) is revised to require the exporting facility name, location, address, contact name and telephone number as part of the pre-shipment notification.

Additionally, § 110.50 (c) is revised to require advance notifications of imports to be submitted seven days in advance of shipment. This change will permit NRC staff adequate time to verify the information provided in the advance notification.

B. Import and Export of Radioactive Waste

This final rule revises the definition of radioactive waste and incorporates aspects of the removed definition of incidental radioactive material (IRM). The revised definition of "radioactive waste" improves consistency with and eliminates some of the differences between the licensing requirements for export and import and the domestic licensing requirements for possession. The revised definition links the specific license requirement for the export and import of radioactive waste to those materials (in the form of waste) that require a specific license in accordance with NRC's domestic regulations. This eliminates the need for a specific license to export or import materials that, under NRC's regulations in 10 CFR chapter 1, do not require a specific license to possess them.

These changes require a specific export or import license for any material that, in accordance with the requirements in 10 CFR chapter 1, requires a specific NRC license to possess it domestically, which is exported or imported for the purposes of (1) disposal in a land disposal facility as defined in part 61, a disposal area as defined in appendix A to part 40, or an equivalent facility; or (2) recycling, waste treatment or other waste management process that generates radioactive material for disposal in a land disposal facility as defined in part 61, a disposal area as defined in Appendix A to part 40, or an equivalent facility. This change simplifies the regulatory framework by clearly stating that exporting or importing material for recycling, waste treatment, or other waste management process that generates radioactive material for disposal in a 10 CFR part 40 or part 61 facility (or the equivalent) requires a specific export or import license.

The final rule removes the definition of "incidental radioactive material" from 10 CFR part 110. This rule does incorporate aspects of IRM into the revised definition of radioactive waste and the exclusions from that definition. The scope of the exclusion related to contamination on service equipment (including service tools) used in nuclear facilities (if the service equipment is being shipped for use in another nuclear facility and not for waste management purposes or disposal) is expanded and broadened to include some of the material that previously fell under the definition of IRM such as launderable protective clothing.

In response to comments, the Commission clarified that the first exclusion to the definition of "radioactive waste" applies only to sources of U.S. origin. Disused sources that originated in a country other than the United States would be considered "radioactive waste" under 10 CFR part 110. Exclusion two is revised to clarify that the broader meaning of "nuclear facility" is intended and that the material must be shipped solely for recovery and beneficial reuse of the non-radioactive material. In addition, an illustrative list of activities that would meet the standard set forth in exclusion two is added to the Statement of Considerations. The Commission also added a sixth exclusion to the definition of "radioactive waste" to address the question of recycling activities that would not be considered as radioactive waste, such as utilizing depleted uranium in shielding applications or catalyst manufacturing. The six exclusions are set forth below:

1. Radioactive material in sealed sources or devices containing sealed sources that are of U.S. origin and being returned to any manufacturer, distributor or other entity which is authorized to receive and possess them. This change allows the return of U.S. origin sources or devices to distributors and other appropriately authorized entities. A specific import license is required for the importation of sources originating outside of the United States for disposal in the United States. Licensing and notification requirements for Category 1 and Category 2 quantities of material listed in Table 1 of Appendix P are applicable.

2. A contaminant on any non-radioactive material (including service tools and protective clothing) used in a nuclear facility (an NRC- or Agreement State-licensed facility (or equivalent facility) or activity authorized to possess or use radioactive material), if the item

is being shipped solely for recovery and beneficial reuse of the non-radioactive component in a nuclear facility and not for waste management purposes or disposal. The scope of the exclusion is expanded and broadened to include some of the material that previously fell under the definition of IRM such as launderable protective clothing. Other examples of materials meeting this exclusion include:

(a) Importing contaminated metal for the purpose of recovery of the non-radioactive metal for beneficial reuse as shield blocks or other industrial/construction purposes in licensed facilities domestically and abroad is an import not "solely" for waste management or disposal purposes. This example is within the scope of exclusion two even though the recycling process will produce some waste that may require disposal at a part 61 disposal site. This is similar to the laundering of protective clothing, which also may have a waste stream to a 10 CFR part 61 facility.

(b) Decontamination and repair of contaminated equipment such as pumps, valves, and motors that after recovery would be beneficially reused in a licensed facility.

(c) Decontaminating shipping containers used to import radioactive material for the purpose of reusing the shipping containers.

(d) Importing contaminated magnesium metal and using the recovered magnesium as a neutralizing agent for disposing of mixed waste in a licensed disposal facility.

3. Materials exempted from regulation by the NRC or equivalent Agreement State regulations. This exclusion is consistent with the previously mentioned revision that links the requirement for a specific import or export license for radioactive waste to the specific licensing requirements in 10 CFR chapter 1 (*e.g.,* 10 CFR parts 30, 40, and 70). This change eliminates some of the differences between NRC's export and import regulations and domestic regulation of the same material or equipment.

4. Materials generated or used in a U.S. Government waste research and development testing program under international arrangements.

5. Materials being returned by or for the U.S. Government or military to a facility that is authorized to possess the material. This exclusion recognizes that the U.S. Government or military will, in certain circumstances, seek to return material to the United States. Material returned must be to a facility that is authorized to possess the material.

6. Materials imported solely for the purposes of recycling and not for waste management or disposal where there is a market for the recycled material and evidence of a contract or business agreement can be produced upon request by the NRC. This exclusion was added to address concerns regarding the legitimate recycling of radioactive material that might otherwise be seen as waste. For example, under certain circumstances, this exclusion would permit the import under general license of depleted uranium for use in shielding applications or catalyst manufacturing.

In response to comments, the Commission revised §§ 110.43 and 110.45 to clarify that the NRC consults, as applicable, with the Agreement State in which the facility is located and low-level waste compact commission(s).

II. Summary of Public Comments

The Commission received 14 letters from the public commenting on the proposed rule. The commenters represent a variety of interests. Comments were received from individuals, licensees, Federal and State agencies, and citizen, environmental, and industry groups. The comments addressed a wide range of issues concerning the proposed changes to 10 CFR part 110. Many of those responding to the proposed rule commented on multiple sections; therefore, several comments have been separated by section and addressed. Likewise, similar comments have been consolidated. The following is a summary of all significant comments, along with the NRC's responses.

A. Section 110.2—Definitions

Comment: One commenter stated that the proposed definition for "bulk material" in § 110.2 is confusing. The commenter seeks clarification on whether the definition is intended to cover "raw" material (material produced in reactors) that is then incorporated into sealed sources. The commenter also states that the proposed definition seems to imply that Category 3, 4 and 5 sources would be considered bulk material. The commenter asked how it is known when the quantity is deemed to pose a risk similar to or greater than a Category 2 source.

Response: The definition of bulk material includes both "raw" material produced for encapsulation in sealed sources, as well as, Category 3, 4, and 5 sealed sources that, in aggregate, are equal to or exceed Category 2 activity thresholds. The NRC believes that no changes are necessary to the proposed definition for "bulk material" and it is unchanged in this final rule.

Comment: One commenter suggested that the definition of "radioactive waste" should include other disposal methods that are approved by the NRC and Agreement States such as alternative disposals under 10 CFR 20.2002.

Response: The intent of the proposed changes to the definition of "radioactive waste" is to align the NRC's export and import regulations with its domestic regulations; therefore, if a specific license is required for a domestic licensee to possess the material, then a specific license to export/import the material would also be required. The NRC and Agreement State licensees may request approval for alternative disposal methods for wastes held under their domestic possession license in accordance with 10 CFR 20.2002 or equivalent Agreement State regulations. Waste could not be imported and directly disposed of under 10 CFR 20.2002, as this type of authorization can only be granted to persons regulated by the NRC or the Agreement States. No change was made to the proposed definition of "radioactive waste" as a result of this comment.

Comment: One commenter suggested revising the proposed definition of "radioactive waste" to clarify that it does not include spent fuel. The respondent noted that it is not clear from the definition what the term "equivalent facility" includes and therefore the definition could be construed to include a facility for the disposal or storage of spent fuel or material that results from recycling, treatment or processing of spent fuel. This commenter also stated that the term "material imported for recycling * * *" could be read to include spent fuel. Another commenter also noted that the term "recycling" could be confused with the reprocessing of nuclear fuel.

Response: The change to the definition of "radioactive waste" in 10 CFR part 110 refers exclusively to low level radioactive waste (LLW). Spent or irradiated fuel is not considered to be LLW; therefore, the definition of "radioactive waste" in 10 CFR part 110 does not include spent or irradiated fuel. A sentence has been added to the proposed definition of "radioactive waste" to clarify in this final rule that it does not include spent or irradiated fuel.

Comment: One commenter expressed concern about implementation of the revised definition of "radioactive waste" and the correlation between the need for a specific export or import license and the need for a specific domestic license for the same material. This commenter asked if the NRC will make its determination based on whether the

conditions in the domestic specific license held by the potential exporter or importer allow possession of the foreign material. The commenter also asked if the NRC will judge the need for an export or import license only against NRC-issued specific licenses or against Agreement State-issued licenses as well. The commenter noted that the NRC and Agreement States have flexibility in writing license conditions and consequently, there may be a lack of national uniformity in the kinds of radioactive materials a domestic specific licensee may possess.

Response: An NRC import license only allows material to be brought into the United States. Once the material is in the United States, the material is subject to the domestic authorization process and operates no differently than if the material were of domestic origin. The import license is not a mechanism to alter the established domestic authorization process, including Agreement State regulations. The NRC will not issue an import license for radioactive waste unless the U.S. importer is authorized to possess the material under the applicable domestic regulation, whether that regulation is an Agreement State's or NRC's. No change was made to the proposed definition of "radioactive waste" as a result of this comment.

Comment: One commenter noted that the NRC's "changes to 10 CFR part 110 will facilitate the licensing process for exports and imports of radioactive waste * * *" This commenter suggested that the NRC complete an Environmental Impact Statement (EIS) to address the increased import of radioactive waste from foreign countries and their shipment within the United States. Further, this commenter would like the EIS to address cumulative impacts from shipments of all radioactive wastes from existing and new nuclear facilities, including shipments resulting from license extensions at existing facilities and the increased shipment of radioactive wastes expected as a result of proposed changes to 10 CFR part 110.

Response: Under 10 CFR 51.22(c)(1), amendments to 10 CFR part 110 are categorically excluded from environmental review based on a Commission finding by rule that this category of action does not individually or cumulatively have a significant effect on the human environment. In any event, the NRC does not anticipate an increase in imports or shipping of radioactive waste as a result of this revision. Therefore, no change was made to the proposed definition of "radioactive waste" as a result of this comment.

Comment: One commenter noted that the United States does not currently have an approved radioactive waste repository and questions how accepting imports of radioactive waste is consistent with the NRC's mission to protect human and environmental health. The commenter further stated that if Yucca Mountain were opened in the near future, the current stockpiles of radioactive waste in the United States would fill the repository. This commenter suggested a moratorium on imports of radioactive waste until an approved repository is opened.

Response: The definition of "radioactive waste" in 10 CFR part 110 refers exclusively to low-level radioactive waste. There are currently several low-level waste disposal facilities in the United States. High-level waste is not addressed in this final rule. Therefore, no change was made to the proposed definition of "radioactive waste" as a result of this comment.

Comment: One commenter suggested that the term "recycling" in the proposed definition of "radioactive waste" be removed or defined further to clarify that recycling under the general license is authorized when the recycling provides for a beneficial re-use of the material. Another commenter noted that the proposed definition of "radioactive waste" is ambiguous with regard to the import of radioactive materials imported and used as "raw" materials directly by manufacturing facilities as opposed to waste processing facilities. The commenter stated that the proposed definition includes "radioactive material" that requires a specific license for possession and is intended for disposal, recycling, waste treatment or some other waste management process. As asserted by the commenter, the ambiguity is that as raw material, waste treatment or waste management would not apply to such non-waste; however, "recycling" without further clarification seems to inadvertently include non-waste, "raw" materials. The commenter suggested that the term "recycling" be modified to a more restrictive phrase such as "waste component recycling" which would clearly not apply to "raw" materials. As another possibility, the commenter suggested restricting the definition of radioactive waste to those imports that are consigned to licensed waste treatment and disposal facilities, so that imports of radioactive material going to licensed manufacturing facilities would not be included.

Another commenter addressed the concept of recycling in the context of exclusion two to the proposed definition of "radioactive waste," stating that the term "recycling" in the main part of the definition seems to conflict with "recovery and beneficial use" in the exclusion. In the commenter's view, recycling means the recovery and beneficial re-use of the recovered material. The commenter stated that it appears the intent of the proposed definition is to clarify that, in general, while radioactive material imported for the purpose of processing and disposal is waste, radioactive material imported for the purpose of beneficial re-use is not waste as long as the re-used non-radioactive material is used in a nuclear facility. The commenter offered two suggestions to clarify this apparent conflict. First, the commenter suggested that we insert the word "recycling" prior to "for recovery and beneficial use" in the text of the exclusion. Second, the commenter suggested that we include a clarifying statement in the Statement of Considerations for the final rule that says the intent of the exclusion is to provide an exception to the general rule that would permit recycling under the general license where the recycling provides for beneficial re-use of the non-radioactive material in an environment licensed by the NRC or an Agreement State.

Response: In order to address the numerous concerns regarding the legitimate recycling of radioactive material that might otherwise be seen as waste, the NRC has decided to add a sixth exclusion to the proposed definition of "radioactive waste" to clarify that the definition does not include material imported solely for the purposes of recycling and not for waste management or disposal where there is a market for the recycled material and evidence of a contract or business agreement can be produced upon request by the NRC. An example of such material would be depleted uranium for use in shielding applications or catalyst manufacturing. An example of "recycling" that would be considered "radioactive waste" is the use of combustible material (such as wood or oil) as an energy source at an NRC- or Agreement State-licensed facility.

An import for the purpose of recycling is similar to the importation of useable radioactive materials and products, which occurs routinely. With respect to recycling of materials, as with products that contain radioactivity, recycled materials have a beneficial use yet waste may be generated as they are recycled. In the United States, these wastes would be managed safely in accordance with domestic licensing requirements.

The Commission is aware that there could be instances in which a person intends to import what is in fact

radioactive waste, but which is argued to be for recycling purposes (*i.e.,* sham recycling). Any person who imports materials under a general license for recycling, but with the purpose of disposing of them in the United States, would be subject to NRC enforcement action. In addition, there may be instances in which some small value may be obtained from the materials that are imported, but the primary intention is for disposal. In such cases, to avoid possible enforcement action, the staff recommends that the Commission be consulted before any such imports are made. This final rule includes the six exclusions under the definition for "radioactive waste."

The Commission does not accept the second commenter's suggestion to add the word "recycling" to exclusion two because the use of the word "recycling" could potentially open exclusion two to other general forms of recycling, which would not meet the intent of the exclusion. The intent of exclusion two is exclusively for the importation of materials being recovered and reused in an NRC- or Agreement State-licensed facility.

Comment: Several commenters addressed the proposed changes to exclusion one to the definition of "radioactive waste" regarding sealed sources and devices. Two commenters expressed support for the proposed changes and stated that they will allow for sources to be transferred and transported easily to an entity that may be able to recertify the source or recycle the source for beneficial use rather than disposal. Another commenter suggested that the purpose of the exclusion should be clarified to indicate that it does not cover importing sources originating in other countries for disposal in the United States.

Response: Exclusion one to the proposed definition of "radioactive waste" has been revised in this final rule to clarify that this exclusion only applies to sources of U.S. origin. Disused sources that originated in a country other than the United States would be considered "radioactive waste" under 10 CFR part 110. Therefore, in the case of an import, a specific license is required for the importation of sources (in the form of waste or disused sources) originating outside of the United States for disposal in the United States. Licensing and notification requirements for Category 1 and 2 quantities of materials listed in Table 1 of appendix P to 10 CFR part 110 are applicable.

Comment: One commenter stated that importation of material destined for re-use should require a specific license. The application for a specific license constitutes a form of public disclosure and the public should be aware of radioactive materials, such as radioactive metals, that may be reused. This commenter asserted that reused radioactive metal could contaminate the general supply of reused scrap metal if it eventually makes its way back to unrestricted use. Consequently, the public should be notified and provided the opportunity to comment on a specific license for the import of radioactive materials proposed for reuse.

Response: The intent of this change is to address the re-use and recovery of these materials for use in an NRC- or Agreement State-licensed facility. Once imported to an NRC- or Agreement State-licensed facility the material and any waste generated as a result of the re-use or recovery process is subject to NRC or Agreement State domestic licensing requirements. Therefore, no change was made to the definition of "radioactive waste" as a result of this comment.

Comment: Several commenters asserted that the second exclusion to the proposed definition of "radioactive waste" could be abused if only a small fraction of the import is for recovery or beneficial use of the non-contaminated material. Two commenters addressed the proposed language "not solely for waste management purposes or disposal" at the end of the exclusion. One commenter stated that this phrase should be further clarified, changed or replaced to indicate that the portion of the import destined for disposal must, at all times, be considered radioactive waste. Another commenter thought the closing phrase unnecessary because, if the import is for recovery and reuse of the non-radioactive material, then the import would never be "solely" for waste management purposes or disposal. This commenter speculated that the intent of the language is to ensure good faith intent for recovery and reuse of the material. This commenter recommended that this concern be addressed by stating that the purpose is "primarily" for recovery and re-use since all recovery efforts will likely have some waste processing or disposal aspects. The term "primarily" is proposed to make it clear that the recovery operation produces a product that is in fact useful and that the recovery operation is in good faith and not a pretense for waste management. The commenter recommended rewording the exclusion to read "* * * if the material is being shipped primarily for recycling, *i.e.,* recovery and beneficial use of the non-radioactive material in a nuclear facility." Another commenter asserted that some of the exclusions under the proposed definition of "radioactive waste" should be more restrictive. Specifically with regard to the second exclusion, the commenter stated that the disposable radioactive portion of the imported material should be recognized as "radioactive waste" at the time of import; otherwise, that disposable radioactive portion could simply appear to be domestic waste resulting from domestic processing.

Response: In the definition of "radioactive waste" in this final rule, the word "solely" has been moved from its proposed location in front of "for waste management" to between "shipped" and "for recovery" in order to clarify the intent of the exclusion. Once items have been imported to an NRC- or Agreement State-licensed facility for beneficial recovery and/or re-use these items would then be subject to the NRC's or Agreement State's domestic licensing requirements. Circumvention of the specific licensing requirements for radioactive waste is subject to NRC or Agreement State enforcement action.

Comment: One commenter noted that "launderable protective clothing" and "service tools" are the examples provided in the second exclusion to the definition of "radioactive waste." This commenter suggested that the Statement of Considerations for the final rule expand on the discussion of examples in order to avoid confusion related to the use of the term "incidental radioactive material." The commenter also asserted that an expanded discussion of examples would help define what satisfies the standard of "primarily for recovery." The commenter recommended including, at a minimum, the following examples:

(a) Importing contaminated metal for the purpose of recovery of the non-radioactive metal for beneficial re-use as shield blocks or other industrial/construction purposes in licensed facilities domestically and abroad is an import not "solely" for waste management or disposal purposes. The commenter noted that this example fits the language in the proposed rule even though the recycling process will produce some waste that will need to be sent to a 10 CFR part 61 disposal site. This is similar to the laundering of protective clothing, which also has a waste stream to a 10 CFR part 61 facility.

(b) Decontamination and repair of contaminated equipment such as pumps, valves, and motors that after recovery would be beneficially reused in a licensed facility.

(c) Incinerating contaminated wood or oil to generate steam in a licensed facility for process heat or electricity.

(d) Decontaminating shipping containers used to import radioactive material for the purpose of reusing the shipping containers.

(e) Importing contaminated magnesium metal and using the recovered magnesium as a neutralizing agent for disposing of mixed waste in a licensed disposal facility.

In addition to the examples provided above, the commenter recommended that the NRC include any other examples that it has found acceptable in the past.

Another commenter also requested the NRC provide such a list and went on to suggest amending § 110.27 to add a paragraph (g) that reads:

> Persons importing material primarily for recovery and beneficial use under a general license on the basis that the import meets [exclusion] 2 of the definition of "radioactive waste" must submit Form 7 to the NRC seven days prior to the import. The submitted form need only address the provisions of paragraphs (a)–(f) of 10 CFR 110.32. The Form 7 shall be submitted to the Deputy Director, Office of International Programs.

The commenter stated that this proposed provision would be solely a notice provision. It would not establish an obligation for the importer to await any NRC action following submittal of the form to the NRC.

Response: The first commenter's examples (a), (b), and (d) would meet the standard for "primarily for recovery" provided there is a market for the recovered product to be reused in an NRC or Agreement State licensed facility and evidence of a contract or business agreement can be produced upon request by the NRC. The commenter's example (e) would also meet the standard but it must be primarily for recovery and reuse of magnesium. Example (c) does not meet the standard for "primarily for recovery" because it is an example of a waste process with a small amount of energy produced as a byproduct. The NRC does not consider waste processes to be "primarily for recovery."

In response to the second commenter's request for the provision of information on NRC Form 7, the NRC does not feel that placing an additional regulatory compliance burden on the public is warranted at this time. The NRC believes that any questions the public may have regarding compliance with exclusion two to the definition of "radioactive waste" would best be addressed individually on a case-by-case basis. In accordance with 10 CFR 2.390, the NRC will make examples of recovery activities under exclusion two to the definition of "radioactive waste" publicly available. No changes to the proposed definition of "radioactive waste" were made as a result of these comments.

Comment: One commenter asserted that the term "nuclear facility" is unclear. The commenter asked whether the term is being used as in the Atomic Energy Act to mean a "production" or "utilization" facility, or is it intended to have a broader meaning to include any plant or activity which is licensed for use or possession of radioactive material? The commenter recommended that the term "nuclear facility" be defined as "a plant or activity licensed by either the Commission or an Agreement State for possession or use of radioactive material."

Response: The NRC has revised exclusion two to the proposed definition of "radioactive waste" to clarify that the broader meaning of facility is intended in this final rule.

Comment: Two commenters addressed exclusion five to the definition of "radioactive waste" regarding the U.S. government or military. One commenter stated that the purpose and intent of this new exclusion is not clear, and that the circumstance, or combination of circumstances, under which the U.S. government or military would need to return material to an authorized U.S. facility could be interpreted very broadly. Another commenter suggested that U.S. government waste research and development testing programs under international arrangements should be specifically identified, along with appropriate caps on the total amounts of relevant wastes to be imported and exported each year.

Response: This is not a new addition to 10 CFR part 110. Current regulations at § 110.27, General license for imports, only allow the return of material under a general license if the material was going to a military or government facility. In the proposed rule, this concept was moved from § 110.27 to § 110.2 as an exclusion to the definition of "radioactive waste" and expanded to include an allowance for the U.S. military to bring radioactive waste items back to a licensed facility in the United States. The proposed provision is unchanged in this final rule.

B. Section 110.6—Retransfers

Comment: One commenter sought clarification on why the retransfer of byproduct material is not included in the requirements of § 110.6. The commenter also sought clarification on whether retransfers of special nuclear material produced through the use of U.S.-obligated material are subject to the requirements of this section.

Response: Byproduct material is not covered by the requirements of § 110.6 because there is no retransfer restriction on byproduct material in the Atomic Energy Act. Retransfers of special nuclear material produced through the use of U.S.-obligated material are subject to the requirements of this section.

C. 110.26—General License for the Export of Nuclear Reactor Components

Comment: One commenter questioned the proposed revision to § 110.26(a) to cover "components solely of U.S. origin" for three reasons:

> (1) U.S. origin has many meanings in the United States today, but given the wording "solely of U.S. origin" or "of U.S. origin," it is rather difficult to purchase anything which is only of U.S. origin. The commenter requested further definition.
>
> (2) While the commenter agreed with the authorization contained in proposed § 110.26(a)(2), the commenter stated that the proposed wording conveys the authority to re-export nuclear components from such generally authorized countries as listed in § 110.26(b) to each other. However, this is an authorization that U.S. companies would not be able to utilize if the component is required to be solely of U.S. origin.
>
> (3) Many nuclear components or parts are imported into the U.S. for ultimate end use as either a standalone nuclear component or for use in a larger nuclear component for future sale in either the U.S. or non-U.S. markets.

The commenter noted that many U.S. companies have international markets as well as foreign-based manufacturing facilities or joint ventures. Such global companies will import nuclear spare parts or components for utilization in larger U.S.-built nuclear components for sale both within the United States as well as outside of the United States. The commenter stated that these U.S. imports and subsequent exports create and maintain U.S. jobs and should not be delayed or subjected to a new NRC component license application process and associated application fees. The commenter said that to do so would remove a vital part of the purpose of § 110.26, which is to enable U.S. companies to export nuclear components quickly to a select list of generally authorized countries that do not require an NRC validated export license. These component exports are subject to NRC reporting requirements, but they enable the U.S. nuclear industry to sell our components in a very efficient manner to pre-approved countries. According to the commenter, the proposed change would penalize the

U.S. nuclear industry in the world marketplace and cause a giant step backwards in the U.S. nuclear industry's ability to freely sell these nuclear components or parts to pre-approved countries that are not subjected themselves subjected to similar restrictions.

Response: The NRC believes the commenter makes a valid point regarding limiting the general license under § 110.26 to "components solely of U.S. origin." With the increasing globalization of the nuclear industry, U.S. nuclear companies are outsourcing more and more items, including parts and components for reactor equipment and fuel assemblies. However, since the U.S. industry has been able to accept the current language of § 110.26 which allows use of the general license for "U.S. origin" component exports to a select list of countries, even when the "U.S. origin" component includes non-U.S. content, the proposed language is retained in this final rule. Further, the NRC added clarifying language to § 110.26 stating that "U.S. origin" includes components produced or finished in the United States, even with non-U.S. content unless the foreign content is obligated by supplier government conditions, such as a prior consent for retransfer condition.

D. 110.27—General License for Imports

Comment: Two commenters addressed the proposed amendment to § 110.27 that would remove the paragraph that addresses activities conducted under a contract with the Department of Energy (DOE). The commenters suggested revising the Section-by-Section Analysis for § 110.27 to state that the NRC's import regulations do not apply to the DOE imports of source, special nuclear or byproduct material, including imports conducted on DOE's behalf by DOE contractors. The commenters also state that the Statement of Considerations for the proposed rule cites sections 54, 64, 82, and 91 of the Atomic Energy Act which govern exports, not imports, and are not applicable in this context.

For purposes of clarification, one commenter, suggested that in § 110.27(b), the words "source or special nuclear" should be inserted before "material" so that the sentence reads as follows:

> The general license in paragraph (a) of this section does not authorize the import of source or special nuclear material in the form of irradiated fuel if the total weight of the [source or special nuclear] material exceeds 100 kilograms per shipment.

Response: The NRC's import regulations do not apply to DOE imports of source, special nuclear, or byproduct material including imports conducted on DOE's behalf by DOE contractors. The removal of § 110.27(a)(1) clarifies that DOE is not subject to NRC import licensing requirements. The Atomic Energy Act citations in the Statement of Considerations for the proposed rule apply to exports, not imports. The sections of the Atomic Energy Act that apply to imports of special nuclear, source or byproduct material are sections 53, 62, and 81. Section 110.27(b) has been rewritten in this final rule in response to the request for clarification.

Comment: One commenter noted that the clear intent of the proposed rule, as expressed in the Statement of Considerations to the proposed rule, is to grant a general license for the import of materials that are exempt from domestic licensing (*e.g.,* material exempted by 10 CFR 40.13(a)) by the NRC. Section 110.27(a) of the proposed rule would grant a general license for the import of byproduct, source, and special nuclear material if the U.S. consignee were authorized to possess such material under a general or specific license from the NRC or an Agreement State. The commenter asserted that while the new definition of "radioactive waste" in the proposed rule would exclude "exempt" material such as 10 CFR 40.13(a) material, the controlling provision for the import of material under proposed § 110.27(a) seems to be the possession of an existing general or specific license. The commenter stated that under the framework for the domestic licensing of byproduct, source, or special nuclear material, general licenses are not synonymous with "exemptions" for material: No license is required for the possession of exempt material. The commenter stated that § 110.27(a)(2) of the current regulations does grant a general license for the import of "exempt" material; however, this section would be deleted under the proposed rule, and the commenter suggested that original language be retained.

Response: The NRC's revisions to the definition of "radioactive waste" in 10 CFR part 110 are designed, in part, to align export/import licensing criteria with domestic regulations that are implemented by the NRC and the Agreement States. If a specific license is required domestically, a specific import or export license would also be required. The changes to the definition of "radioactive waste" and the deletion of § 110.27(a)(2) are consistent with the intended alignment in that if the material (meaning any exempt material, not just material in the form of waste) is exempt from requiring a license domestically (*e.g.,* 10 CFR 40.13(a) is only one example of an exemption), then that same material would be exempt from requiring a general import license as well. Therefore, an additional provision to provide authorization to import under a general license is redundant and unnecessary. As proposed, § 110.27(a)(1) and (a)(2) are removed in this final rule.

Comment: Two commenters generally addressed the proposal to allow imports of Category 2 quantities of materials under a general license. Specifically, they noted that imports conducted under the authority of a general license are not subject to the same public notification and comment requirements as imports conducted under specific licenses. One respondent stated that the general license could be used for unlimited imports without public knowledge.

Response: While it is correct that imports under a general license are not subject to the same public notification requirements as a specific license, the NRC is aware of and continues to regulate such imports. In accordance with § 110.50, pre-shipment notification is still required by the importer. Additionally, domestic licensees must report receipt of Category 1 and 2 radioactive sources to the NSTS. Imports of radioactive material into the United States are contingent on the consignee being authorized to receive and possess the material under a general or specific NRC or Agreement State license.

E. 110.43—Import Licensing Criteria

Comment: One commenter recommended that the NRC require more specificity in the application for a specific license to import radioactive waste and that foreign waste retain its "country of origin" attribution from import through disposal. With regard to the specificity in an application, this commenter is primarily concerned with the concept of waste characterization versus waste classification prior to its import. Specifically, the commenter noted that under the proposed rule, the NRC would only require an applicant to classify the radioactive waste in accordance with 10 CFR 61.55 when the waste is being imported for direct disposal. The commenter stated that this provision is too narrowly written and most waste would escape classification. The commenter asserted that if the imported waste was first processed or managed and then disposed of, under the proposed rule, the waste would not be classified prior to import. This commenter also stated that by allowing

the importer to characterize the waste rather than classify it prior to import, the NRC may allow the import of radioactive waste that cannot be disposed of in this country. Further, the host state or compact would have insufficient information to make an informed decision about the appropriateness of the waste for disposal at facilities under its jurisdiction. Another commenter stated that in the past, there have been situations where all the disposition pathways for waste resulting from the processing of imported radioactive wastes were not clearly identified in the original import license application. The commenter recommended that the NRC require license applications for the import of radioactive waste to include a list of all facilities that are projected to receive wastes for disposal that result from imported wastes. This should include licensed low-level waste disposal facilities as well as landfills that are licensed to accept materials such as those surveyed for bulk release (exempt wastes). The commenter stated that this would ensure that parties responsible for evaluating the application have the information necessary to conduct a thorough review.

Response: As discussed above in Section I.B of this document, the NRC's revisions to the definition of "radioactive waste" in 10 CFR part 110 are designed, in part, to align export and import licensing criteria with domestic regulations that are implemented by the NRC and the Agreement States. Therefore, if a specific license is required to possess the material domestically, a specific license would be required to import or export that waste material. In accordance with domestic regulations, the NRC, when processing applications for the import of radioactive waste, would follow the waste attribution approaches used in the United States, which are, in almost all cases, developed by the Agreement States and compacts.

Under domestic licensing requirements, waste disposed of at a 10 CFR part 61 or equivalent Agreement State-licensed facility must be classified in accordance with 10 CFR 61.55. Under the shipping manifest requirements in Appendix G to 10 CFR part 20, waste must be classified when it is being shipped for disposal. It is not required to be classified before shipment for disposal, *i.e.,* waste being sent to a processor need not be classified, but waste being shipped directly for disposal must be classified in accordance with 10 CFR 61.55. The waste classification requirements are designed to provide for protection against an inadvertent intruder into a waste disposal site 100 years or more after the site is closed. For higher concentrations of waste (and higher waste classes), additional measures are required at the disposal site to ensure that the intruder is protected even from wastes that pose a greater hazard. Thus, the classification of waste at intermediate points in its processing is not relevant to the purpose of waste classification.

The final rule does not require classification of waste being imported to a waste processor because such classification would have no safety relevance at that time. The licensed waste processor, after processing the waste, must classify the waste which would ensure that the disposal site facility requirements are met. This approach is consistent with domestic requirements. It should be noted that the NRC Chairman, on October 8, 2009, requested a vote paper from the NRC staff addressing blending of low-level radioactive waste. While blending is not related to the import of waste, the issue of when waste is to be classified will be addressed in the paper. Current regulations require that waste be classified when shipped for disposal. If, as a result of this current review, changes are made in classification requirements or practices, the staff will implement review procedures for waste import applications consistent with new domestic practices or requirements.

While it is agreed that it is undesirable to import waste that cannot be disposed of in the United States, the NRC will ensure, in its review of license applications, that when there is uncertainty regarding the final waste classification of waste to be disposed of, that an export license application has been applied for to ensure that no waste is left in the United States without a disposal option. This ensures that any waste without a domestic disposal option will not be orphaned in the United States, but will be returned to the country of origin.

With respect to Agreement States and compacts making informed decisions, the NRC will ensure in its consultations with States and compacts, as applicable, that the waste to be processed and disposed of meets the classification requirements of the disposal facility and the license conditions of any intermediate facilities, such as a waste processor. The final rule notes that license applicants would need to characterize the waste before import to ensure that it meets the license requirements for a domestic processor. However, consistent with domestic regulations, classification is not required, since waste classification is designed to ensure safety of waste to be disposed of, and is not related to safety of the waste at intermediate points in its processing.

In response to the concerns raised by the second commenter regarding clearly identifying an imported waste's disposition pathway, the NRC will consult with the Agreement State and, if applicable, the low-level waste compact commission to ensure that an appropriate facility is authorized to accept waste for management or disposal.

With respect to the commenter's recommendation that import license applications include a list of all facilities projected to receive imported waste, under domestic regulations a waste processor receiving foreign waste could only transfer processed waste to authorized recipients. Thus, there would be no safety or security concerns, once waste was received by an authorized waste processor.

It is possible that other waste management or disposal facilities receiving waste from a processor could be subject to laws or regulations applicable to foreign wastes; however, assurances that foreign waste could be accepted at these facilities would be needed. Such assurance could come from consultations with the States and compacts. In cases where foreign waste is attributed to the foreign low-level waste generator, the NRC will consult with other affected States and compacts that receive processed waste. Section 110.32(f)(6) places an obligation on the foreign waste import applicant to identify where the waste, not attributed to the processor (*i.e.* foreign waste that remains attributed to the foreign low-level waste generator), will be disposed of within the United States. Again, in accordance with domestic regulations, the NRC will follow the waste attribution approaches developed by the Agreement States and compacts in its processing of applications to import foreign waste. There, the applicable provisions of the proposed rule are unchanged in this final rule.

Comment: Several commenters expressed support for the proposed revisions to §§ 110.43 and 110.45, that provided clarification that the NRC consults (with respect to the import of radioactive waste) with the host State(s), and, if applicable, the appropriate low-level waste compact commission(s) to confirm that an appropriate facility has agreed to accept and is authorized to possess the waste for management or disposal. However, one commenter suggested that the NRC should codify the requirement to obtain the consent of

any host State that is the proposed destination for imported radioactive waste before approving an import application by adding a new paragraph (g) to § 110.43.

Another commenter sought clarification regarding what the NRC intends to do if there is an impasse between the NRC and a host State or compact concerning whether an appropriate facility is authorized to accept foreign radioactive waste for disposal.

A third commenter suggested that the NRC should distinguish between Agreement States that should be consulted to determine if the site is licensed for disposal and host States under the compact system that are consulted to determine if the disposal is allowed under compact rules. Citing *EnergySolutions, LLC* v. *NW Interstate Compact on Low-Level Radioactive Waste Mgmt.,* No. 2:08–CV, D. Utah, June 17, 2009, this commenter stated that for a non-compact site such as the EnergySolutions Clive site, the concepts of host States and compacts do not apply. For a non-compact site, consultation with the State in which the site is located should only address the authorization for disposal under the State's Agreement State authority. This commenter recommended that §§ 110.32(f)(6), 110.43(d), and 110.45(b)(4) should be changed to address these distinctions.

Response: The NRC revised §§ 110.43 and 110.45 in this final rule to further clarify those contacted and the intent of the proposed change. In response to the commenter's question regarding the NRC's actions in an impasse, the NRC believes that such an impasse is unlikely because the appropriateness and authorization of a facility will be determined by the regulatory authority (*i.e.* the NRC or Agreement State) and compacts as applicable.

F. 110.44—Physical Security Standards

Comment: One commenter sought clarification of the intent and purpose of the incorporation by reference of the current INFCIRC/225/Rev. 4 (corrected), June 1999, in § 110.44(a). The commenter stated that it is their understanding that INFCIRC/225/Rev. 4 (corrected), June 1999, is currently undergoing review and revision by the IAEA and international community; incorporation by reference of the current INFCIRC document may not address the applicability of substantial INFCIRC changes underway that could be potentially incorporated in the future. The commenter stated that changes to INFCIRC/225/Rev. 4 (corrected), June 1999, may have a significant impact on physical security standards, policy, and guidance, both domestic and international.

Response: The NRC is aware of the current review by the IAEA and the international community and will make any necessary changes to this section once that document is finalized. Therefore, INFCIRC/225/Rev. 4 (corrected), June 1999, "The Physical Protection of Nuclear Materials and Nuclear Facilities" continues to be incorporated by reference in § 110.44(a) of this final rule.

G. 110.50—Terms

Comment: Currently, notifications for imports are required to be submitted at least seven days in advance of each shipment, to the extent practical, but in no case less than 24 hours in advance of each shipment. Several commenters addressed the proposed amendment to § 110.50(c) that would require advance notification for imports to be submitted seven days in advance of shipment. Specifically, one commenter stated that a seven-day advance notification requirement would cause many importers of Category 2 sources to be out of compliance with the proposed regulation. This commenter noted that there are many instances where his customers do not tell him when a source is being returned.

Another commenter stated that it is unclear why the NRC now needs seven-days advance notice. The commenter stated that the only explanation is to allow NRC adequate time to verify information. The commenter questioned the verification information if the importer is an established licensee and routinely receives returned sources. This commenter also noted that the NSTS would account for imported sources once received under an NRC or Agreement State license. The commenter recommended that the NRC have no requirement for advance notification for the import of Category 2 sources because the sources will be accounted for in the NSTS and there is no documented benefit to the advance notification requirement.

One commenter noted that with regard to imports of Category 1 quantities of material, which are typically bulk and raw material shipments, 24-hour advance notification is currently received and that seven-day advance notification is not provided because final shipping arrangements often change on a daily basis. The commenter recommended that the NRC retain the current requirement that allows for 24-hour advance notification.

Response: The pre-shipment notification requirement contained in § 110.50 is being included in this final rule as proposed because the current policy of "no less than 24 hours in advance" is insufficient for NRC staff to verify pre-shipment information and coordinate with other applicable government agencies, such as an Agreement State and/or the U.S. Customs and Border Protection. Insufficient time to complete these activities could result in a delay of the import entering the United States. The NRC suggests that licensees work with their clients to better inform them of their obligations to comply with United States' regulations so that the client can provide the requisite information to ensure the U.S. licensee is not out of compliance. In the event the shipment date is changed after the NRC has been notified, the NRC will not require a revised notification submission if the shipment will take place within 14 days of the initial shipment date provided to the NRC. If the shipment date will be delayed for a longer period of time, a new notification should be provided to the NRC.

III. Section-by-Section Analysis of the Final Rule

Subpart A—General Provisions

Section 110.1, Purpose and scope. This final rule removes paragraph (b)(1) and the remainder of paragraph (b) is renumbered accordingly. Paragraph (b) is clarified regarding the regulation of U.S. Munitions List nuclear items.

Section 110.2, Definitions. This final rule revises the definitions for *Agreement for Cooperation, Atomic Energy Act, Classified Information, Conversion facility, Depleted uranium, Effective kilograms of special nuclear material, Embargoed, Executive Branch, General license, Heels, Medical isotope, Natural uranium, Non-Nuclear Weapons State, NRC Public Document Room, Obligations, Person, Physical security, Production facility, Radioactive waste, Radiopharmaceutical, Recipient Country, Restricted destinations,* and *Specific license.* The revision to the definition of *radioactive waste* is discussed in detail in Section I.B of this document. The definitions for *Bulk material, Low-level waste compact,* and *Nuclear Suppliers Group* are added for clarification purposes. In addition, this final rule removes the definition of *Incidental radioactive material* as discussed in Section I.B of this document.

Section 110.6, Retransfers. This final rule adds language clarifying the scope of the provisions to be consistent with the requirements of the Atomic Energy

Act. Paragraph (b) is amended to update the address for the Department of Energy.

Section 110.7, Information collection requirements: OMB approval. This final rule restructures the section for clarification and makes a minor editorial change.

Section 110.7a, Completeness and accuracy information. This final rule makes an editorial change to paragraph (b).

Subpart B—Exemptions

Section 110.10, General. This final rule amends paragraph (c) to clarify that an exemption does not relieve any person from complying with the regulations of other U.S. Federal and/or State government agencies.

Section 110.11, Export of IAEA safeguards samples. This final rule makes editorial changes.

Subpart C—Licenses

Section 110.19, Types of licenses. This final rule removes paragraph (b) which relates to exports of incidental radioactive material. This final rule also amends paragraph (a) by removing the last sentence regarding compliance with other applicable regulations, and the paragraphs designation. The requirement that general and specific licensees are subject to other applicable laws or regulations is addressed in § 110.50(a).

Section 110.20, General license information. This final rule removes references to "incidental radioactive material" and corrects citations in paragraph (a). Paragraph (d) is amended to preclude use of generally licensed material in any illegal or inappropriate activity such as use in a radiological dispersion device, diversion of material or equipment, and other malicious acts.

Section 110.21, General license for the export of special nuclear material. This final rule removes the general license provision related to the export of incidental radioactive material in paragraph (e) and makes editorial changes to paragraphs (a), (b), and (c).

Section 110.22, General license for the export of source material. This final rule deletes paragraph (c), makes editorial changes, corrects internal reference errors in the section, and adds a reference to paragraph (d) to the text of paragraph (e). Paragraph (c) is removed because it repeats rule text found in § 110.21(b)(3). The final rule also removes the general license provision related to the export of incidental radioactive material in paragraph (g).

Section 110.23, General license for the export of byproduct material. This final rule makes editorial and organizational changes to clarify requirements. The reporting requirements in paragraph (b) for exports of americium and neptunium are moved to § 110.54, Reporting requirements.

Section 110.24, General license for the export of deuterium. This final rule makes editorial changes to clarify the text in order to improve readability.

Section 110.25. This final rule adds and reserves § 110.25. This change is made to clarify that there is not a printing error in 10 CFR part 110 and reserves this section for possible future changes to the regulations.

Section 110.26, General license for the export of nuclear reactor components. This final rule restructures paragraph (a) to clarify that the general license covers components of U.S. origin. In response to a comment received on the proposed rule, a clarifying note is added at the end of § 110.26 regarding "U.S. origin". The text of paragraph (a)(1) is incorporated into the introductory text of paragraph (a). Paragraphs (a)(2) and (a)(3) are redesignated as (a)(1) and (a)(2), respectively. New paragraph (a)(2) is revised to allow a component to be returned to the United States after final fabrication or repair or to be used in a nuclear power or research reactor in one of the destinations listed in the section. This allows, for example, a component that was sent to Japan for final fabrication or repair to be sent to Spain for use in a nuclear power or research reactor in that country. The list of destinations previously contained in paragraph (a) are now in the new paragraph (b) of this final rule. Subsequent paragraphs are renumbered accordingly.

New paragraph (b) is revised to include additional destinations to which exports may be sent under a general license. These destinations are Cyprus, Estonia, Hungary, Malta, Poland, Slovak Republic, and Slovenia. The United States has received broad generic assurances from EURATOM which also apply to these new EURATOM member countries for purposes of section 109b. of the Atomic Energy Act.

The reporting requirements contained in paragraph (d) for exports of reactor components are moved to § 110.54, Reporting requirements, in this final rule.

Section 110.27, General license for imports. This final rule removes paragraphs (a)(1) and (a)(2). NRC's import regulations do not apply to DOE imports of source, special nuclear, or byproduct material including imports conducted on DOE's behalf by DOE contractors. Paragraph (a)(2) is removed because a general license is not required for the import of byproduct, source, or special nuclear material when that same material is exempt from NRC domestic licensing requirements. This change clarifies that material that is exempt or else not subject to domestic licensing requirements (*e.g.,* § 31.18 and § 40.13) does not require a general or specific import license unless otherwise mandated in 10 CFR part 110.

Paragraph (b) is revised to clarify that the 100 kilograms per shipment limit only applies to the material and does not include the weight of the container. As revised, this paragraph states that the general license in paragraph (a) does not authorize the import of more than 100 kilograms per shipment of source and/or special nuclear material in the form of irradiated fuel.

This final rule revises paragraph (f) by removing the specific license requirement for imports of radioactive material listed in Table 1 of Appendix P to 10 CFR part 110 and referencing the advance notification requirement in § 110.50.

Section 110.30, Members of the Nuclear Suppliers Group. This final rule updates the list of Nuclear Suppliers Group members by adding China, Croatia, Estonia, Iceland, Kazakhstan, Lithuania, and Malta.

Section 110.31, Application for a specific license. The final rule amends this section to require requests for an exemption from a licensing requirement to be filed on NRC Form 7. This is consistent with NRC regulations that require all licensing requests (*e.g.,* exports, imports, amendment, and renewal applications) to be made using NRC Form 7. *See* 71 FR 19102; April 13, 2006.

This final rule also requires a request for an exemption from a licensing requirement to be accompanied by the appropriate fee in accordance with the fee schedules in §§ 170.21 and 170.31. This change is consistent with the Fiscal Year 2007 NRC Fee Rule which established a flat fee for requests for exemptions from the NRC's export and import licensing requirements. *See* 72 FR 31402; June 6, 2007. This change updates 10 CFR part 110 to reflect recent changes to the fee schedule in 10 CFR part 170.

Additionally, this final rule adds a signature requirement to § 110.31 that each application submitted on NRC Form 7 must be signed by the applicant or licensee or a person duly authorized to act for and on behalf of the applicant or licensee. This change is consistent with requirements related to applications for specific licenses in other parts of the NRC's regulations. It also clarifies that a signature is required

to certify the veracity of information submitted to the agency on the NRC Form 7.

Finally, the order of paragraphs (b) and (c) is reversed so that § 110.31 flows in a more logical manner where the requirement for an application for a specific license to export or import or a request for an exemption from a licensing requirement precedes the requirement that such an application or request be accompanied by the appropriate license fee. In paragraph (b), as revised, "combined export/import" is removed to be consistent with the proposal to allow imports of Category 1 and 2 materials listed in Table 1 of Appendix P of 10 CFR part 110 under general license.

Section 110.32, Information required on an application for a specific license/ NRC Form 7. This final rule change to paragraph (b) to clarify that the name and address of any other party, including the supplier of the equipment or material, if different from the applicant, must be provided on the application. Paragraphs (f)(1) and (f)(2) are amended for consistency purposes. Specifically, for the export of nuclear equipment to a foreign reactor, a license application will include the name of the facility so the NRC will know whether Executive Branch review is required, per § 110.41(a)(7).

This section is also amended to clarify that applicants for the import of radioactive waste must provide the classification of that waste as defined in 10 CFR 61.55 when the waste is being imported for direct disposal. If the waste is being imported for treatment or management at an NRC- or Agreement State-licensed waste processor, classification, as defined in 10 CFR 61.55, is not required. Rather, a detailed characterization (physical and chemical characteristics) of the waste being imported for treatment or management must be provided in the application.

Paragraph (g) is deleted to conform to the change that allows Category 1 and Category 2 quantities of radioactive materials to be imported under a general license. This change is discussed in more detail in the section-by-section analysis for § 110.27.

Paragraph (h) is redesignated as new paragraph (g) and allows the exporter of Category 2 quantities of material listed in Table 1 of Appendix P to provide the pertinent documentation that the recipient of the material has the necessary authorization under the laws and regulations of the importing country to receive and possess the material to the NRC at least 24 hours prior to the shipment. The requirement that the applicant for a Category 1 export license provide the NRC, at the time the application is submitted, with pertinent documentation demonstrating that the recipient of the radioactive material has the necessary authorization (usually in the form of a license) under the laws and regulations of the importing country to receive and possess the material remain unchanged.

Subpart D—Review of License Applications

Section 110.40, Commission review. This final rule amends this section to reduce the number of export license applications that require Commission review, and instead focuses Commission review on the export license applications that raise significant policy issues. For example, mandatory Commission review of export applications for nuclear grade graphite for nuclear end use and 1,000 kilograms or more of deuterium oxide are no longer required unless the export raises an important policy issue. This change also increases the proposed export of one effective kilogram of high-enriched uranium, plutonium or uranium-233 to five effective kilograms for mandatory Commission review. The change mandates Commission review of export and import license applications that raise significant policy issues. Significant policy issues include, but are not limited to, the proposed initial decision on whether to issue a license with special limitations to a country, or the proposed decision on issuance of a license covering a facility where major safety or security issues have been recently raised. If the staff is uncertain whether a license application raises a significant policy issue, the license application should receive Commission review. However, any export that is subject to special limitations as determined by the staff or the Executive Branch will be considered one that raises a significant policy issue and will continue to require Commission review. By focusing on policy issues, this change increases efficiency and reduces fees on routine NRC export applications. This final rule also adds a requirement for Commission review of export applications of material listed in Table 1 of appendix P to 10 CFR part 110 involving exceptional circumstances, as defined in § 110.42, or Category 1 quantities of material to any country listed in § 110.28.

Section 110.41, Executive Branch review. The final rule makes a minor editorial change and requires Executive Branch review of exports raising significant policy issues, including exports of radioactive material listed in Table 1 of appendix P to 10 CFR part 110 involving exceptional circumstances, as defined in § 110.42. Also, the export of radioactive material listed in Table 1 of Appendix P to any country listed in §§ 110.28 or 110.29 requires the review of the Executive Branch in accordance with § 110.41(a)(9).

Section 110.43, Import licensing criteria. This final rule clarifies that, with respect to the import of radioactive waste, the NRC consults with, as applicable, the Agreement State in which the facility is located and the low-level waste compact commission(s) to confirm that an appropriate facility has agreed to accept and is authorized to possess the waste for management or disposal. This change addresses commenters questions that the NRC received on the scope of the Agreement State and low-level waste compact commission's role (if applicable) regarding the NRC's review of import applications for radioactive waste.

Additionally, this final rule removes the import licensing criteria related to the imports of radioactive material listed in Appendix P. This change conforms § 110.43 with the change to allow Category 1 and Category 2 quantities of radioactive materials to be imported under a general license. This change is discussed in more detail in the section-by-section analysis for § 110.27.

Section 110.44, Physical security standards. This final rule corrects the Web site address for the National Archives and Records Administration. Changes to § 110.44(b)(1) clarify that the Commission determinations on the adequacy of physical security measures are based on receipt by the appropriate U.S. Executive Branch agency of written assurances from the relevant recipient country governments that physical security measures for providing protection are at least comparable to the recommendations set forth in INFCIRC/ 225/Rev. 4 (corrected), June 1999.

Section 110.45, Issuance or denial of license. This final rule removes the parenthetical text in paragraph (a) that states "If an Executive Order provides an exemption pursuant to section 126a of the Atomic Energy Act, proposed exports to EURATOM countries are not required to meet the criteria in § 110.42(a)(4) and (5)". This is no longer needed because the Agreement for Cooperation in the Peaceful Uses of Nuclear Energy between the European Atomic Energy Community (EURATOM) and the United States of America that went into effect in 1995 obviates the need for a presidential exemption.

This final rule makes conforming changes to paragraph (b)(4) which are consistent with the changes to § 110.43(d), regarding the issuance of an import license for radioactive waste. Paragraph (b)(5) is removed to eliminate the criteria related to the imports of radioactive material listed in Appendix P to 10 CFR part 110. This change conforms § 110.45 with the change to allow Category 1 and Category 2 quantities of radioactive materials to be imported under a general license. This change is discussed in more detail in the section-by-section analysis for § 110.27. Additionally, paragraph (d) is amended to clarify that the provisions in this paragraph do not apply to Commission decisions regarding license applications for specific licenses to export radioactive material listed in Table 1 of Appendix P.

Subpart E—License Terms and Related Provisions

Section 110.50, Terms. This final rule makes several editorial, clarifying, and conforming changes to this section. In paragraph (a)(1), changes clarify that each license is subject to all applicable provisions of the Atomic Energy Act or other applicable law. Paragraph (a)(4) is rewritten and renumbered as paragraph (a)(5) to make clear that each license issued by the NRC for the export or import of nuclear material authorizes only the export or import of that nuclear material and accompanying packaging, fuel element, hardware, or other associated devices or products. Paragraph (b)(5) is revised to remove reference to 10 CFR parts 40, 70, 71, and 73 and renumbered as paragraph (a)(3). This license term applies to both general and specific licenses and is moved to paragraph (a).

In paragraph (b)(2), changes clarify that a licensee may export or import only for the purpose(s) and/or end-use(s) stated in the specific export or import license issued by the NRC. Paragraph (b)(3) is amended by adding a new paragraph (b)(3)(i) and renumbering current paragraphs (b)(3)(i) and (b)(3)(ii) as (b)(3)(ii) and (b)(3)(iii), respectively. New paragraph (b)(3)(i) clarifies that prior to shipment of certain nuclear material or equipment that has associated with it export controls imposed by other countries (foreign-obligated material or equipment), a license amendment may be required to authorize the shipment. Alternatively, the licensee is to give the NRC 40-days advance notice of the intended shipment.

Paragraph (b)(4) is redesignated as new paragraph (c) and includes the requirements for advanced notifications related to the export or import of radioactive material listed in Table 1 of appendix P to 10 CFR part 110. Changes to the advance notification requirements conforms this section to the change to allow Category 1 and Category 2 quantities of radioactive materials to be imported under a general license. This change is discussed in more detail in the section-by-section analysis for § 110.27. Additionally, editorial changes update the Web site information for the Office of International Programs and provide specific details on where to send the information required for export and import notifications.

Section 110.51, Amendment and renewal of licenses. This final rule separates the requirements for license amendments and renewals into separate paragraphs. This change clarifies the differences in requirements between amendment and renewal requests and improves readability of the section. No substantive changes are made to the requirements of the paragraphs.

Section 110.53, United States address, records, and inspections. This final rule clarifies that both general and specific licensees are required to have an office in the United States where papers may be served and where records required by the Commission will be maintained. Also, similar clarifying language is added to paragraph (b) of this section that license applicants and both general and specific licensees shall maintain records concerning its exports and imports. Clarifying language is added that byproduct material records must be retained for three years after the date of each export or import shipment.

Section 110.54, Reporting requirements. The reporting requirements in § 110.23 for exports of americium and neptunium, and in § 110.26 for exports of reactor components have been moved to § 110.54. This change consolidates the reporting requirements in 10 CFR part 110 into one section.

Subpart F—Violations and Enforcement

Sections 110.60, Violations, 110.66, Enforcement hearing, and 110.67, Criminal penalties. This final rule makes non-substantive changes for the purposes of consistency and clarification.

Subpart G—Public Notification and Availability of Documents and Records

Section 110.70, Public notice of receipt of an application. This final rule clarifies that the Commission will publish in the **Federal Register** a notice of receipt for applications for amendment or renewal for the export of the nuclear equipment and material listed in § 110.70(b)(1) through (b)(5) and for applications for amendment or renewal for the import of radioactive waste. Once a notice has been published, the Commission would not publish in the **Federal Register** proposed minor amendments to the application or license. Proposed amendments would be posted on the NRC's Web site.

Subpart H—Public Participation Procedures Concerning License Applications

Section 110.80, Basis for hearings. This final rule corrects the omission of the word "import" from the section. This change clarifies that the procedures in 10 CFR part 110 constitute the exclusive basis for hearings on export and import license applications.

Section 110.81, Written comments. This final rule clarifies that 30 days after public notice of receipt of the application means 30 days after the application is posted on the NRC Web site at *http://www.nrc.gov* or in the **Federal Register** for those applications required to be published in the **Federal Register.**

Section 110.82, Hearing request or intervention petition. This final rule adds language stating that hearing requests and intervention petitions are considered timely when filed no later than 30 days after publication of notice on the NRC Web site. This change is consistent with § 110.70, which states that the Commission will notice the receipt of each specific license application for an export or import by making a copy available at the NRC Web site, *http://www.nrc.gov.* Paragraphs (c)(2) and (c)(3) are renumbered accordingly.

Subpart I—Hearings

Section 110.112, Reporter and transcript for an oral hearing. This final rule clarifies the scope of information that will be made available at the NRC Web site or Public Document Room. Any portions of the transcript for an oral hearing containing classified information, Restricted Data, Safeguards information, proprietary information, or other sensitive unclassified information will not be made available to the public.

Appendix L to 10 CFR part 110—Illustrative list of byproduct material under NRC export/import licensing authority.

This final rule revises the list of byproduct material in Appendix L to include several radionuclides that are now classified as byproduct material as a result of the Energy Policy Act of 2005, which expanded the definition of

byproduct material in Section 11e. of the Atomic Energy Act.

Agreement State Compatibility

Under the "Policy Statement on Adequacy and Compatibility of Agreement State Programs" approved by the Commission on June 30, 1997, and published in the **Federal Register** on September 3, 1997 (62 FR 46517), this rule is classified as Compatibility Category "NRC." Compatibility is not required for Category "NRC" regulations. The NRC program elements in this category are those that relate directly to areas of regulation reserved to the NRC by the Atomic Energy Act of 1954, as amended, or the provisions of Title 10 of the Code of Federal Regulations. Although an Agreement State may not adopt program elements reserved to NRC, it may wish to inform its licensees of certain requirements via a mechanism that is consistent with the particular State's administrative procedure laws but does not confer regulatory authority on the State. The NRC will provide the Agreement States additional information so that they can inform their licensees of the change to and obligations under the revised import/export regulations.

Voluntary Consensus Standards

The National Technology Transfer and Advancement Act of 1995 (Pub. L. 104–113) requires that Federal Agencies use technical standards that are developed or adopted by voluntary consensus standards bodies unless using such a standard is inconsistent with applicable law or otherwise impractical. This action does not constitute the establishment of a standard for which the use of a voluntary consensus standard would be applicable.

Environmental Impact: Categorical Exclusion

The NRC has determined that this final rule is the type of action described in categorical exclusion 10 CFR 51.22(c)(1). Therefore, neither an environmental impact statement nor an environmental assessment has been prepared for this rule.

Paperwork Reduction Act Statement

This final rule decreases the information collection burden on licensees to update, clarify, and correct several provisions. The public burden for this information collection is estimated to be a reduction of 6 hours, which is insignificant. Because the burden for this information collection is insignificant, Office of Management and Budget (OMB) approval of the final rule is not required. Existing requirements were approved by the Office of Management and Budget, approval number 3150–0036.

Abstract

The NRC is amending its regulations that govern the export and import of nuclear equipment and material. In addition to updating, clarifying, and correcting several provisions, the final rule allows Category 1 and 2 quantities of material to be imported under a general license.

Public Protection Notification

The NRC may not conduct or sponsor, and a person is not required to respond to, a request for information or an information collection requirement unless the requesting document displays a currently valid OMB control number.

Regulatory Analysis

A regulatory analysis has not been prepared for this regulation. The NRC is amending its regulations at 10 CFR part 110 to update, clarify, and correct several provisions improving NRC's regulatory framework for the export and import of nuclear equipment, material, and radioactive waste. Most of the changes are administrative in nature and result in no changes to the information collection burden or costs to the public. In addition to updating, clarifying and correcting several provisions of 10 CFR part 110, this final rule allows imports of Category 1 and 2 quantities of material under a general license instead of a specific license. The final rule also revises the definition of "radioactive waste." In addition, the definition of "incidental radioactive material" has been removed and aspects of it have been incorporated into the revised definition of "radioactive waste." The changes to 10 CFR part 110 facilitate the licensing process for exports and imports of radioactive waste and improve the efficiency and consistency of licensing actions. These changes do not result in a significant increase to the information collection burden or costs to the public.

Regulatory Flexibility Certification

As required by the Regulatory Flexibility Act of 1980, (5 U.S.C. 605(b)), the Commission certifies that this rule does not have a significant economic impact on a substantial number of small entities. This rule affects only companies exporting or importing nuclear equipment, material, and radioactive waste to and from the United States and does not fall within the scope of the definition of "small entities" set forth in the Regulatory Flexibility Act (5 U.S.C. 601(3)), or the Size Standards established by the NRC (10 CFR 2.810).

Backfit Analysis

The NRC has determined that a backfit analysis is not required for this rule because these amendments do not involve any provisions that impose backfits as defined in 10 CFR chapter I.

Congressional Review Act

In accordance with the Congressional Review Act of 1996, the NRC has determined that this action is not a major rule and has verified this determination with the Office of Information and Regulatory Affairs of OMB.

List of Subjects in 10 CFR Part 110

Administrative practice and procedure, Classified information, Criminal penalties, Export, Import, Incorporation by reference, Intergovernmental relations, Nuclear materials, Nuclear power plants and reactors, Reporting and recordkeeping requirements, Scientific equipment.

■ For the reasons set out in the preamble and under the authority of the Atomic Energy Act of 1954, as amended; the Energy Reorganization Act of 1974, as amended; and 5 U.S.C. 553, the NRC is adopting the following amendments to 10 CFR part 110.

PART 110—EXPORT AND IMPORT OF NUCLEAR EQUIPMENT AND MATERIAL

■ 1. The authority citation for part 110 continues to read as follows:

Authority: Secs. 51, 53, 54, 57, 63, 64, 65, 81, 82, 103, 104, 109, 111, 126, 127, 128, 129, 134, 161, 181, 182, 183, 187, 189, 68 Stat. 929, 930, 931, 932, 933, 936, 937, 948, 953, 954, 955, 956, as amended (42 U.S.C. 2071, 2073, 2074, 2077, 2092–2095, 2111, 2112, 2133, 2134, 2139, 2139a, 2141, 2154–2158, 2201, 2231–2233, 2237, 2239); sec. 201, 88 Stat. 1242, as amended (42 U.S.C. 5841; sec. 5, Pub. L. 101–575, 104 Stat 2835 (42 U.S.C. 2243); sec. 1704, 112 Stat. 2750 (44 U.S.C. 3504 note); Energy Policy Act of 2005; Pub. L. 109–58, 119 Stat. 594 (2005).

Sections 110.1(b)(2) and 110.1(b)(3) also issued under Pub. L. 96–92, 93 Stat. 710 (22 U.S.C. 2403). Section 110.11 also issued under sec. 122, 68 Stat. 939 (42 U.S.C. 2152) and secs. 54c and 57d, 88 Stat. 473, 475 (42 U.S.C. 2074). Section 110.27 also issued under sec. 309(a), Pub. L. 99–440. Section 110.50(b)(3) also issued under sec. 123, 92 Stat. 142 (42 U.S.C. 2153). Section 110.51 also issued under sec. 184, 68 Stat. 954, as amended (42 U.S.C. 2234). Section 110.52 also issued under sec. 186, 68 Stat. 955 (42 U.S.C. 2236). Sections 110.80–110.113 also issued under 5 U.S.C. 552, 554. Sections 110.130–110.135 also issued under 5 U.S.C.

553. Sections 110.2 and 110.42(a)(9) also issued under sec. 903, Pub. L. 102–496 (42 U.S.C. 2151 *et seq.*).

■ 2. In § 110.1, paragraph (b) is revised to read as follows:

§ 110.1 Purpose and scope.

* * * * *

(b) The regulations in this part apply to all persons in the United States except:

(1) Persons who import or export U.S. Munitions List nuclear items such as uranium depleted in the isotope-235 and incorporated in defense articles. These persons are subject to the regulations promulgated pursuant to the Arms Export Control Act and administered by the Department of State, Directorate of Defense Trade Controls, and the Department of Justice, Bureau of Alcohol, Tobacco, Firearms and Explosives, as authorized by section 110 of the International Security and Development Cooperation Act of 1980.

(2) Persons who export uranium depleted in the isotope-235 and incorporated in commodities solely to take advantage of high density or pyrophoric characteristics. These persons are subject to the controls of the Department of Commerce under the Export Administration Act, as continued in force under Executive Order 13222 (August 22, 2001), as extended;

(3) Persons who export nuclear referral list commodities such as bulk zirconium, rotor and bellows equipment, maraging steel, nuclear reactor related equipment, including process control systems and simulators. These persons are subject to the licensing authority of the Department of Commerce pursuant to 15 CFR part 730 *et seq.;*

(4) Persons who import deuterium, nuclear grade graphite, or nuclear equipment other than production or utilization facilities. A uranium enrichment facility is not a production facility for the purposes of import; and

(5) Shipments which are only passing through the U.S. (in bond shipments) do not require an NRC import or export license; however, they must comply with the Department of Transportation/IAEA packaging, and State transportation requirements.

■ 3. In § 110.2:

■ a. The definition of "Incidental radioactive material" is removed;

■ b. The definitions of "Agreement for Cooperation", "Atomic Energy Act", "Classified Information", "Conversion facility", "Depleted uranium", "Effective kilograms of special nuclear material", "Embargoed", "Executive Branch", "General license", "Heels", "Medical isotope", "Natural uranium", "Non-Nuclear Weapons State", "NRC Public Document Room", "Obligations", "Person", "Physical security", "Production facility", "Radioactive waste", "Radiopharmaceutical", "Recipient Country", "Restricted destinations", and "Specific license" are revised; and

■ c. The definitions of "Bulk material", "Low-level waste compact", and "Nuclear Suppliers Group" are added in alphabetical order.

The revisions and additions read as follows:

§ 110.2 Definitions.

* * * * *

Agreement for Cooperation means any agreement with another nation or group of nations concluded under section 123 of the Atomic Energy Act.

Atomic Energy Act means the Atomic Energy Act of 1954, as amended (42 U.S.C. 2011 *et seq.*).

Bulk Material means any quantity of any one or more of the radionuclides listed in Table 1 of Appendix P to this part in a form that is:

(1) Not a Category 1 radioactive source;

(2) Not a Category 2 radioactive source;

(3) Not plutonium-238; and

(4) Deemed to pose a risk similar to or greater than a Category 2 radioactive source.

* * * * *

Classified Information means Classified National Security Information under Executive Order 12958, as amended, or any successor Executive Order and Restricted Data under the Atomic Energy Act.

* * * * *

Conversion facility means any facility for the transformation from one uranium chemical species to another, including conversion of uranium ore concentrates to uranium trioxide (UO3), conversion of UO3 to uranium dioxide (UO2), conversion of uranium oxides to uranium tetrafluoride (UF4) or uranium hexafluoride (UF6), conversion of UF4 to UF6, conversion of UF6 to UF4, conversion of UF4 to uranium metal, and conversion of uranium fluorides to UO2.

Depleted uranium means uranium having a percentage of uranium-235 less than the naturally occurring distribution of uranium-235 found in natural uranium (less than 0.711 weight percent uranium-235). It is obtained from spent (used) fuel elements or as byproduct tails or residues from uranium isotope separation.

* * * * *

Effective kilograms of special nuclear material means:

(1) For plutonium and uranium-233, their weight in kilograms;

(2) For uranium enriched 1 percent or greater in the isotope uranium-235, its element weight in kilograms multiplied by the square of its enrichment expressed as a decimal weight fraction; and

(3) For uranium enriched below 1 percent in the isotope uranium-235, its element weight in kilograms multiplied by 0.0001.

Embargoed means that no nuclear material or equipment can be exported to certain countries under an NRC general license. Exports to embargoed countries must be pursuant to a specific license issued by the NRC and require Executive Branch review pursuant to § 110.41.

* * * * *

Executive Branch means the Departments of State, Energy, Defense and Commerce.

* * * * *

General license means an export or import license effective without the filing of a specific application with the Commission or the issuance of licensing documents to a particular person. A general license is a type of license issued through rulemaking by the NRC and is not an exemption from the requirements in this part. A general license does not relieve a person from complying with other applicable NRC, Federal, and State requirements.

Heels means small quantities of natural, depleted or low-enriched uranium (to a maximum of 20 percent), in the form of uranium hexaflouride (UF6) left in emptied transport cylinders being returned to suppliers after delivery of the product.

* * * * *

Low-level waste compact, as used in this part, means a compact entered into by two or more States pursuant to the Low-Level Radioactive Waste Policy Amendments Act of 1985.

* * * * *

Medical isotope, for the purposes of § 110.42(a)(9), includes molybdenum-99, iodine-131, xenon-133, and other radioactive materials used to produce a radiopharmaceutical for diagnostic, therapeutic procedures or for research and development.

Natural uranium means uranium as found in nature, containing about 0.711 percent of uranium-235, 99.283 percent of uranium-238, and a trace (0.006 percent) of uranium-234.

* * * * *

Non-Nuclear Weapon State means any State not a nuclear weapon State as

defined in the Treaty on the Non-Proliferation of Nuclear Weapons. *Nuclear Weapon State* means any State which has manufactured and exploded a nuclear weapon or other nuclear explosive device prior to January 1, 1967 (China, France, Russia, United Kingdom, United States).

* * * * *

NRC Public Document Room means the facility at One White Flint North, 11555 Rockville Pike (first floor), Rockville, Maryland, where certain public records of the NRC that were made available for public inspection in paper or microfiche prior to the implementation of the NRC Agencywide Documents Access and Management System, commonly referred to as ADAMS, will remain available for public inspection. It is also the place where NRC makes computer terminals available to access the Publicly Available Records System (PARS) component of ADAMS on the NRC Web site, *http://www.nrc.gov,* and where copies can be viewed or ordered for a fee as set forth in § 9.35 of this chapter. The facility is staffed with reference librarians to assist the public in identifying and locating documents and in using the NRC Website and ADAMS. The NRC Public Document Room is open from 7:45 a.m. to 4:15 p.m., Monday through Friday, except on Federal holidays. Reference service and access to documents may also be requested by telephone (301–415–4737 or 800–397–4209) between 8:30 a.m. and 4:15 p.m., or by e-mail (*PDR.Resource@nrc.gov*), facsimile (301–415–3548), or letter (NRC Public Document Room, One White Flint North, 11555 Rockville Pike (first floor), Rockville, Maryland 20852–2738).

* * * * *

Nuclear Suppliers Group (NSG) is a group of nuclear supplier countries which seeks to contribute to the non-proliferation of nuclear weapons through the implementation of Guidelines for nuclear exports and nuclear-related exports.

Obligations means the commitments undertaken by the U.S. Government or by foreign governments or groups of nations with respect to imports or exports of nuclear material (except byproduct material) and equipment listed in §§ 110.8 and 110.9. Imports and exports of material or equipment subject to these commitments involve conditions placed on the transfer of the material or equipment, such as peaceful end-use assurances, prior consent for retransfer, and exchanges of information on the import or export. The U.S. Government informs the licensee of obligations attached to material or equipment being imported into the United States and approves changes to those obligations.

* * * * *

Person means any individual, corporation, partnership, firm, association, trust, estate, public or private institution, group, Government agency, other than the Commission or the Department of Energy, except that the Department of Energy shall be considered a person within the meaning of the regulations in this part to the extent that its activities are subject to the licensing and related regulatory authority of the Commission pursuant to section 111 of the Atomic Energy Act; any State or political subdivision of, or any political entity within a State, any foreign government or nation or any political subdivision of any such government or nation, or other entity; and any legal successor, representative, agent, or agency of the foregoing.

Physical security or *Physical protection* means measures to reasonably ensure that source or special nuclear material will only be used for authorized purposes and to prevent theft or sabotage.

Production facility means any nuclear reactor or plant specially designed or used to produce special nuclear material through the irradiation of source material or special nuclear material, the chemical reprocessing of irradiated source or special nuclear material, or the separation of isotopes, other than a uranium enrichment facility for purposes of import.

* * * * *

Radioactive waste, for the purposes of this part, means any material that contains or is contaminated with source, byproduct, or special nuclear material that by its possession would require a specific radioactive material license in accordance with this Chapter and is imported or exported for the purposes of disposal in a land disposal facility as defined in 10 CFR part 61, a disposal area as defined in Appendix A to 10 CFR part 40, or an equivalent facility; or recycling, waste treatment or other waste management process that generates radioactive material for disposal in a land disposal facility as defined in 10 CFR part 61, a disposal area as defined in Appendix A to 10 CFR part 40, or an equivalent facility. Radioactive waste does not include radioactive material that is—

(1) Of U.S. origin and contained in a sealed source, or device containing a sealed source, that is being returned to a manufacturer, distributor or other entity which is authorized to receive and possess the sealed source or the device containing a sealed source;

(2) A contaminant on any non-radioactive material (including service tools and protective clothing) used in a nuclear facility (an NRC- or Agreement State-licensed facility (or equivalent facility) or activity authorized to possess or use radioactive material), if the material is being shipped solely for recovery and beneficial reuse of the non-radioactive material in a nuclear facility and not for waste management purposes or disposal;

(3) Exempted from regulation by the Nuclear Regulatory Commission or equivalent Agreement State regulations;

(4) Generated or used in a U.S. Government waste research and development testing program under international arrangements;

(5) Being returned by or for the U.S. Government or military to a facility that is authorized to possess the material; or

(6) Imported solely for the purposes of recycling and not for waste management or disposal where there is a market for the recycled material and evidence of a contract or business agreement can be produced upon request by the NRC.

Note: The definition of *radioactive waste* in this part does not include spent or irradiated fuel.

Radiopharmaceutical, for the purposes of § 110.42(a)(9), means a radioactive isotope that contains byproduct material combined with chemical or biological material and is designed to accumulate temporarily in a part of the body for therapeutic purposes or for enabling the production of a useful image for use in a diagnosis of a medical condition.

Recipient Country, for the purposes of § 110.42(a)(9), means Canada, Belgium, France, Germany, and the Netherlands.

Restricted destinations means countries that are listed in § 110.29 based on recommendations from the Executive Branch. These countries may receive exports of certain materials and quantities under a general license, but some exports to restricted destinations will require issuance of a specific license by the NRC including Executive Branch review pursuant to § 110.41.

* * * * *

Specific license means an export or import license document issued to a named person and authorizing the export or import of specified nuclear equipment or materials based upon the review and approval of an NRC Form 7 application filed pursuant to this part and other related submittals in support of the application.

* * * * *

■ 4. Section 110.6 is revised to read as follows:

§ 110.6 Retransfers.

(a) Retransfer of any nuclear equipment or material listed in §§ 110.8 and 110.9 (except byproduct material), including special nuclear material produced through the use of equipment, source material, or special nuclear material bearing obligations to the United States pursuant to an agreement for cooperation, requires authorization by the Department of Energy, unless the export to the new destination is authorized by the NRC under a specific or general license or an exemption from licensing requirements. See definition of "obligations" in § 110.2.

(b) Requests for authority to retransfer are processed by the Department of Energy, National Nuclear Security Administration, Office of International Regimes and Agreements, Washington, DC 20585.

■ 5. In § 110.7, paragraph (c) is revised to read as follows:

§ 110.7 Information collection requirements: OMB approval.

* * * * *

(c) This part contains information collection requirements in addition to those approved under the control number specified in paragraph (a) of this section. The information collection requirements contained in §§ 110.19, 110.20, 110.21, 110.22, 110.23, 110.31, 110.32, and 110.51, and NRC Form 7 are approved under control number 3150–0027.

■ 6. In § 110.7a, paragraph (b) is revised to read as follows:

§ 110.7a Completeness and accuracy of information.

* * * * *

(b) Each licensee or applicant for a license shall notify the Commission of information identified by the applicant or licensee as having, for the regulated activity, a significant implication for public health and safety or common defense and security. An applicant or licensee violates this paragraph if the applicant or licensee fails to notify the Commission of information that the applicant or licensee has identified as having a significant implication for public health and safety or common defense and security. Notification shall be provided to the Administrator of the appropriate Regional Office within two working days of identifying the information. This requirement is not applicable to information which is already required to be provided to the Commission by other reporting or updating requirements.

■ 7. In § 110.10, paragraph (c) is revised to read as follows:

§ 110.10 General.

* * * * *

(c) The granting of an exemption does not relieve any person from complying with the regulations of other U.S. Federal and/or State government agencies applicable to exports or imports under their authority.

■ 8. Section 110.11 is revised to read as follows:

§ 110.11 Export of IAEA safeguards samples.

A person is exempt from the requirements for a license to export special nuclear material set forth in sections 53 and 54d. of the Atomic Energy Act and from the regulations in this part to the extent that the person exports special nuclear material in IAEA safeguards samples, if the samples are exported in accordance with § 75.8 of this chapter, or a comparable Department of Energy order, and are in quantities not exceeding a combined total of 100 grams of contained plutonium, uranium-233 and uranium-235 per facility per year. This exemption does not relieve any person from complying with parts 71 or 73 of this chapter or any Commission order under section 201(a) of the Energy Reorganization Act of 1974 (42 U.S.C. 5841(a)).

■ 9. Section 110.19 is revised to read as follows:

§ 110.19 Types of licenses.

Licenses for the export and import of nuclear equipment and material in this part consist of general licenses and specific licenses. A general license is effective without the filing of an application with the Commission or the issuance of licensing documents to a particular person. A specific license is issued to a named person and is effective upon approval by the Commission of an application filed pursuant to the regulations in this part and issuance of licensing documents to the applicant.

■ 10. In § 110.20, paragraphs (a) and (d) are revised to read as follows:

§ 110.20 General license information.

(a) A person may use an NRC general license as authority to export or import nuclear equipment or material, if the nuclear equipment or material to be exported or imported is covered by the NRC general licenses described in §§ 110.21 through 110.27. If an export or import is not covered by the NRC general licenses described in §§ 110.21 through 110.27, a person must file an application with the Commission for a specific license in accordance with §§ 110.31 through 110.32.

* * * * *

(d) A general license for export may not be used if the exporter knows, or has reason to believe, that the material will be used in any illegal activity or any activity related to isotope separation, chemical reprocessing, heavy water production or the fabrication of nuclear fuel containing plutonium, unless these activities are generically authorized under an appropriate agreement for cooperation.

* * * * *

■ 11. In § 110.21 paragraph (e) is removed and paragraphs (a)(3), (a)(4), (b), and (c) are revised to read as follows:

§ 110.21 General license for the export of special nuclear material.

(a) * * *

(3) Special nuclear material, other than plutonium-236 and plutonium-238, in sensing components in instruments, if no more than 3 grams of enriched uranium or 0.1 gram of plutonium or uranium-233 are contained in each sensing component.

(4) Plutonium-236 and plutonium-238 when contained in a device, or a source for use in a device, in quantities of less than 3.7×10^{-3} TBq (100 millicuries) of alpha activity (189 micrograms plutonium-236, 5.88 milligrams plutonium-238) per device or source.

(b) Except as provided in paragraph (d) of this section, a general license is issued to any person to export the following to any country not listed in § 110.28 or § 110.29:

(1) Special nuclear material, other than plutonium-236 and plutonium-238, in individual shipments of 0.001 effective kilogram or less (*e.g.,* 1.0 gram of plutonium, uranium-233 or uranium-235, or 10 kilograms of 1 percent enriched uranium), not to exceed 0.1 effective kilogram per calendar year to any one country.

(2) Special nuclear material in fuel elements as replacements for damaged or defective unirradiated fuel elements previously exported under a specific license, subject to the same terms as the original export license and the condition that the replaced fuel elements must be returned to the United States within a reasonable time period.

(3) Uranium, enriched to less than 20 percent in uranium-235, in the form of uranium hexafluoride (UF6) heels in cylinders being returned to suppliers in EURATOM.

(c) Except as provided in paragraph (d) of this section, a general license is

issued to any person to export plutonium-236 or plutonium-238 to any country listed in § 110.30 in individual shipments of 1 gram or less, not to exceed 100 grams per calendar year to any one country.

* * * * *

■ 12. Section 110.22 is revised to read as follows:

§ 110.22 General license for the export of source material.

(a) Except as provided in paragraph (e) of this section, a general license is issued to any person to export the following to any country not listed in § 110.28:

(1) Uranium or thorium, other than uranium-230, uranium-232, thorium-227, and thorium-228, in any substance in concentrations of less than 0.05 percent by weight.

(2) Thorium, other than thorium-227 and thorium-228, in incandescent gas mantles or in alloys in concentrations of 5 percent or less.

(3) Thorium-227, thorium-228, uranium-230, and uranium-232 when contained in a device, or a source for use in a device, in quantities of less than 3.7×10^{-3} TBq (100 millicuries) of alpha activity (3.12 micrograms thorium-227, 122 micrograms thorium-228, 3.7 micrograms uranium-230, 4.7 milligrams uranium-232) per device or source.

(b) Except as provided in paragraph (f) of this section, a general license is issued to any person to export uranium or thorium, other than uranium-230, uranium-232, thorium-227, or thorium-228, in individual shipments of 10 kilograms or less to any country not listed in § 110.28 or § 110.29, not to exceed 1,000 kilograms per calendar year to any one country or 500 kilograms per calendar year to any one country when the uranium or thorium is Canadian-obligated.

(c) Except as provided in paragraph (e) of this section, a general license is issued to any person to export uranium or thorium, other than uranium-230, uranium-232, thorium-227, or thorium-228, in individual shipments of 1 kilogram or less to any country listed in § 110.29, not to exceed 100 kilograms per calendar year to any one country.

(d) Except as provided in paragraph (e) of this section, a general license is issued to any person to export uranium-230, uranium-232, thorium-227, or thorium-228 in individual shipments of 10 kilograms or less to any country listed in § 110.30, not to exceed 1,000 kilograms per calendar year to any one country or 500 kilograms per calendar year to any one country when the uranium or thorium is Canadian-obligated.

(e) Paragraphs (a), (b), (c), and (d) of this section do not authorize the export under general license of source material in radioactive waste.

■ 13. Section 110.23 is revised to read as follows:

§ 110.23 General license for the export of byproduct material.

(a) A general license is issued to any person to export byproduct material (see Appendix L to this part) to any country not listed in § 110.28 and subject to the following limitations:

(1) The general license in this section does not authorize the export of byproduct material in the form of radioactive waste.

(2) The general license in this section does not authorize the export of the following radionuclides:

Americium-242m
Californium-249
Californium-251
Curium-245
Curium-247

(3) For byproduct materials listed in Table 1 of Appendix P to this part, individual shipments under a general license for export must be less than the terabequeral (TBq) values specified in Category 2 of Table 1 unless a more restrictive requirement applies.

(4) The general license authorizes exports of the following radionuclides when contained in a device, or a source for use in a device, in quantities less than 3.7×10^{-3} TBq (100 millicuries) of alpha activity per device or source, unless the export is to a country listed in § 110.30:

Actinium-225
Actinium-227
Californium-248
Californium-250
Californium-252
Californium-253
Californium-254
Curium-240
Curium-241
Curium-242
Curium-243
Curium-244
Einsteinium-252
Einsteinium-253
Einsteinium-254
Einsteinium-255
Fermium-257
Gadolinium-148
Mendelevium-258
Neptunium-235
Polonium-208
Polonium-209
Polonium-210
Radium-223

(5)(i) For americium-241, exports under the general license to a country listed in § 110.29 must not exceed 3.7×10^{-2} TBq (one curie) per shipment.

(ii) For americium-241, exports under the general license to a country listed in § 110.29 that exceed 3.7×10^{-2} TBq (one curie) per shipment, must be contained in industrial process control equipment or petroleum exploration equipment in quantities not exceeding 0.60 TBq (16 curies) per device and not exceeding 7.4 TBq/calendar year (200 curies/calendar year) to any one country.

(iii) All exports of americium are subject to the reporting requirements listed in § 110.54(b).

(6) For neptunium-235 and -237, exports under the general license must not exceed one gram for individual shipment and must not exceed a cumulative total of 10 grams per calendar year to any one country. All exports of neptunium are subject to the reporting requirements listed in § 110.54(b).

(7) For polonium-210, exports under the general license, when contained in static eliminators, must not exceed 3.7 TBq (100 curies) per individual shipment.

(8)(i) For tritium in any dispersed form (*e.g.,* luminescent light sources and paint, accelerator targets, calibration standards, labeled compounds), exports under the general license must not exceed 0.37 TBq (10 curies (1.03 milligrams)) per item, not to exceed 37 TBq (1,000 curies (103 milligrams)) per shipment, or 370 TBq (10,000 curies (1.03 grams)) per calendar year to any one country.

(ii) For tritium in any dispersed form (*e.g.,* luminescent light sources and paint, accelerator targets, calibration standards, labeled compounds), exports under the general license to the countries listed in § 110.30 must not exceed the quantity of 1.48 TBq (40 curies (4.12 milligrams)) per item, not to exceed 37 TBq (1,000 curies (103 milligrams)) per shipment or 370 TBq (10,000 curies (1.03 grams)) per calendar year to any one country.

(iii) For tritium in luminescent safety devices installed in an aircraft, exports under the general license must not exceed 1.48 TBq (40 curies (4.12 milligrams)) per light source.

(iv) The general license in this section does not authorize the export of tritium for recovery or recycle purposes.

■ 14. Section 110.24 is revised to read as follows:

§ 110.24 General license for the export of deuterium.

(a) A general license is issued to any person to export to any country not listed in § 110.28 or § 110.29 deuterium

in individual shipments of 10 kilograms or less (50 kilograms of heavy water). No person may export more than 200 kilograms (1,000 kilograms of heavy water) per calendar year to any one country.

(b) A general license is issued to any person to export to any country listed in § 110.29 deuterium in individual shipments of 1 kilogram or less (5 kilograms of heavy water). No person may export more than 5 kilograms (25 kilograms of heavy water) per calendar year to any one country listed in § 110.29.

§ 110.25 [Reserved]

■ 15. Section 110.25 is reserved.

■ 16. Section 110.26 is revised to read as follows:

§ 110.26 General license for the export of nuclear reactor components.

(a) A general license is issued to any person to export to a destination listed in paragraph (b) of this section any nuclear reactor component of U.S. origin described in paragraphs (5) through (9) of Appendix A to this part if—

(1) The component will be used in a light or heavy water-moderated power or research reactor; or

(2) The component is in semifabricated form and will be undergoing final fabrication or repair in those countries for either subsequent return to the United States for use in a nuclear power or research reactor in the United States or in one of the destinations listed in paragraph (b) of this section.

(b) The export of nuclear reactor components under the general license established in paragraph (a) of this section is approved to the following destinations:

Austria
Belgium
Bulgaria
Canada
Cyprus
Czech Republic
Denmark
Estonia
Finland
France
Germany
Greece
Hungary
Indonesia
Ireland
Italy
Japan
Latvia
Lithuania
Luxembourg
Malta
Netherlands
New Zealand
Philippines
Poland
Portugal
Republic of Korea
Romania
Slovak Republic
Slovenia
Spain
Sweden
Switzerland
Taiwan
United Kingdom

(c) This general license does not authorize the export of components, in final or semi-fabricated form, for research reactors capable of continuous operation above 5 MW thermal.

(d) This general license does not authorize the export of essentially complete reactors through piecemeal exports of facility components. When individual exports of components would amount in the aggregate to export of an essentially complete nuclear reactor, a facility export license is required.

(e) All exports under paragraph (a) of this section are subject to the reporting requirements in § 110.54(c).

Note to § 110.26: U.S. Origin includes components produced or finished in the United States, even with non-U.S. content unless the foreign content is obligated by supplier government conditions, such as a prior consent for retransfer condition.

■ 17. In § 110.27, paragraphs (a), (b), (c), and (f) are revised to read as follows:

§ 110.27 General license for import.

(a) Except as provided in paragraphs (b) and (c) of this section, a general license is issued to any person to import byproduct, source, or special nuclear material if the U.S. consignee is authorized to receive and possess the material under a general or specific NRC or Agreement State license issued by the Commission or a State with which the Commission has entered into an agreement under Section 274b. of the Atomic Energy Act.

(b) The general license in paragraph (a) of this section does not authorize the import of more than 100 kilograms per shipment of source and/or special nuclear material in the form of irradiated fuel.

(c) Paragraph (a) of this section does not authorize the import under a general license of radioactive waste.

* * * * *

(f) Importers of radioactive material listed in Appendix P to this part must provide the notifications required by § 110.50.

§ 110.30 [Amended]

■ 18. Section 110.30 is amended by adding "China", "Croatia", "Estonia", "Iceland", "Kazakhstan", "Lithuania", and "Malta" in alphabetical order.

■ 19. Section 110.31 is revised to read as follows:

§ 110.31 Application for a specific license.

(a) A person shall file an application for a specific license to export or import with the Deputy Director of the NRC's Office of International Programs, using an appropriate method listed in § 110.4.

(b) Applications for an export, import, amendment or renewal licenses or a request for an exemption from a licensing requirement under this part shall be filed on NRC Form 7.

(c) An application for a specific license to export or import or a request for an exemption from a licensing requirement must be accompanied by the appropriate fee in accordance with the fee schedules in § 170.21 and § 170.31 of this chapter. A license application will not be processed unless the specified fee is received.

(d) Each application on NRC Form 7 shall be signed by the applicant or licensee or a person duly authorized to act for and on behalf of the applicant or licensee.

(e) Each person shall provide in the license application, as appropriate, the information specified in § 110.32. The Commission also may require the submission of additional information if necessary to complete its review.

(f) An application may cover multiple shipments and destinations.

(g) The applicant shall withdraw an application when it is no longer needed. The Commission's official files retain all documents related to a withdrawn application.

■ 20. Section 110.32 is revised to read as follows:

§ 110.32 Information required in an application for a specific license/NRC Form 7.

(a) Name and address of applicant.

(b) Name and address of any other party, including the supplier of equipment or material, if different from the applicant.

(c) Country of origin of equipment or material, and any other countries that have processed the material prior to its import into the U.S.

Note: This is meant to include all obligations attached to the material, according to the definition of *obligations* in § 110.2. Licensees must keep records of obligations attached to material which they own or is in their possession.

(d) Names and addresses of all intermediate and ultimate consignees,

other than intermediate consignees performing shipping services only.

(e) Dates of proposed first and last shipments.

(f) Description of the equipment or material including, as appropriate, the following:

(1) Maximum quantity of material in grams or kilograms (terabequerels or TBq for byproduct material) and its chemical and physical form.

(2) For enriched uranium, the maximum weight percentage of enrichment and maximum weight of contained uranium-235.

(3) For nuclear equipment, the name of the facility and its total dollar value.

(4) For nuclear reactors, the name of the facility, its design power level and its total dollar value.

(5) For proposed exports or imports of radioactive waste, the volume, physical and chemical characteristics, route of transit of shipment, classification (as defined in § 61.55 of this chapter) if imported or exported for direct disposal at part 61 or equivalent Agreement State licensed facility, and ultimate disposition (including forms of management or treatment) of the waste.

(6) For proposed imports of radioactive waste, the industrial or other process responsible for generation of the waste, and the status of the arrangements for disposition, including pertinent documentation of these arrangements.

(7) Description of end use by all consignees in sufficient detail to permit accurate evaluation of the justification for the proposed export or import, including the need for shipment by the dates specified.

(g)(1) For proposed exports of Category 1 quantities of material listed in Table 1 of appendix P to this part, pertinent documentation that the recipient of the material has the necessary authorization under the laws and regulations of the importing country to receive and possess the material.

(2) For proposed exports of Category 2 quantities of material listed in Table 1 of appendix P to this part, pertinent documentation that the recipient of the material has the necessary authorization under the laws and regulations of the importing country to receive and possess the material. This documentation must be provided to the NRC at least 24 hours prior to the shipment.

(3) Pertinent documentation shall consist of a copy of the recipient's authorization to receive and possess the material to be exported or a confirmation from the government of the importing country that the recipient is so authorized. The recipient authorization shall include the following information:

(i) Name of the recipient;

(ii) Recipient location and legal address or principal place of business;

(iii) Relevant radionuclides and radioactivity being imported or that the recipient is authorized to receive and possess;

(iv) Uses, if appropriate; and

(v) The expiration date of the recipient's authorization (if any).

■ 21. Section 110.40 is revised to read as follows:

§ 110.40 Commission review.

(a) Immediately after receipt of a license application for an export or import requiring a specific license under this part, the Commission will initiate its licensing review and, to the maximum extent feasible, will expeditiously process the application concurrently with any applicable review by the Executive Branch.

(b) The Commissioners shall review a license application for export of the following:

(1) A production or utilization facility.

(2) More than 5 effective kilograms of high-enriched uranium, plutonium or uranium-233.

(3) An export involving assistance to end uses related to isotope separation, chemical reprocessing, heavy water production, advanced reactors, or the fabrication of nuclear fuel containing plutonium, except for exports of source material or low-enriched uranium to EURATOM or Japan for enrichment up to 5 percent in the isotope uranium-235, and those categories of exports which the Commission has approved in advance as constituting permitted incidental assistance.

(4) The initial export to a country since March 10, 1978 of source or special nuclear material for nuclear end use.

(5) An initial export to any country listed in § 110.28 or § 110.29 involving over:

(i) 10 grams of plutonium, uranium-233 or high-enriched uranium;

(ii) 1 effective kilogram of low-enriched uranium;

(iii) 250 kilograms of source material or heavy water; or

(iv) 37 TBq (1,000 curies) of tritium.

(6) The export of radioactive material listed in Table 1 of Appendix P of this part involving:

(i) Exceptional circumstances in § 110.42(e); or

(ii) Category 1 quantities of material to any country listed in § 110.28.

(c) The Commission will review export and import license applications raising significant policy issues.

(d) If the Commission has not completed action on a license application within 60 days after receipt of the Executive Branch judgment, as provided for in § 110.41, or the license application when an Executive Branch judgment is not required, it will inform the applicant in writing of the reason for delay and, as appropriate, provide follow-up reports.

■ 22. In § 110.41, paragraphs (a)(2) and (a)(10) are revised to read as follows:

§ 110.41 Executive Branch review.

(a) * * *

(2) More than one effective kilogram of high-enriched uranium or 10 grams of plutonium or uranium-233.

* * * * *

(10) An export raising significant policy issues or subject to special limitations as determined by the Commission or the Executive Branch, including exports of radioactive material listed in Table 1 of appendix P to this part involving exceptional circumstances in § 110.42(e).

* * * * *

■ 23. In § 110.43, paragraphs (e) and (f) are removed and paragraph (d) is revised to read as follows:

§ 110.43 Import licensing criteria.

* * * * *

(d) With respect to the import of radioactive waste, an appropriate facility has agreed to accept and is authorized to possess the waste for management or disposal as confirmed by NRC consultations with, as applicable, the Agreement State in which the facility is located and low-level waste compact commission(s).

■ 24. Section 110.44 is revised to read as follows:

§ 110.44 Physical security standards.

(a) Physical security measures in recipient countries must provide protection at least comparable to the recommendations in the current version of IAEA publication INFCIRC/225/Rev. 4 (corrected), June 1999, "The Physical Protection of Nuclear Material and Nuclear Facilities," and is incorporated by reference in this part. This incorporation by reference was approved by the Director of the Office of the Federal Register in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. Notice of any changes made to the material incorporated by reference will be published in the **Federal Register**. Copies of INFCIRC/225/Rev. 4 may be obtained from the Deputy Director, Office of International Programs, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001, and are

available for inspection at the NRC library, 11545 Rockville Pike, Rockville, Maryland 20852–2738, telephone, (301–415–4737 or 800–397–4209) between 8:30 a.m. and 4:15 p.m. A copy 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/cfr/ibr-locations.html.*

(b) Commission determinations on the adequacy of physical security measures are based on:

(1) Receipt by the appropriate U.S. Executive Branch Agency of written assurances from the relevant recipient country government that physical security measures providing protection at least comparable to the recommendations set forth in INFCIRC/225/Rev. 4 (corrected).

(2) Information obtained through country visits, information exchanges, or other sources. Determinations are made on a country-wide basis and are subject to continuing review. Appendix M to this part describes the different categories of nuclear material to which physical security measures are applied.

■ 25. In § 110.45, paragraphs (a), (b) and (d) are revised to read as follows:

§ 110.45 Issuance or denial of license.

(a) The Commission will issue an export license if it has been notified by the State Department that it is the judgment of the Executive Branch that the proposed export will not be inimical to the common defense and security, and:

(1) Finds, based upon a reasonable judgment of the assurances provided and other information available to the Federal government, that the applicable criteria in § 110.42, or their equivalent, are met.

(2) Finds that there are no material changed circumstances associated with an export license application (except for byproduct material applications) from those existing at the time of issuance of a prior license to export to the same country, if the prior license was issued under the provisions of paragraph (a)(1) of this section.

(b) The Commission will issue an import license if it finds that:

(1) The proposed import will not be inimical to the common defense and security;

(2) The proposed import will not constitute an unreasonable risk to the public health and safety;

(3) The requirements of subpart A of part 51 of this chapter (to the extent applicable to the proposed import) have been satisfied; and

(4) With respect to a proposed import of radioactive waste, an appropriate facility has agreed to accept and is authorized to posses the waste for management or disposal as confirmed by NRC consultations with, as applicable, the Agreement State(s) in which the facility is located and the low-level waste compact commission(s).

* * * * *

(d) If, after receiving the Executive Branch judgment that the issuance of a proposed export license will not be inimical to the common defense and security, the Commission does not issue the proposed license on a timely basis because it is unable to make the statutory determinations required under the Atomic Energy Act, the Commission will publicly issue a decision to that effect and will submit the license application to the President. The Commission's decision will include an explanation of the basis for the decision and any dissenting or separate views. The provisions in this paragraph do not apply to Commission decisions regarding applications for specific licenses to export byproduct material, including radioactive material listed in Table 1 of Appendix P to this part, or radioactive waste.

* * * * *

■ 26. Section 110.50 is revised to read as follows:

§ 110.50 Terms.

(a) *General and specific licenses.*

(1) Each license is subject to all applicable provisions of the Atomic Energy Act and other applicable law and to all applicable rules, regulations, decisions and orders of the Commission.

(2) Each license is subject to amendment, suspension, revocation or incorporation of separate conditions when required by amendments of the Atomic Energy Act or other applicable law, or by other rules, regulations, decisions or orders issued in accordance with the terms of the Atomic Energy Act or other applicable law.

(3) A licensee authorized to export or import nuclear material is responsible for compliance with applicable requirements of this chapter, unless a domestic licensee of the Commission has assumed that responsibility and the Commission has been so notified.

(4) Each license authorizes export or import only and does not authorize any person to receive title to, acquire, receive, possess, deliver, use, transport or transfer any nuclear equipment or material subject to this part.

(5) Each license issued by the NRC for the export or import of nuclear material authorizes only the export or import of that nuclear material and accompanying packaging, fuel element, hardware, or other associated devices or products.

(6) No nuclear equipment license confers authority to export or import nuclear material.

(7) Each nuclear equipment export license authorizes the export of only those items required for use in the foreign nuclear installation for which the items are intended.

(8) A licensee shall not proceed to export or import and shall notify the Commission promptly if he knows or has reason to believe that the packaging requirements of part 71 of this chapter have not been met.

(b) *Specific licenses.*

(1) Each specific license will have an expiration date.

(2) A licensee may export or import only for the purpose(s) and/or end-use(s) stated in the specific export or import license issued by NRC.

(3) Unless a license specifically authorizes the export of certain foreign-obligated nuclear material or equipment, a licensee may not ship such material or equipment until:

(i) The licensee has requested and the Commission has issued an amendment to the license authorizing such shipment; or

(ii) The licensee has given at least 40 days advance notice of the intended shipment in writing to the Deputy Director, Office of International Programs (OIP); and

(iii) The Deputy Director, OIP has:

(A) Obtained confirmation, through either the Department of Energy or State, that the foreign government in question has given its consent to the intended shipment pursuant to its agreement for cooperation with the United States; and

(B) Communicated this in writing to the licensee.

(c) *Advanced notification.*

(1) A licensee authorized to export or import the radioactive material listed in Appendix P to this part is responsible for notifying NRC and, in cases of exports, the government of the importing country in advance of each shipment. A list of points of contact in importing countries is available at NRC's Office of International Programs Web site, accessible on the NRC Public Web site at *http://www.nrc.gov.*

(2) The NRC's office responsible for receiving advance notifications for all export and import shipments is the NRC Operations Center. Notifications are to be e-mailed to *Hoo.Hoc@nrc.gov* (preferred method) or faxed to (301) 816–5151. In the subject line of the e-mail or on the fax cover page include "10 CFR 110.50(c) Notification." To

contact the NRC Operations Center, use the same e-mail address or call (301) 816–5100. Difficulties notifying the NRC Operations Center must be promptly reported to the Office of International Programs at (301) 415–2336.

(3) Notifications may be electronic or in writing on business stationary, and must contain or be accompanied by the information which follows.

(i) For export notifications:

(A) 10 CFR part 110 export license number and expiration date;

(B) Name of the individual and licensee making the notification, address, and telephone number;

(C) Foreign recipient name, address, and end use location(s) (if different than recipient's address);

(D) Radionuclides and activity level in TBq, both for single and aggregate shipments;

(E) Make, model and serial number, for any Category 1 and 2 sealed sources, if available;

(F) End use in the importing country, if known;

(G) Shipment date; and

(H) A copy of the foreign recipient's authorization or confirmation of that authorization from the government of the importing country as required by § 110.32(g) unless the authorization has already been provided to the NRC.

(ii) For import notifications:

(A) Name of individual and licensee making the notification, address, and telephone number;

(B) Recipient name, location, and address (if different than above);

(C) Name, location, address, contact name and telephone number for exporting facility;

(D) Radionuclides and activity level in TBq, both for single and aggregate shipments;

(E) Make, model and serial number, radionuclide, and activity level for any Category 1 and 2 sealed sources, if available;

(F) End use in the U.S.;

(G) Shipment date from exporting facility and estimated arrival date at the end use location; and

(H) NRC or Agreement State license number to possess the import in the U.S. and expiration date.

(4) Export notifications must be received by the NRC at least 7 days in advance of each shipment, to the extent practical, but in no case less than 24 hours in advance of each shipment. Import notifications must be received by the NRC at least 7 days in advance of each shipment.

(5) Advance notifications containing the above information must be controlled, handled, and transmitted in accordance with § 2.390 of this chapter and other applicable NRC requirements governing protection of sensitive information.

(d) A specific license may be transferred, disposed of or assigned to another person only with the approval of the Commission by license amendment.

■ 27. Section 110.51 is revised to read as follows:

§ 110.51 Amendment and renewal of licenses.

(a) *Amendments.*

(1) Applications for amendment of a specific license shall be filed on NRC Form 7 in accordance with §§ 110.31 and 110.32 and shall specify the respects in which the licensee desires the license to be amended and the grounds for such amendment.

(2) An amendment is not required for:

(i) Changes in monetary value (but not amount or quantity);

(ii) Changes in the names and/or mailing addresses within the same countries of the intermediate or ultimate consignees listed on the license; or

(iii) The addition of intermediate consignees in any of the importing countries specified in the license (for a nuclear equipment license only).

(b) *Renewals.*

(1) Applications for renewal of a specific license shall be filed on NRC Form 7 in accordance with §§ 110.31 and 110.32.

(2) If an application to renew a license is submitted 30 days or more before the license expires, the license remains valid until the Commission acts on the renewal application. An expired license is not renewable.

(c) *General.* In considering an application by a licensee to renew or amend a license, the Commission will apply, as appropriate, the same procedures and criteria it uses for initial license applications.

■ 28. In § 110.53, paragraphs (a) and (b)(1) are revised to read as follows:

§ 110.53 United States address, records, and inspections.

(a) Each licensee (general or specific) shall have an office in the United States where papers may be served and where records required by the Commission will be maintained.

(b)(1) Each license applicant or licensee (general or specific) shall maintain records concerning his exports or imports. The licensee shall retain these records for five years after each export or import except that byproduct material records must be retained for three years after the date of each export or import shipment.

* * * * *

■ 29. Section 110.54 is revised to read as follows:

§ 110.54 Reporting requirements.

(a)(1) Reports of exports of nuclear facilities and equipment, nuclear grade graphite for nuclear end use, and deuterium shipped during the previous quarter must be submitted by licensees making exports under the general license or specific license of this part by January 15, April 15, July 15, and October 15 of each year on DOC/NRC Forms AP–M or AP–13, and associated forms. The reports must contain information on all nuclear facilities, equipment, and non-nuclear materials (nuclear grade graphite for nuclear end use and deuterium) listed in Annex II of the Additional Protocol.

(2) These required reports must be sent via facsimile to (202) 482–1731, emailed to *aprp@bis.doc.gov,* or hand-delivered or submitted by courier to the Bureau of Industry and Security, in hard copy, to the following address: Treaty Compliance Division, Bureau of Industry and Security, U.S. Department of Commerce, Attn: AP Reports, 14th Street and Pennsylvania Avenue, NW., Room 4515, Washington, DC 20230. Telephone: (202) 482–1001.

(b) Persons making exports under the general license established by § 110.23(a) or under a specific license shall submit by February 1 of each year one copy of a report of all americium and neptunium shipments during the previous calendar year. This report shall be submitted to the Deputy Director, Office of International Programs at the address provided in § 110.4. The report must include:

(1) A description of the material, including quantity in TBq and gram;

(2) Approximate shipment dates; and

(3) A list of recipient countries, end users, and intended use keyed to the items shipped.

(c) Persons making exports under the general license established by § 110.26(a) shall submit by February 1 of each year one copy of a report of all components shipped during the previous calendar year. This report must include:

(1) A description of the components keyed to the categories listed in appendix A to this part.

(2) Approximate shipment dates.

(3) A list of recipient countries and end users keyed to the items shipped.

■ 30. Section 110.60 is revised to read as follows:

§ 110.60 Violations.

(a) The Commission may obtain an injunction or other court order to

prevent a violation of the provisions of—

(1) The Atomic Energy Act;

(2) Title II of the Energy Reorganization Act of 1974; or

(3) A regulation or order pursuant to those Acts.

(b) The Commission may obtain a court order for the payment of a civil penalty imposed under section 234 of the Atomic Energy Act:

(1) For violations of:

(i) Sections 53, 57, 62, 63, 81, 82, 101, 103, 104, 107, or 109 of the Atomic Energy Act;

(ii) Section 206 of the Energy Reorganization Act;

(iii) Any rule, regulation, or order issued pursuant to the sections specified in paragraph (b)(1)(i) of this section;

(iv) Any term, condition, or limitation of any license issued under the sections specified in paragraph (b)(1)(i) of this section.

(2) For any violation for which a license may be revoked under section 186 of the Atomic Energy Act.

■ 31. In § 110.66, paragraph (b) is revised to read as follows:

§ 110.66 Enforcement hearing.

* * * * *

(b) A hearing pursuant to this subpart will be conducted under the procedures in subpart G of part 2 of this chapter.

■ 32. In § 110.67, paragraph (a) is revised to read as follows:

§ 110.67 Criminal penalties.

(a) Section 223 of the Atomic Energy Act provides for criminal sanctions for willful violation of, attempted violation of, or conspiracy to violate, any regulation issued under sections 161b., 161i., or 161o. of the Atomic Energy Act. For purposes of section 223, all the regulations in 10 CFR part 110 are issued under one or more of sections 161b, 161i, or 161o, except for the sections listed in paragraph (b) of this section.

* * * * *

■ 33. Section 110.70 is revised to read as follows:

§ 110.70 Public notice of receipt of an application.

(a) The Commission will notice the receipt of each license application, including applications for amendment or renewal, for an export or import for which a specific license is required by making a copy available at the NRC Web site, *http://www.nrc.gov.*

(b) The Commission will also publish in the **Federal Register** a notice of receipt of each license application, including applications for amendment or renewal, to export the following:

(1) A production or utilization facility.

(2) Five effective kilograms or more of plutonium, high-enriched uranium or uranium-233.

(3) 10,000 kilograms or more of heavy water. (Note: Does not apply to exports of heavy water to Canada.)

(4) Nuclear grade graphite for nuclear end use.

(5) Radioactive waste.

(c) The Commission will also publish in the **Federal Register** a notice of receipt of a license application, including applications for amendment or renewal, for an import of radioactive waste for which a specific license is required.

■ 34. Section 110.80 is revised to read as follows:

§ 110.80 Basis for hearings.

The procedures in this part will constitute the exclusive basis for hearings on export and import license applications.

■ 35. In § 110.81, paragraph (b) is revised to read as follows:

§ 110.81 Written comments.

* * * * *

(b) These comments should be submitted within 30 days after public notice of receipt of the application on the NRC Web site or in the **Federal Register** and addressed to the Secretary, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001, Attention: Rulemakings and Adjudications Staff.

* * * * *

■ 36. In § 110.82, paragraph (c) is revised to read as follows:

§ 110.82 Hearing request or intervention petition.

* * * * *

(c) Hearing requests and intervention petitions will be considered timely only if filed not later than:

(1) 30 days after notice of receipt in the **Federal Register**, for those applications published in the **Federal Register**;

(2) 30 days after publication of notice on the NRC Web site at *http://www.nrc.gov;*

(3) 30 days after notice of receipt in the Public Document Room; or

(4) Such other time as may be provided by the Commission.

■ 37. In § 110.112, paragraph (b) is revised to read as follows:

§ 110.112 Reporter and transcript for an oral hearing.

* * * * *

(b) Except for any portions containing classified information, Restricted Data, Safeguards Information, proprietary information, or other sensitive unclassified information, transcripts will be made available at the NRC Web site, *http://www.nrc.gov,* and/or at the NRC Public Document Room.

* * * * *

Appendix L—[Amended]

■ 38. Appendix L to 10 CFR Part 110 is amended by adding "Carbon 11 (C 11)," "Cesium 129 (Cs 129)," "Cobalt 57 (Co 57)," "Gallium 67 (Ga 67)," "Gold 195 (Au 195)," "Indium 111 (In 111)," "Iodine 123 (I 123)," Iron 52 (Fe 52)," "Nitrogen 13 (N 13)," "Oxygen 15 (O 15)," "Potassium 43 (K 43)," "Rubidium 81 (Rb 81)," "Yttrium 87 (Y 87)," and "Yttrium 88 (Y 88)" in alphabetical order.

Dated at Rockville, Maryland, this 19th day of July, 2010.

For the Nuclear Regulatory Commission.

Annette Vietti-Cook,

Secretary of the Commission.

[FR Doc. 2010–18219 Filed 7–27–10; 8:45 am]

BILLING CODE 7590–01–P

FEDERAL RESERVE SYSTEM

12 CFR Part 226

[Regulation Z; Docket No. R–1384]

Truth in Lending

June 29, 2010.

AGENCY: Board of Governors of the Federal Reserve System.

ACTION: Final rule, correction.

SUMMARY: This document corrects a typographical error in the amendatory instructions published in the **Federal Register** of June 29, 2010, regarding final rules amending Regulation Z, which implements the Truth in Lending Act, and the staff commentary to the regulation in order to implement provisions of the Credit Card Accountability Responsibility and Disclosure Act of 2009 that go into effect on August 22, 2010.

DATES: *Effective Date:* The rule is effective August 22, 2010.

FOR FURTHER INFORMATION CONTACT: Stephen Shin, Attorney, or Amy Henderson or Benjamin K. Olson, Senior Attorneys, Division of Consumer and Community Affairs, Board of Governors of the Federal Reserve System, at (202) 452–3667 or 452–2412; for users of Telecommunications Device for the Deaf (TDD) only, contact (202) 263–4869.

SUPPLEMENTARY INFORMATION: The Board published a final rule in the **Federal Register** on June 29, 2010, (75 FR 37526)

(FR Doc. 2010–14717) amending Regulation Z, which implements the Truth in Lending Act, and the staff commentary to the regulation in order to implement provisions of the Credit Card Accountability Responsibility and Disclosure Act of 2009 that go into effect on August 22, 2010. However, the citation to the authority for part 226 was inadvertently omitted from that document's amendatory instructions. This document corrects that error.

■ In final rule, FR Doc. 2010–14717, published on June 29, 2010, (75 FR 37526) make the following corrections:

PART 226—TRUTH IN LENDING (REGULATION Z)

■ 1. On page 37568, in the second column, under the amendatory instructions, insert the authority citation shown below and renumber the remainder of the amendatory instructions as applicable.

"■1. The authority citation for part 226 continues to read as follows:

Authority: 12 U.S.C. 3806; 15 U.S.C. 1604, 1637(c)(5), and 1639(l); Pub. L. 111–24;§§ 2, 101(c), 102(b), 123 Stat. 1734."

By order of the Board of Governors of the Federal Reserve System, July 22, 2010.

Jennifer J. Johnson,

Secretary of the Board.

[FR Doc. 2010–18410 Filed 7–27–10; 8:45 am]

BILLING CODE 6210–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

18 CFR Part 11

[Docket No. RM10–27–000]

Update of the Federal Energy Regulatory Commission's Fees Schedule for Annual Charges for the Use of Government Lands

AGENCY: Federal Energy Regulatory Commission, DOE.

ACTION: Final rule.

SUMMARY: In accordance with the Commission's regulations, the Commission by its designee, the Executive Director, is updating its schedule of fees for the use of government lands. The yearly update is based on the most recent schedule of fees for the use of linear rights-of-way prepared by the United States Forest Service. Since the next fiscal year will cover the period from October 1, 2009 through September 30, 2010 the fees in this rule will become effective October 1, 2010. The fees will apply to fiscal year 2010 annual charges for the use of government lands.

DATES: *Effective Date:* July 27, 2010.

FOR FURTHER INFORMATION CONTACT: Fannie Kingsberry, Division of Financial Services, Office of the Executive Director, Federal Energy Regulatory Commission, 888 First Street, NE., Washington, DC 20426, (202) 502–6108.

SUPPLEMENTARY INFORMATION: *Document Availability:* In addition to publishing the full text of this document in the Federal Register, the Commission provides all interested persons an opportunity to view and/or print the contents of this document via the Internet through the Commission's Home Page (*http://www.ferc.gov*) and in the Commission's Public Reference Room during normal business hours (8:30 a.m. to 5 p.m. Eastern time) at 888 First Street, NE., Room 2A, Washington, DC 20426.

From the Commission's Home Page on the Internet, this information is available in the eLibrary. The full text of this document is available on eLibrary in PDF and MSWord format for viewing, printing, and/or downloading. To access this document in eLibrary, type the docket number excluding the last three digits of this document in the docket number field.

User assistance is available for eLibrary and the Commission's Web site during normal business hours from FERC's Online Support at (202) 502–6652 (toll free 1–866 208–3676) or e-mail at *ferconlinesupport@ferc.gov,* or the Public Reference Room at (202) 502–8371, TTY (202) 502–8659. E-mail the Public Reference Room at *public.referenceroom@ferc.gov.*

The Commission has concluded, with the concurrence of the Administrator of the Office of Information and Regulatory Affairs of OMB that this rule is not a "major rule"as defined in section 251 of the Small Business Regulatory Enforcement Fairness Act of 1996, 5 U.S.C 804(2).

List of Subjects in 18 CFR Part 11

Electric power, Reporting and recordkeeping requirements.

Thomas R. Herlihy,

Executive Director, Office of the Executive Director.

■ Accordingly, the Commission amends part 11 of Chapter I, Title 18 of the Code of Federal Regulations, as follows:

PART 11—[AMENDED]

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

Authority: 16 U.S.C. 791a–825r; 42 U.S.C. 7101–7352.

■ 2. In part 11, Appendix A is revised to read as follows.

APPENDIX A TO PART 11—FEE SCHEDULE FOR FY 2010

State	County	(Fee/acre/YR)
Alabama	Autauga	$62.78
Alabama	Baldwin	94.17
Alabama	Barbour	31.39
Alabama	Bibb	47.08
Alabama	Blount	94.17
Alabama	Bullock	47.08
Alabama	Butler	47.08
Alabama	Calhoun	94.17
Alabama	Chambers	31.39
Alabama	Cherokee	47.08
Alabama	Chilton	47.08
Alabama	Choctaw	47.08
Alabama	Clarke	47.08
Alabama	Clay	47.08

APPENDIX A TO PART 11—FEE SCHEDULE FOR FY 2010—Continued

State	County	(Fee/acre/YR)
Alabama	Cleburne	62.78
Alabama	Coffee	31.39
Alabama	Colbert	47.08
Alabama	Conecuh	31.39
Alabama	Coosa	47.08
Alabama	Covington	47.08
Alabama	Crenshaw	47.08
Alabama	Cullman	94.17
Alabama	Dale	47.08
Alabama	Dallas	31.39
Alabama	DeKalb	62.78
Alabama	Elmore	62.78
Alabama	Escambia	47.08
Alabama	Etowah	94.17
Alabama	Fayette	31.39
Alabama	Franklin	47.08
Alabama	Geneva	47.08
Alabama	Greene	31.39
Alabama	Hale	31.39
Alabama	Henry	31.39
Alabama	Houston	47.08
Alabama	Jackson	62.78
Alabama	Jefferson	94.17
Alabama	Lamar	31.39
Alabama	Lauderdale	47.08
Alabama	Lawrence	47.08
Alabama	Lee	62.78
Alabama	Limestone	62.78
Alabama	Lowndes	31.39
Alabama	Macon	47.08
Alabama	Madison	62.78
Alabama	Marengo	31.39
Alabama	Marion	47.08
Alabama	Marshall	94.17
Alabama	Mobile	94.17
Alabama	Monroe	47.08
Alabama	Montgomery	62.78
Alabama	Morgan	94.17
Alabama	Perry	31.39
Alabama	Pickens	47.08
Alabama	Pike	47.08
Alabama	Randolph	62.78
Alabama	Russell	47.08
Alabama	Shelby	94.17
Alabama	St. Clair	62.78
Alabama	Sumter	31.39
Alabama	Talladega	94.17
Alabama	Tallapoosa	47.08
Alabama	Tuscaloosa	62.78
Alabama	Walker	47.08
Alabama	Washington	47.08
Alabama	Wilcox	31.39
Alabama	Winston	62.78
Alaska	Aleutian Islands Area **	7.85
Alaska	Anchorage Area **	62.78
Alaska	Fairbanks Area **	31.39
Alaska	Juneau Area **	1,569.43
Alaska	Kenai Peninsula **	47.08
Arizona	Apache	7.85
Arizona	Cochise	31.39
Arizona	Coconino	7.85
Arizona	Gila	7.85
Arizona	Graham	15.69
Arizona	Greenlee	47.08
Arizona	La Paz	31.39
Arizona	Maricopa	94.17
Arizona	Mohave	15.69
Arizona	Navajo	7.85
Arizona	Pima	7.85
Arizona	Pinal	31.39
Arizona	Santa Cruz	47.08
Arizona	Yavapai	15.69

APPENDIX A TO PART 11—FEE SCHEDULE FOR FY 2010—Continued

State	County	(Fee/acre/YR)
Arizona	Yuma	156.94
Arkansas	Arkansas	47.08
Arkansas	Ashley	47.08
Arkansas	Baxter	47.08
Arkansas	Benton	94.17
Arkansas	Boone	47.08
Arkansas	Bradley	62.78
Arkansas	Calhoun	47.08
Arkansas	Carroll	47.08
Arkansas	Chicot	31.39
Arkansas	Clark	47.08
Arkansas	Clay	47.08
Arkansas	Cleburne	47.08
Arkansas	Cleveland	62.78
Arkansas	Columbia	47.08
Arkansas	Conway	47.08
Arkansas	Craighead	47.08
Arkansas	Crawford	47.08
Arkansas	Crittenden	47.08
Arkansas	Cross	47.08
Arkansas	Dallas	47.08
Arkansas	Desha	31.39
Arkansas	Drew	47.08
Arkansas	Faulkner	47.08
Arkansas	Franklin	47.08
Arkansas	Fulton	31.39
Arkansas	Garland	62.78
Arkansas	Grant	47.08
Arkansas	Greene	47.08
Arkansas	Hempstead	47.08
Arkansas	Hot Spring	47.08
Arkansas	Howard	47.08
Arkansas	Independence	31.39
Arkansas	Izard	31.39
Arkansas	Jackson	31.39
Arkansas	Jefferson	31.39
Arkansas	Johnson	62.78
Arkansas	Lafayette	31.39
Arkansas	Lawrence	47.08
Arkansas	Lee	31.39
Arkansas	Lincoln	31.39
Arkansas	Little River	31.39
Arkansas	Logan	47.08
Arkansas	Lonoke	47.08
Arkansas	Madison	47.08
Arkansas	Marion	47.08
Arkansas	Miller	31.39
Arkansas	Mississippi	47.08
Arkansas	Monroe	31.39
Arkansas	Montgomery	47.08
Arkansas	Nevada	31.39
Arkansas	Newton	47.08
Arkansas	Ouachita	47.08
Arkansas	Perry	47.08
Arkansas	Phillips	31.39
Arkansas	Pike	47.08
Arkansas	Poinsett	47.08
Arkansas	Polk	47.08
Arkansas	Pope	62.78
Arkansas	Prairie	31.39
Arkansas	Pulaski	47.08
Arkansas	Randolph	47.08
Arkansas	Saline	62.78
Arkansas	Scott	47.08
Arkansas	Searcy	31.39
Arkansas	Sebastian	62.78
Arkansas	Sevier	47.08
Arkansas	Sharp	31.39
Arkansas	St. Francis	31.39
Arkansas	Stone	31.39
Arkansas	Union	62.78
Arkansas	Van Buren	47.08

APPENDIX A TO PART 11—FEE SCHEDULE FOR FY 2010—Continued

State	County	(Fee/acre/YR)
Arkansas	Washington	94.17
Arkansas	White	47.08
Arkansas	Woodruff	31.39
Arkansas	Yell	47.08
California	Alameda	94.17
California	Alpine	62.78
California	Amador	62.78
California	Butte	156.94
California	Calaveras	47.08
California	Colusa	94.17
California	Contra Costa	313.89
California	Del Norte	156.94
California	El Dorado	94.17
California	Fresno	94.17
California	Glenn	62.78
California	Humboldt	31.39
California	Imperial	94.17
California	Inyo	31.39
California	Kern	47.08
California	Kings	94.17
California	Lake	156.94
California	Lassen	31.39
California	Los Angeles	627.77
California	Madera	94.17
California	Marin	94.17
California	Mariposa	31.39
California	Mendocino	62.78
California	Merced	156.94
California	Modoc	31.39
California	Mono	47.08
California	Monterey	94.17
California	Napa	627.77
California	Nevada	94.17
California	Orange	313.89
California	Placer	156.94
California	Plumas	31.39
California	Riverside	156.94
California	Sacramento	156.94
California	San Benito	62.78
California	San Bernardino	62.78
California	San Diego	313.89
California	San Francisco	941.66
California	San Joaquin	313.89
California	San Luis Obispo	94.17
California	San Mateo	156.94
California	Santa Barbara	94.17
California	Santa Clara	94.17
California	Santa Cruz	313.89
California	Shasta	47.08
California	Sierra	47.08
California	Siskiyou	47.08
California	Solano	156.94
California	Sonoma	313.89
California	Stanislaus	156.94
California	Sutter	156.94
California	Tehama	47.08
California	Trinity	31.39
California	Tulare	156.94
California	Tuolumne	47.08
California	Ventura	313.89
California	Yolo	94.17
California	Yuba	94.17
Colorado	Adams	31.39
Colorado	Alamosa	31.39
Colorado	Arapahoe	31.39
Colorado	Archuleta	47.08
Colorado	Baca	7.85
Colorado	Bent	15.69
Colorado	Boulder	313.89
Colorado	Broomfield*	31.39
Colorado	Chaffee	62.78
Colorado	Cheyenne	15.69

APPENDIX A TO PART 11—FEE SCHEDULE FOR FY 2010—Continued

State	County	(Fee/acre/YR)
Colorado	Clear Creek	47.08
Colorado	Conejos	31.39
Colorado	Costilla	15.69
Colorado	Crowley	7.85
Colorado	Custer	47.08
Colorado	Delta	62.78
Colorado	Denver*	31.39
Colorado	Dolores	31.39
Colorado	Douglas	94.17
Colorado	Eagle	47.08
Colorado	El Paso	31.39
Colorado	Elbert	31.39
Colorado	Fremont	31.39
Colorado	Garfield	47.08
Colorado	Gilpin	94.17
Colorado	Grand	31.39
Colorado	Gunnison	47.08
Colorado	Hinsdale	94.17
Colorado	Huerfano	15.69
Colorado	Jackson	15.69
Colorado	Jefferson	156.94
Colorado	Kiowa	7.85
Colorado	Kit Carson	15.69
Colorado	La Plata	31.39
Colorado	Lake	47.08
Colorado	Larimer	62.78
Colorado	Las Animas	7.85
Colorado	Lincoln	7.85
Colorado	Logan	15.69
Colorado	Mesa	47.08
Colorado	Mineral	47.08
Colorado	Moffat	15.69
Colorado	Montezuma	15.69
Colorado	Montrose	31.39
Colorado	Morgan	31.39
Colorado	Otero	15.69
Colorado	Ouray	47.08
Colorado	Park	31.39
Colorado	Phillips	31.39
Colorado	Pitkin	156.94
Colorado	Prowers	15.69
Colorado	Pueblo	15.69
Colorado	Rio Blanco	31.39
Colorado	Rio Grande	47.08
Colorado	Routt	62.78
Colorado	Saguache	31.39
Colorado	San Juan*	31.39
Colorado	San Miguel	31.39
Colorado	Sedgwick	31.39
Colorado	Summit	47.08
Colorado	Teller	47.08
Colorado	Washington	15.69
Colorado	Weld	47.08
Colorado	Yuma	15.69
Connecticut	Fairfield	941.66
Connecticut	Hartford	627.77
Connecticut	Litchfield	313.89
Connecticut	Middlesex	313.89
Connecticut	New Haven	627.77
Connecticut	New London	313.89
Connecticut	Tolland	156.94
Connecticut	Windham	313.89
Delaware	Kent	94.17
Delaware	New Castle	156.94
Delaware	Sussex	156.94
Florida	Alachua	94.17
Florida	Baker	156.94
Florida	Bay	94.17
Florida	Bradford	62.78
Florida	Brevard	62.78
Florida	Broward	627.77
Florida	Calhoun	47.08

APPENDIX A TO PART 11—FEE SCHEDULE FOR FY 2010—Continued

State	County	(Fee/acre/YR)
Florida	Charlotte	47.08
Florida	Citrus	62.78
Florida	Clay	62.78
Florida	Collier	94.17
Florida	Columbia	47.08
Florida	Dade	313.89
Florida	DeSoto	62.78
Florida	Dixie	47.08
Florida	Duval	156.94
Florida	Escambia	62.78
Florida	Flagler	47.08
Florida	Franklin	31.39
Florida	Gadsden	62.78
Florida	Gilchrist	62.78
Florida	Glades	47.08
Florida	Gulf	62.78
Florida	Hamilton	47.08
Florida	Hardee	62.78
Florida	Hendry	156.94
Florida	Hernando	156.94
Florida	Highlands	62.78
Florida	Hillsborough	156.94
Florida	Holmes	47.08
Florida	Indian River	94.17
Florida	Jackson	47.08
Florida	Jefferson	47.08
Florida	Lafayette	47.08
Florida	Lake	156.94
Florida	Lee	94.17
Florida	Leon	62.78
Florida	Levy	62.78
Florida	Liberty	47.08
Florida	Madison	47.08
Florida	Manatee	94.17
Florida	Marion	156.94
Florida	Martin	94.17
Florida	Monroe	627.77
Florida	Nassau	156.94
Florida	Okaloosa	94.17
Florida	Okeechobee	62.78
Florida	Orange	156.94
Florida	Osceola	47.08
Florida	Palm Beach	94.17
Florida	Pasco	156.94
Florida	Pinellas	941.66
Florida	Polk	94.17
Florida	Putnam	62.78
Florida	Santa Rosa	94.17
Florida	Sarasota	94.17
Florida	Seminole	156.94
Florida	St. Johns	156.94
Florida	St. Lucie	94.17
Florida	Sumter	62.78
Florida	Suwannee	94.17
Florida	Taylor	47.08
Florida	Union	47.08
Florida	Volusia	156.94
Florida	Wakulla	94.17
Florida	Walton	62.78
Florida	Washington	62.78
Georgia	Appling	47.08
Georgia	Atkinson	47.08
Georgia	Bacon	62.78
Georgia	Baker	47.08
Georgia	Baldwin	62.78
Georgia	Banks	156.94
Georgia	Barrow	156.94
Georgia	Bartow	94.17
Georgia	Ben Hill	47.08
Georgia	Berrien	47.08
Georgia	Bibb	62.78
Georgia	Bleckley	47.08

APPENDIX A TO PART 11—FEE SCHEDULE FOR FY 2010—Continued

State	County	(Fee/acre/YR)
Georgia	Brantley	47.08
Georgia	Brooks	47.08
Georgia	Bryan	47.08
Georgia	Bulloch	47.08
Georgia	Burke	47.08
Georgia	Butts	62.78
Georgia	Calhoun	47.08
Georgia	Camden	47.08
Georgia	Candler	47.08
Georgia	Carroll	156.94
Georgia	Catoosa	156.94
Georgia	Charlton	62.78
Georgia	Chatham	62.78
Georgia	Chattahoochee	47.08
Georgia	Chattooga	47.08
Georgia	Cherokee	313.89
Georgia	Clarke	156.94
Georgia	Clay	31.39
Georgia	Clayton	156.94
Georgia	Clinch	47.08
Georgia	Cobb	313.89
Georgia	Coffee	47.08
Georgia	Colquitt	47.08
Georgia	Columbia	156.94
Georgia	Cook	47.08
Georgia	Coweta	156.94
Georgia	Crawford	62.78
Georgia	Crisp	47.08
Georgia	Dade	62.78
Georgia	Dawson	156.94
Georgia	Decatur	47.08
Georgia	DeKalb	313.89
Georgia	Dodge	31.39
Georgia	Dooly	47.08
Georgia	Dougherty	47.08
Georgia	Douglas	156.94
Georgia	Early	47.08
Georgia	Echols	47.08
Georgia	Effingham	47.08
Georgia	Elbert	62.78
Georgia	Emanuel	31.39
Georgia	Evans	47.08
Georgia	Fannin	94.17
Georgia	Fayette	156.94
Georgia	Floyd	94.17
Georgia	Forsyth	313.89
Georgia	Franklin	156.94
Georgia	Fulton	156.94
Georgia	Gilmer	156.94
Georgia	Glascock	47.08
Georgia	Glynn	47.08
Georgia	Gordon	156.94
Georgia	Grady	47.08
Georgia	Greene	94.17
Georgia	Gwinnett	313.89
Georgia	Habersham	156.94
Georgia	Hall	156.94
Georgia	Hancock	31.39
Georgia	Haralson	94.17
Georgia	Harris	62.78
Georgia	Hart	94.17
Georgia	Heard	62.78
Georgia	Henry	156.94
Georgia	Houston	62.78
Georgia	Irwin	47.08
Georgia	Jackson	156.94
Georgia	Jasper	62.78
Georgia	Jeff Davis	47.08
Georgia	Jefferson	47.08
Georgia	Jenkins	47.08
Georgia	Johnson	47.08
Georgia	Jones	62.78

APPENDIX A TO PART 11—FEE SCHEDULE FOR FY 2010—Continued

State	County	(Fee/acre/YR)
Georgia	Lamar	62.78
Georgia	Lanier	31.39
Georgia	Laurens	47.08
Georgia	Lee	47.08
Georgia	Liberty	62.78
Georgia	Lincoln	94.17
Georgia	Long	47.08
Georgia	Lowndes	62.78
Georgia	Lumpkin	156.94
Georgia	Macon	47.08
Georgia	Madison	156.94
Georgia	Marion	47.08
Georgia	McDuffie	62.78
Georgia	McIntosh	47.08
Georgia	Meriwether	62.78
Georgia	Miller	47.08
Georgia	Mitchell	47.08
Georgia	Monroe	62.78
Georgia	Montgomery	47.08
Georgia	Morgan	94.17
Georgia	Murray	94.17
Georgia	Muscogee	94.17
Georgia	Newton	156.94
Georgia	Oconee	156.94
Georgia	Oglethorpe	94.17
Georgia	Paulding	313.89
Georgia	Peach	62.78
Georgia	Pickens	156.94
Georgia	Pierce	47.08
Georgia	Pike	94.17
Georgia	Polk	62.78
Georgia	Pulaski	47.08
Georgia	Putnam	94.17
Georgia	Quitman	47.08
Georgia	Rabun	156.94
Georgia	Randolph	31.39
Georgia	Richmond	94.17
Georgia	Rockdale	156.94
Georgia	Schley	47.08
Georgia	Screven	47.08
Georgia	Seminole	47.08
Georgia	Spalding	156.94
Georgia	Stephens	156.94
Georgia	Stewart	47.08
Georgia	Sumter	47.08
Georgia	Talbot	47.08
Georgia	Taliaferro	47.08
Georgia	Tattnall	62.78
Georgia	Taylor	47.08
Georgia	Telfair	47.08
Georgia	Terrell	47.08
Georgia	Thomas	47.08
Georgia	Tift	62.78
Georgia	Toombs	47.08
Georgia	Towns	156.94
Georgia	Treutlen	47.08
Georgia	Troup	47.08
Georgia	Turner	47.08
Georgia	Twiggs	47.08
Georgia	Union	156.94
Georgia	Upson	62.78
Georgia	Walker	94.17
Georgia	Walton	313.89
Georgia	Ware	47.08
Georgia	Warren	47.08
Georgia	Washington	47.08
Georgia	Wayne	47.08
Georgia	Webster	47.08
Georgia	Wheeler	31.39
Georgia	White	156.94
Georgia	Whitfield	62.78
Georgia	Wilcox	47.08

APPENDIX A TO PART 11—FEE SCHEDULE FOR FY 2010—Continued

State	County	(Fee/acre/YR)
Georgia	Wilkes	47.08
Georgia	Wilkinson	47.08
Georgia	Worth	47.08
Hawaii	Hawaii	94.17
Hawaii	Honolulu	313.89
Hawaii	Kauai	156.94
Hawaii	Maui	156.94
Idaho	Ada	94.17
Idaho	Adams	15.69
Idaho	Bannock	31.39
Idaho	Bear Lake	31.39
Idaho	Benewah	31.39
Idaho	Bingham	31.39
Idaho	Blaine	47.08
Idaho	Boise	31.39
Idaho	Bonner	94.17
Idaho	Bonneville	47.08
Idaho	Boundary	62.78
Idaho	Butte	31.39
Idaho	Camas	31.39
Idaho	Canyon	156.94
Idaho	Caribou	31.39
Idaho	Cassia	31.39
Idaho	Clark	31.39
Idaho	Clearwater	47.08
Idaho	Custer	47.08
Idaho	Elmore	31.39
Idaho	Franklin	31.39
Idaho	Fremont	31.39
Idaho	Gem	31.39
Idaho	Gooding	94.17
Idaho	Idaho	31.39
Idaho	Jefferson	47.08
Idaho	Jerome	62.78
Idaho	Kootenai	62.78
Idaho	Latah	47.08
Idaho	Lemhi	31.39
Idaho	Lewis	31.39
Idaho	Lincoln	31.39
Idaho	Madison	62.78
Idaho	Minidoka	62.78
Idaho	Nez Perce	31.39
Idaho	Oneida	31.39
Idaho	Owyhee	31.39
Idaho	Payette	47.08
Idaho	Power	31.39
Idaho	Shoshone	94.17
Idaho	Teton	62.78
Idaho	Twin Falls	62.78
Idaho	Valley	47.08
Idaho	Washington	31.39
Illinois	Adams	62.78
Illinois	Alexander	47.08
Illinois	Bond	62.78
Illinois	Boone	94.17
Illinois	Brown	47.08
Illinois	Bureau	94.17
Illinois	Calhoun	47.08
Illinois	Carroll	62.78
Illinois	Cass	62.78
Illinois	Champaign	94.17
Illinois	Christian	94.17
Illinois	Clark	62.78
Illinois	Clay	47.08
Illinois	Clinton	62.78
Illinois	Coles	94.17
Illinois	Cook	313.89
Illinois	Crawford	47.08
Illinois	Cumberland	62.78
Illinois	De Witt	94.17
Illinois	DeKalb	156.94
Illinois	Douglas	94.17

APPENDIX A TO PART 11—FEE SCHEDULE FOR FY 2010—Continued

State	County	(Fee/acre/YR)
Illinois	DuPage	156.94
Illinois	Edgar	62.78
Illinois	Edwards	47.08
Illinois	Effingham	62.78
Illinois	Fayette	47.08
Illinois	Ford	94.17
Illinois	Franklin	47.08
Illinois	Fulton	62.78
Illinois	Gallatin	47.08
Illinois	Greene	47.08
Illinois	Grundy	94.17
Illinois	Hamilton	47.08
Illinois	Hancock	94.17
Illinois	Hardin	47.08
Illinois	Henderson	62.78
Illinois	Henry	62.78
Illinois	Iroquois	62.78
Illinois	Jackson	47.08
Illinois	Jasper	62.78
Illinois	Jefferson	47.08
Illinois	Jersey	62.78
Illinois	Jo Daviess	62.78
Illinois	Johnson	47.08
Illinois	Kane	156.94
Illinois	Kankakee	94.17
Illinois	Kendall	156.94
Illinois	Knox	62.78
Illinois	La Salle	94.17
Illinois	Lake	156.94
Illinois	Lawrence	47.08
Illinois	Lee	94.17
Illinois	Livingston	94.17
Illinois	Logan	94.17
Illinois	Macon	94.17
Illinois	Macoupin	62.78
Illinois	Madison	62.78
Illinois	Marion	47.08
Illinois	Marshall	94.17
Illinois	Mason	62.78
Illinois	Massac	31.39
Illinois	McDonough	62.78
Illinois	McHenry	156.94
Illinois	McLean	94.17
Illinois	Menard	62.78
Illinois	Mercer	62.78
Illinois	Monroe	94.17
Illinois	Montgomery	62.78
Illinois	Morgan	62.78
Illinois	Moultrie	94.17
Illinois	Ogle	94.17
Illinois	Peoria	94.17
Illinois	Perry	47.08
Illinois	Piatt	94.17
Illinois	Pike	47.08
Illinois	Pope	31.39
Illinois	Pulaski	47.08
Illinois	Putnam	94.17
Illinois	Randolph	62.78
Illinois	Richland	47.08
Illinois	Rock Island	94.17
Illinois	Saline	47.08
Illinois	Sangamon	94.17
Illinois	Schuyler	47.08
Illinois	Scott	62.78
Illinois	Shelby	62.78
Illinois	St. Clair	94.17
Illinois	Stark	94.17
Illinois	Stephenson	62.78
Illinois	Tazewell	94.17
Illinois	Union	62.78
Illinois	Vermilion	62.78
Illinois	Wabash	47.08

APPENDIX A TO PART 11—FEE SCHEDULE FOR FY 2010—Continued

State	County	(Fee/acre/YR)
Illinois	Warren	94.17
Illinois	Washington	62.78
Illinois	Wayne	31.39
Illinois	White	47.08
Illinois	Whiteside	94.17
Illinois	Will	156.94
Illinois	Williamson	62.78
Illinois	Winnebago	94.17
Illinois	Woodford	94.17
Indiana	Adams	94.17
Indiana	Allen	94.17
Indiana	Bartholomew	94.17
Indiana	Benton	62.78
Indiana	Blackford	62.78
Indiana	Boone	94.17
Indiana	Brown	94.17
Indiana	Carroll	94.17
Indiana	Cass	62.78
Indiana	Clark	94.17
Indiana	Clay	62.78
Indiana	Clinton	94.17
Indiana	Crawford	47.08
Indiana	Daviess	62.78
Indiana	Dearborn	94.17
Indiana	Decatur	94.17
Indiana	DeKalb	62.78
Indiana	Delaware	94.17
Indiana	Dubois	62.78
Indiana	Elkhart	156.94
Indiana	Fayette	62.78
Indiana	Floyd	94.17
Indiana	Fountain	62.78
Indiana	Franklin	62.78
Indiana	Fulton	62.78
Indiana	Gibson	62.78
Indiana	Grant	94.17
Indiana	Greene	62.78
Indiana	Hamilton	156.94
Indiana	Hancock	94.17
Indiana	Harrison	94.17
Indiana	Hendricks	94.17
Indiana	Henry	94.17
Indiana	Howard	94.17
Indiana	Huntington	62.78
Indiana	Jackson	62.78
Indiana	Jasper	62.78
Indiana	Jay	94.17
Indiana	Jefferson	62.78
Indiana	Jennings	62.78
Indiana	Johnson	156.94
Indiana	Knox	62.78
Indiana	Kosciusko	94.17
Indiana	LaGrange	94.17
Indiana	Lake	94.17
Indiana	LaPorte	94.17
Indiana	Lawrence	47.08
Indiana	Madison	94.17
Indiana	Marion	156.94
Indiana	Marshall	62.78
Indiana	Martin	62.78
Indiana	Miami	62.78
Indiana	Monroe	62.78
Indiana	Montgomery	62.78
Indiana	Morgan	94.17
Indiana	Newton	62.78
Indiana	Noble	94.17
Indiana	Ohio	94.17
Indiana	Orange	62.78
Indiana	Owen	62.78
Indiana	Parke	62.78
Indiana	Perry	47.08
Indiana	Pike	62.78

APPENDIX A TO PART 11—FEE SCHEDULE FOR FY 2010—Continued

State	County	(Fee/acre/YR)
Indiana	Porter	94.17
Indiana	Posey	62.78
Indiana	Pulaski	62.78
Indiana	Putnam	62.78
Indiana	Randolph	62.78
Indiana	Ripley	94.17
Indiana	Rush	94.17
Indiana	Scott	62.78
Indiana	Shelby	94.17
Indiana	Spencer	62.78
Indiana	St. Joseph	94.17
Indiana	Starke	62.78
Indiana	Steuben	62.78
Indiana	Sullivan	62.78
Indiana	Switzerland	62.78
Indiana	Tippecanoe	94.17
Indiana	Tipton	94.17
Indiana	Union	62.78
Indiana	Vanderburgh	94.17
Indiana	Vermillion	62.78
Indiana	Vigo	62.78
Indiana	Wabash	94.17
Indiana	Warren	62.78
Indiana	Warrick	62.78
Indiana	Washington	62.78
Indiana	Wayne	62.78
Indiana	Wells	62.78
Indiana	White	94.17
Indiana	Whitley	94.17
Iowa	Adair	47.08
Iowa	Adams	47.08
Iowa	Allamakee	47.08
Iowa	Appanoose	31.39
Iowa	Audubon	47.08
Iowa	Benton	62.78
Iowa	Black Hawk	94.17
Iowa	Boone	62.78
Iowa	Bremer	94.17
Iowa	Buchanan	62.78
Iowa	Buena Vista	62.78
Iowa	Butler	62.78
Iowa	Calhoun	62.78
Iowa	Carroll	62.78
Iowa	Cass	47.08
Iowa	Cedar	62.78
Iowa	Cerro Gordo	62.78
Iowa	Cherokee	62.78
Iowa	Chickasaw	62.78
Iowa	Clarke	31.39
Iowa	Clay	62.78
Iowa	Clayton	62.78
Iowa	Clinton	62.78
Iowa	Crawford	62.78
Iowa	Dallas	94.17
Iowa	Davis	31.39
Iowa	Decatur	31.39
Iowa	Delaware	62.78
Iowa	Des Moines	62.78
Iowa	Dickinson	62.78
Iowa	Dubuque	62.78
Iowa	Emmet	62.78
Iowa	Fayette	62.78
Iowa	Floyd	62.78
Iowa	Franklin	62.78
Iowa	Fremont	47.08
Iowa	Greene	62.78
Iowa	Grundy	94.17
Iowa	Guthrie	47.08
Iowa	Hamilton	62.78
Iowa	Hancock	62.78
Iowa	Hardin	62.78
Iowa	Harrison	47.08

APPENDIX A TO PART 11—FEE SCHEDULE FOR FY 2010—Continued

State	County	(Fee/acre/YR)
Iowa	Henry	62.78
Iowa	Howard	62.78
Iowa	Humboldt	62.78
Iowa	Ida	62.78
Iowa	Iowa	47.08
Iowa	Jackson	47.08
Iowa	Jasper	62.78
Iowa	Jefferson	47.08
Iowa	Johnson	62.78
Iowa	Jones	62.78
Iowa	Keokuk	47.08
Iowa	Kossuth	62.78
Iowa	Lee	47.08
Iowa	Linn	94.17
Iowa	Louisa	62.78
Iowa	Lucas	31.39
Iowa	Lyon	62.78
Iowa	Madison	47.08
Iowa	Mahaska	47.08
Iowa	Marion	47.08
Iowa	Marshall	62.78
Iowa	Mills	47.08
Iowa	Mitchell	62.78
Iowa	Monona	47.08
Iowa	Monroe	31.39
Iowa	Montgomery	47.08
Iowa	Muscatine	62.78
Iowa	O'Brien	94.17
Iowa	Osceola	62.78
Iowa	Page	47.08
Iowa	Palo Alto	62.78
Iowa	Plymouth	62.78
Iowa	Pocahontas	62.78
Iowa	Polk	62.78
Iowa	Pottawattamie	62.78
Iowa	Poweshiek	47.08
Iowa	Ringgold	31.39
Iowa	Sac	62.78
Iowa	Scott	94.17
Iowa	Shelby	62.78
Iowa	Sioux	94.17
Iowa	Story	62.78
Iowa	Tama	62.78
Iowa	Taylor	31.39
Iowa	Union	47.08
Iowa	Van Buren	31.39
Iowa	Wapello	47.08
Iowa	Warren	47.08
Iowa	Washington	62.78
Iowa	Wayne	31.39
Iowa	Webster	62.78
Iowa	Winnebago	62.78
Iowa	Winneshiek	47.08
Iowa	Woodbury	47.08
Iowa	Worth	62.78
Iowa	Wright	62.78
Kansas	Allen	31.39
Kansas	Anderson	31.39
Kansas	Atchison	31.39
Kansas	Barber	15.69
Kansas	Barton	15.69
Kansas	Bourbon	31.39
Kansas	Brown	31.39
Kansas	Butler	31.39
Kansas	Chase	15.69
Kansas	Chautauqua	15.69
Kansas	Cherokee	31.39
Kansas	Cheyenne	15.69
Kansas	Clark	15.69
Kansas	Clay	31.39
Kansas	Cloud	15.69
Kansas	Coffey	31.39

APPENDIX A TO PART 11—FEE SCHEDULE FOR FY 2010—Continued

State	County	(Fee/acre/YR)
Kansas	Comanche	15.69
Kansas	Cowley	31.39
Kansas	Crawford	31.39
Kansas	Decatur	15.69
Kansas	Dickinson	31.39
Kansas	Doniphan	47.08
Kansas	Douglas	62.78
Kansas	Edwards	15.69
Kansas	Elk	15.69
Kansas	Ellis	15.69
Kansas	Ellsworth	15.69
Kansas	Finney	15.69
Kansas	Ford	15.69
Kansas	Franklin	31.39
Kansas	Geary	31.39
Kansas	Gove	15.69
Kansas	Graham	15.69
Kansas	Grant	31.39
Kansas	Gray	31.39
Kansas	Greeley	15.69
Kansas	Greenwood	15.69
Kansas	Hamilton	15.69
Kansas	Harper	15.69
Kansas	Harvey	31.39
Kansas	Haskell	31.39
Kansas	Hodgeman	15.69
Kansas	Jackson	31.39
Kansas	Jefferson	31.39
Kansas	Jewell	31.39
Kansas	Johnson	62.78
Kansas	Kearny	15.69
Kansas	Kingman	31.39
Kansas	Kiowa	15.69
Kansas	Labette	31.39
Kansas	Lane	15.69
Kansas	Leavenworth	47.08
Kansas	Lincoln	15.69
Kansas	Linn	31.39
Kansas	Logan	15.69
Kansas	Lyon	31.39
Kansas	Marion	31.39
Kansas	Marshall	31.39
Kansas	McPherson	31.39
Kansas	Meade	15.69
Kansas	Miami	47.08
Kansas	Mitchell	31.39
Kansas	Montgomery	31.39
Kansas	Morris	31.39
Kansas	Morton	15.69
Kansas	Nemaha	31.39
Kansas	Neosho	31.39
Kansas	Ness	15.69
Kansas	Norton	15.69
Kansas	Osage	31.39
Kansas	Osborne	15.69
Kansas	Ottawa	15.69
Kansas	Pawnee	15.69
Kansas	Phillips	15.69
Kansas	Pottawatomie	31.39
Kansas	Pratt	31.39
Kansas	Rawlins	15.69
Kansas	Reno	31.39
Kansas	Republic	31.39
Kansas	Rice	31.39
Kansas	Riley	31.39
Kansas	Rooks	15.69
Kansas	Rush	15.69
Kansas	Russell	15.69
Kansas	Saline	31.39
Kansas	Scott	15.69
Kansas	Sedgwick	31.39
Kansas	Seward	31.39

APPENDIX A TO PART 11—FEE SCHEDULE FOR FY 2010—Continued

State	County	(Fee/acre/YR)
Kansas	Shawnee	47.08
Kansas	Sheridan	15.69
Kansas	Sherman	15.69
Kansas	Smith	31.39
Kansas	Stafford	31.39
Kansas	Stanton	15.69
Kansas	Stevens	31.39
Kansas	Sumner	31.39
Kansas	Thomas	15.69
Kansas	Trego	15.69
Kansas	Wabaunsee	31.39
Kansas	Wallace	15.69
Kansas	Washington	31.39
Kansas	Wichita	15.69
Kansas	Wilson	31.39
Kansas	Woodson	15.69
Kansas	Wyandotte	156.94
Kentucky	Adair	47.08
Kentucky	Allen	47.08
Kentucky	Anderson	62.78
Kentucky	Ballard	47.08
Kentucky	Barren	47.08
Kentucky	Bath	47.08
Kentucky	Bell	47.08
Kentucky	Boone	94.17
Kentucky	Bourbon	94.17
Kentucky	Boyd	47.08
Kentucky	Boyle	62.78
Kentucky	Bracken	47.08
Kentucky	Breathitt	31.39
Kentucky	Breckinridge	47.08
Kentucky	Bullitt	94.17
Kentucky	Butler	47.08
Kentucky	Caldwell	31.39
Kentucky	Calloway	47.08
Kentucky	Campbell	156.94
Kentucky	Carlisle	47.08
Kentucky	Carroll	62.78
Kentucky	Carter	47.08
Kentucky	Casey	31.39
Kentucky	Christian	47.08
Kentucky	Clark	62.78
Kentucky	Clay	31.39
Kentucky	Clinton	47.08
Kentucky	Crittenden	31.39
Kentucky	Cumberland	31.39
Kentucky	Daviess	62.78
Kentucky	Edmonson	31.39
Kentucky	Elliott	31.39
Kentucky	Estill	31.39
Kentucky	Fayette	156.94
Kentucky	Fleming	47.08
Kentucky	Floyd	47.08
Kentucky	Franklin	62.78
Kentucky	Fulton	47.08
Kentucky	Gallatin	62.78
Kentucky	Garrard	47.08
Kentucky	Grant	94.17
Kentucky	Graves	47.08
Kentucky	Grayson	47.08
Kentucky	Green	47.08
Kentucky	Greenup	31.39
Kentucky	Hancock	47.08
Kentucky	Hardin	62.78
Kentucky	Harlan	62.78
Kentucky	Harrison	47.08
Kentucky	Hart	47.08
Kentucky	Henderson	62.78
Kentucky	Henry	62.78
Kentucky	Hickman	47.08
Kentucky	Hopkins	47.08
Kentucky	Jackson	31.39

APPENDIX A TO PART 11—FEE SCHEDULE FOR FY 2010—Continued

State	County	(Fee/acre/YR)
Kentucky	Jefferson	156.94
Kentucky	Jessamine	94.17
Kentucky	Johnson	47.08
Kentucky	Kenton	156.94
Kentucky	Knott	47.08
Kentucky	Knox	47.08
Kentucky	Larue	62.78
Kentucky	Laurel	62.78
Kentucky	Lawrence	31.39
Kentucky	Lee	31.39
Kentucky	Leslie	31.39
Kentucky	Letcher	31.39
Kentucky	Lewis	31.39
Kentucky	Lincoln	47.08
Kentucky	Livingston	31.39
Kentucky	Logan	47.08
Kentucky	Lyon	31.39
Kentucky	Madison	62.78
Kentucky	Magoffin	31.39
Kentucky	Marion	47.08
Kentucky	Marshall	47.08
Kentucky	Martin	15.69
Kentucky	Mason	62.78
Kentucky	McCracken	47.08
Kentucky	McCreary	62.78
Kentucky	McLean	47.08
Kentucky	Meade	62.78
Kentucky	Menifee	62.78
Kentucky	Mercer	94.17
Kentucky	Metcalfe	47.08
Kentucky	Monroe	47.08
Kentucky	Montgomery	62.78
Kentucky	Morgan	31.39
Kentucky	Muhlenberg	47.08
Kentucky	Nelson	62.78
Kentucky	Nicholas	47.08
Kentucky	Ohio	47.08
Kentucky	Oldham	156.94
Kentucky	Owen	47.08
Kentucky	Owsley	47.08
Kentucky	Pendleton	47.08
Kentucky	Perry	31.39
Kentucky	Pike	31.39
Kentucky	Powell	47.08
Kentucky	Pulaski	47.08
Kentucky	Robertson	31.39
Kentucky	Rockcastle	47.08
Kentucky	Rowan	47.08
Kentucky	Russell	62.78
Kentucky	Scott	94.17
Kentucky	Shelby	94.17
Kentucky	Simpson	62.78
Kentucky	Spencer	94.17
Kentucky	Taylor	47.08
Kentucky	Todd	47.08
Kentucky	Trigg	47.08
Kentucky	Trimble	47.08
Kentucky	Union	47.08
Kentucky	Warren	62.78
Kentucky	Washington	47.08
Kentucky	Wayne	62.78
Kentucky	Webster	47.08
Kentucky	Whitley	47.08
Kentucky	Wolfe	31.39
Kentucky	Woodford	156.94
Louisiana	Acadia	47.08
Louisiana	Allen	31.39
Louisiana	Ascension	94.17
Louisiana	Assumption	47.08
Louisiana	Avoyelles	47.08
Louisiana	Beauregard	47.08
Louisiana	Bienville	47.08

APPENDIX A TO PART 11—FEE SCHEDULE FOR FY 2010—Continued

State	County	(Fee/acre/YR)
Louisiana	Bossier	47.08
Louisiana	Caddo	47.08
Louisiana	Calcasieu	47.08
Louisiana	Caldwell	47.08
Louisiana	Cameron	47.08
Louisiana	Catahoula	31.39
Louisiana	Claiborne	47.08
Louisiana	Concordia	31.39
Louisiana	De Soto	47.08
Louisiana	East Baton Rouge	94.17
Louisiana	East Carroll	31.39
Louisiana	East Feliciana	62.78
Louisiana	Evangeline	47.08
Louisiana	Franklin	31.39
Louisiana	Grant	47.08
Louisiana	Iberia	62.78
Louisiana	Iberville	47.08
Louisiana	Jackson	94.17
Louisiana	Jefferson	62.78
Louisiana	Jefferson Davis	31.39
Louisiana	La Salle	47.08
Louisiana	Lafayette	94.17
Louisiana	Lafourche	47.08
Louisiana	Lincoln	62.78
Louisiana	Livingston	94.17
Louisiana	Madison	31.39
Louisiana	Morehouse	31.39
Louisiana	Natchitoches	47.08
Louisiana	Orleans	1,569.43
Louisiana	Ouachita	47.08
Louisiana	Plaquemines	94.17
Louisiana	Pointe Coupee	47.08
Louisiana	Rapides	47.08
Louisiana	Red River	31.39
Louisiana	Richland	31.39
Louisiana	Sabine	62.78
Louisiana	St. Bernard	156.94
Louisiana	St. Charles	156.94
Louisiana	St. Helena	62.78
Louisiana	St. James	47.08
Louisiana	St. John the Baptist	94.17
Louisiana	St. Landry	47.08
Louisiana	St. Martin	47.08
Louisiana	St. Mary	47.08
Louisiana	St. Tammany	156.94
Louisiana	Tangipahoa	94.17
Louisiana	Tensas	31.39
Louisiana	Terrebonne	47.08
Louisiana	Union	62.78
Louisiana	Vermilion	47.08
Louisiana	Vernon	47.08
Louisiana	Washington	62.78
Louisiana	Webster	94.17
Louisiana	West Baton Rouge	62.78
Louisiana	West Carroll	47.08
Louisiana	West Feliciana	47.08
Louisiana	Winn	47.08
Maine	Androscoggin	62.78
Maine	Aroostook	31.39
Maine	Cumberland	156.94
Maine	Franklin	47.08
Maine	Hancock	62.78
Maine	Kennebec	62.78
Maine	Knox	94.17
Maine	Lincoln	94.17
Maine	Oxford	62.78
Maine	Penobscot	47.08
Maine	Piscataquis	31.39
Maine	Sagadahoc	94.17
Maine	Somerset	47.08
Maine	Waldo	47.08
Maine	Washington	31.39

APPENDIX A TO PART 11—FEE SCHEDULE FOR FY 2010—Continued

State	County	(Fee/acre/YR)
Maine	York	156.94
Maryland	Allegany	62.78
Maryland	Anne Arundel	313.89
Maryland	Baltimore	313.89
Maryland	Calvert	156.94
Maryland	Caroline	94.17
Maryland	Carroll	156.94
Maryland	Cecil	156.94
Maryland	Charles	94.17
Maryland	Dorchester	94.17
Maryland	Frederick	156.94
Maryland	Garrett	62.78
Maryland	Harford	156.94
Maryland	Howard	156.94
Maryland	Kent	94.17
Maryland	Montgomery	156.94
Maryland	Prince George's	313.89
Maryland	Queen Anne's	94.17
Maryland	Somerset	94.17
Maryland	St. Mary's	94.17
Maryland	Talbot	156.94
Maryland	Washington	156.94
Maryland	Wicomico	94.17
Maryland	Worcester	62.78
Massachusetts	Barnstable	627.77
Massachusetts	Berkshire	156.94
Massachusetts	Bristol	627.77
Massachusetts	Dukes	313.89
Massachusetts	Essex	627.77
Massachusetts	Franklin	156.94
Massachusetts	Hampden	313.89
Massachusetts	Hampshire	313.89
Massachusetts	Middlesex	627.77
Massachusetts	Nantucket	1,569.43
Massachusetts	Norfolk	627.77
Massachusetts	Plymouth	627.77
Massachusetts	Suffolk	1,569.43
Massachusetts	Worcester	313.89
Michigan	Alcona	62.78
Michigan	Alger	47.08
Michigan	Allegan	94.17
Michigan	Alpena	62.78
Michigan	Antrim	94.17
Michigan	Arenac	62.78
Michigan	Baraga	31.39
Michigan	Barry	94.17
Michigan	Bay	94.17
Michigan	Benzie	94.17
Michigan	Berrien	156.94
Michigan	Branch	62.78
Michigan	Calhoun	62.78
Michigan	Cass	62.78
Michigan	Charlevoix	94.17
Michigan	Cheboygan	62.78
Michigan	Chippewa	47.08
Michigan	Clare	62.78
Michigan	Clinton	62.78
Michigan	Crawford	94.17
Michigan	Delta	47.08
Michigan	Dickinson	47.08
Michigan	Eaton	94.17
Michigan	Emmet	94.17
Michigan	Genesee	156.94
Michigan	Gladwin	62.78
Michigan	Gogebic	47.08
Michigan	Grand Traverse	156.94
Michigan	Gratiot	62.78
Michigan	Hillsdale	62.78
Michigan	Houghton	47.08
Michigan	Huron	62.78
Michigan	Ingham	94.17
Michigan	Ionia	94.17

APPENDIX A TO PART 11—FEE SCHEDULE FOR FY 2010—Continued

State	County	(Fee/acre/YR)
Michigan	Iosco	62.78
Michigan	Iron	47.08
Michigan	Isabella	62.78
Michigan	Jackson	94.17
Michigan	Kalamazoo	94.17
Michigan	Kalkaska	62.78
Michigan	Kent	156.94
Michigan	Keweenaw	62.78
Michigan	Lake	62.78
Michigan	Lapeer	156.94
Michigan	Leelanau	156.94
Michigan	Lenawee	94.17
Michigan	Livingston	156.94
Michigan	Luce	47.08
Michigan	Mackinac	47.08
Michigan	Macomb	156.94
Michigan	Manistee	62.78
Michigan	Marquette	47.08
Michigan	Mason	62.78
Michigan	Mecosta	62.78
Michigan	Menominee	47.08
Michigan	Midland	94.17
Michigan	Missaukee	62.78
Michigan	Monroe	94.17
Michigan	Montcalm	62.78
Michigan	Montmorency	62.78
Michigan	Muskegon	94.17
Michigan	Newaygo	94.17
Michigan	Oakland	313.89
Michigan	Oceana	94.17
Michigan	Ogemaw	62.78
Michigan	Ontonagon	31.39
Michigan	Osceola	62.78
Michigan	Oscoda	62.78
Michigan	Otsego	62.78
Michigan	Ottawa	156.94
Michigan	Presque Isle	62.78
Michigan	Roscommon	94.17
Michigan	Saginaw	62.78
Michigan	Sanilac	62.78
Michigan	Schoolcraft	47.08
Michigan	Shiawassee	62.78
Michigan	St. Clair	156.94
Michigan	St. Joseph	62.78
Michigan	Tuscola	62.78
Michigan	Van Buren	94.17
Michigan	Washtenaw	156.94
Michigan	Wayne	313.89
Michigan	Wexford	94.17
Minnesota	Aitkin	31.39
Minnesota	Anoka	156.94
Minnesota	Becker	31.39
Minnesota	Beltrami	31.39
Minnesota	Benton	62.78
Minnesota	Big Stone	31.39
Minnesota	Blue Earth	62.78
Minnesota	Brown	62.78
Minnesota	Carlton	31.39
Minnesota	Carver	94.17
Minnesota	Cass	31.39
Minnesota	Chippewa	47.08
Minnesota	Chisago	94.17
Minnesota	Clay	31.39
Minnesota	Clearwater	31.39
Minnesota	Cook	47.08
Minnesota	Cottonwood	47.08
Minnesota	Crow Wing	31.39
Minnesota	Dakota	94.17
Minnesota	Dodge	62.78
Minnesota	Douglas	47.08
Minnesota	Faribault	62.78
Minnesota	Fillmore	47.08

APPENDIX A TO PART 11—FEE SCHEDULE FOR FY 2010—Continued

State	County	(Fee/acre/YR)
Minnesota	Freeborn	62.78
Minnesota	Goodhue	62.78
Minnesota	Grant	47.08
Minnesota	Hennepin	156.94
Minnesota	Houston	47.08
Minnesota	Hubbard	31.39
Minnesota	Isanti	62.78
Minnesota	Itasca	31.39
Minnesota	Jackson	47.08
Minnesota	Kanabec	47.08
Minnesota	Kandiyohi	47.08
Minnesota	Kittson	15.69
Minnesota	Koochiching	31.39
Minnesota	Lac qui Parle	31.39
Minnesota	Lake	47.08
Minnesota	Lake of the Woods	15.69
Minnesota	Le Sueur	62.78
Minnesota	Lincoln	31.39
Minnesota	Lyon	47.08
Minnesota	Mahnomen	31.39
Minnesota	Marshall	15.69
Minnesota	Martin	62.78
Minnesota	McLeod	62.78
Minnesota	Meeker	47.08
Minnesota	Mille Lacs	47.08
Minnesota	Morrison	47.08
Minnesota	Mower	62.78
Minnesota	Murray	47.08
Minnesota	Nicollet	62.78
Minnesota	Nobles	47.08
Minnesota	Norman	31.39
Minnesota	Olmsted	62.78
Minnesota	Otter Tail	31.39
Minnesota	Pennington	15.69
Minnesota	Pine	47.08
Minnesota	Pipestone	47.08
Minnesota	Polk	31.39
Minnesota	Pope	31.39
Minnesota	Ramsey	627.77
Minnesota	Red Lake	31.39
Minnesota	Redwood	47.08
Minnesota	Renville	62.78
Minnesota	Rice	94.17
Minnesota	Rock	47.08
Minnesota	Roseau	15.69
Minnesota	Scott	94.17
Minnesota	Sherburne	94.17
Minnesota	Sibley	62.78
Minnesota	St. Louis	47.08
Minnesota	Stearns	47.08
Minnesota	Steele	62.78
Minnesota	Stevens	47.08
Minnesota	Swift	31.39
Minnesota	Todd	31.39
Minnesota	Traverse	31.39
Minnesota	Wabasha	47.08
Minnesota	Wadena	31.39
Minnesota	Waseca	62.78
Minnesota	Washington	156.94
Minnesota	Watonwan	47.08
Minnesota	Wilkin	31.39
Minnesota	Winona	62.78
Minnesota	Wright	94.17
Minnesota	Yellow Medicine	47.08
Mississippi	Adams	31.39
Mississippi	Alcorn	47.08
Mississippi	Amite	47.08
Mississippi	Attala	47.08
Mississippi	Benton	31.39
Mississippi	Bolivar	31.39
Mississippi	Calhoun	31.39
Mississippi	Carroll	31.39

APPENDIX A TO PART 11—FEE SCHEDULE FOR FY 2010—Continued

State	County	(Fee/acre/YR)
Mississippi	Chickasaw	31.39
Mississippi	Choctaw	31.39
Mississippi	Claiborne	31.39
Mississippi	Clarke	47.08
Mississippi	Clay	31.39
Mississippi	Coahoma	31.39
Mississippi	Copiah	47.08
Mississippi	Covington	47.08
Mississippi	DeSoto	62.78
Mississippi	Forrest	94.17
Mississippi	Franklin	47.08
Mississippi	George	94.17
Mississippi	Greene	47.08
Mississippi	Grenada	31.39
Mississippi	Hancock	62.78
Mississippi	Harrison	156.94
Mississippi	Hinds	47.08
Mississippi	Holmes	31.39
Mississippi	Humphreys	31.39
Mississippi	Issaquena	31.39
Mississippi	Itawamba	31.39
Mississippi	Jackson	156.94
Mississippi	Jasper	47.08
Mississippi	Jefferson	47.08
Mississippi	Jefferson Davis	47.08
Mississippi	Jones	62.78
Mississippi	Kemper	31.39
Mississippi	Lafayette	47.08
Mississippi	Lamar	62.78
Mississippi	Lauderdale	47.08
Mississippi	Lawrence	47.08
Mississippi	Leake	47.08
Mississippi	Lee	47.08
Mississippi	Leflore	31.39
Mississippi	Lincoln	62.78
Mississippi	Lowndes	31.39
Mississippi	Madison	47.08
Mississippi	Marion	47.08
Mississippi	Marshall	47.08
Mississippi	Monroe	31.39
Mississippi	Montgomery	31.39
Mississippi	Neshoba	62.78
Mississippi	Newton	94.17
Mississippi	Noxubee	31.39
Mississippi	Oktibbeha	47.08
Mississippi	Panola	31.39
Mississippi	Pearl River	94.17
Mississippi	Perry	62.78
Mississippi	Pike	62.78
Mississippi	Pontotoc	31.39
Mississippi	Prentiss	31.39
Mississippi	Quitman	31.39
Mississippi	Rankin	47.08
Mississippi	Scott	47.08
Mississippi	Sharkey	31.39
Mississippi	Simpson	62.78
Mississippi	Smith	62.78
Mississippi	Stone	47.08
Mississippi	Sunflower	31.39
Mississippi	Tallahatchie	31.39
Mississippi	Tate	47.08
Mississippi	Tippah	31.39
Mississippi	Tishomingo	47.08
Mississippi	Tunica	31.39
Mississippi	Union	47.08
Mississippi	Walthall	94.17
Mississippi	Warren	31.39
Mississippi	Washington	47.08
Mississippi	Wayne	47.08
Mississippi	Webster	31.39
Mississippi	Wilkinson	47.08
Mississippi	Winston	47.08

APPENDIX A TO PART 11—FEE SCHEDULE FOR FY 2010—Continued

State	County	(Fee/acre/YR)
Mississippi	Yalobusha	31.39
Mississippi	Yazoo	31.39
Missouri	Adair	31.39
Missouri	Andrew	47.08
Missouri	Atchison	47.08
Missouri	Audrain	47.08
Missouri	Barry	47.08
Missouri	Barton	31.39
Missouri	Bates	31.39
Missouri	Benton	31.39
Missouri	Bollinger	47.08
Missouri	Boone	94.17
Missouri	Buchanan	47.08
Missouri	Butler	47.08
Missouri	Caldwell	47.08
Missouri	Callaway	47.08
Missouri	Camden	47.08
Missouri	Cape Girardeau	62.78
Missouri	Carroll	47.08
Missouri	Carter	31.39
Missouri	Cass	47.08
Missouri	Cedar	31.39
Missouri	Chariton	47.08
Missouri	Christian	62.78
Missouri	Clark	31.39
Missouri	Clay	94.17
Missouri	Clinton	47.08
Missouri	Cole	62.78
Missouri	Cooper	47.08
Missouri	Crawford	31.39
Missouri	Dade	47.08
Missouri	Dallas	47.08
Missouri	Daviess	31.39
Missouri	DeKalb	31.39
Missouri	Dent	31.39
Missouri	Douglas	31.39
Missouri	Dunklin	62.78
Missouri	Franklin	62.78
Missouri	Gasconade	47.08
Missouri	Gentry	31.39
Missouri	Greene	94.17
Missouri	Grundy	31.39
Missouri	Harrison	31.39
Missouri	Henry	31.39
Missouri	Hickory	31.39
Missouri	Holt	47.08
Missouri	Howard	47.08
Missouri	Howell	47.08
Missouri	Iron	47.08
Missouri	Jackson	94.17
Missouri	Jasper	47.08
Missouri	Jefferson	94.17
Missouri	Johnson	47.08
Missouri	Knox	47.08
Missouri	Laclede	47.08
Missouri	Lafayette	47.08
Missouri	Lawrence	47.08
Missouri	Lewis	31.39
Missouri	Lincoln	62.78
Missouri	Linn	31.39
Missouri	Livingston	47.08
Missouri	Macon	31.39
Missouri	Madison	31.39
Missouri	Maries	31.39
Missouri	Marion	31.39
Missouri	McDonald	62.78
Missouri	Mercer	156.94
Missouri	Miller	47.08
Missouri	Mississippi	47.08
Missouri	Moniteau	47.08
Missouri	Monroe	31.39
Missouri	Montgomery	47.08

APPENDIX A TO PART 11—FEE SCHEDULE FOR FY 2010—Continued

State	County	(Fee/acre/YR)
Missouri	Morgan	47.08
Missouri	New Madrid	47.08
Missouri	Newton	47.08
Missouri	Nodaway	31.39
Missouri	Oregon	31.39
Missouri	Osage	47.08
Missouri	Ozark	47.08
Missouri	Pemiscot	47.08
Missouri	Perry	47.08
Missouri	Pettis	47.08
Missouri	Phelps	47.08
Missouri	Pike	47.08
Missouri	Platte	62.78
Missouri	Polk	47.08
Missouri	Pulaski	47.08
Missouri	Putnam	31.39
Missouri	Ralls	47.08
Missouri	Randolph	31.39
Missouri	Ray	47.08
Missouri	Reynolds	31.39
Missouri	Ripley	31.39
Missouri	Saline	47.08
Missouri	Schuyler	31.39
Missouri	Scotland	31.39
Missouri	Scott	47.08
Missouri	Shannon	31.39
Missouri	Shelby	31.39
Missouri	St Louis	94.17
Missouri	St. Charles	156.94
Missouri	St. Clair	31.39
Missouri	St. Francois	62.78
Missouri	Ste. Genevieve	47.08
Missouri	Stoddard	62.78
Missouri	Stone	62.78
Missouri	Sullivan	31.39
Missouri	Taney	47.08
Missouri	Texas	31.39
Missouri	Vernon	31.39
Missouri	Warren	62.78
Missouri	Washington	47.08
Missouri	Wayne	31.39
Missouri	Webster	47.08
Missouri	Worth	31.39
Missouri	Wright	47.08
Montana	Beaverhead	15.69
Montana	Big Horn	7.85
Montana	Blaine	7.85
Montana	Broadwater	15.69
Montana	Carbon	31.39
Montana	Carter	7.85
Montana	Cascade	15.69
Montana	Chouteau	15.69
Montana	Custer	7.85
Montana	Daniels	7.85
Montana	Dawson	7.85
Montana	Deer Lodge	31.39
Montana	Fallon	7.85
Montana	Fergus	15.69
Montana	Flathead	62.78
Montana	Gallatin	31.39
Montana	Garfield	7.85
Montana	Glacier	15.69
Montana	Golden Valley	7.85
Montana	Granite	31.39
Montana	Hill	15.69
Montana	Jefferson	15.69
Montana	Judith Basin	15.69
Montana	Lake	31.39
Montana	Lewis and Clark	15.69
Montana	Liberty	15.69
Montana	Lincoln	94.17
Montana	Madison	31.39

APPENDIX A TO PART 11—FEE SCHEDULE FOR FY 2010—Continued

State	County	(Fee/acre/YR)
Montana	McCone	7.85
Montana	Meagher	15.69
Montana	Mineral	62.78
Montana	Missoula	47.08
Montana	Musselshell	7.85
Montana	Park	31.39
Montana	Petroleum	7.85
Montana	Phillips	7.85
Montana	Pondera	15.69
Montana	Powder River	7.85
Montana	Powell	15.69
Montana	Prairie	7.85
Montana	Ravalli	94.17
Montana	Richland	7.85
Montana	Roosevelt	7.85
Montana	Rosebud	7.85
Montana	Sanders	31.39
Montana	Sheridan	15.69
Montana	Silver Bow	31.39
Montana	Stillwater	15.69
Montana	Sweet Grass	15.69
Montana	Teton	15.69
Montana	Toole	15.69
Montana	Treasure	7.85
Montana	Valley	7.85
Montana	Wheatland	7.85
Montana	Wibaux	7.85
Montana	Yellowstone	15.69
Nebraska	Adams	47.08
Nebraska	Antelope	31.39
Nebraska	Arthur	7.85
Nebraska	Banner	7.85
Nebraska	Blaine	7.85
Nebraska	Boone	31.39
Nebraska	Box Butte	15.69
Nebraska	Boyd	15.69
Nebraska	Brown	15.69
Nebraska	Buffalo	47.08
Nebraska	Burt	47.08
Nebraska	Butler	62.78
Nebraska	Cass	62.78
Nebraska	Cedar	31.39
Nebraska	Chase	31.39
Nebraska	Cherry	7.85
Nebraska	Cheyenne	15.69
Nebraska	Clay	47.08
Nebraska	Colfax	47.08
Nebraska	Cuming	47.08
Nebraska	Custer	15.69
Nebraska	Dakota	47.08
Nebraska	Dawes	15.69
Nebraska	Dawson	31.39
Nebraska	Deuel	15.69
Nebraska	Dixon	31.39
Nebraska	Dodge	62.78
Nebraska	Douglas	156.94
Nebraska	Dundy	15.69
Nebraska	Fillmore	47.08
Nebraska	Franklin	31.39
Nebraska	Frontier	15.69
Nebraska	Furnas	15.69
Nebraska	Gage	31.39
Nebraska	Garden	7.85
Nebraska	Garfield	15.69
Nebraska	Gosper	31.39
Nebraska	Grant	7.85
Nebraska	Greeley	31.39
Nebraska	Hall	47.08
Nebraska	Hamilton	47.08
Nebraska	Harlan	31.39
Nebraska	Hayes	15.69
Nebraska	Hitchcock	15.69

APPENDIX A TO PART 11—FEE SCHEDULE FOR FY 2010—Continued

State	County	(Fee/acre/YR)
Nebraska	Holt	15.69
Nebraska	Hooker	7.85
Nebraska	Howard	31.39
Nebraska	Jefferson	31.39
Nebraska	Johnson	31.39
Nebraska	Kearney	47.08
Nebraska	Keith	15.69
Nebraska	Keya Paha	15.69
Nebraska	Kimball	7.85
Nebraska	Knox	31.39
Nebraska	Lancaster	62.78
Nebraska	Lincoln	15.69
Nebraska	Logan	7.85
Nebraska	Loup	7.85
Nebraska	Madison	47.08
Nebraska	McPherson	7.85
Nebraska	Merrick	47.08
Nebraska	Morrill	15.69
Nebraska	Nance	31.39
Nebraska	Nemaha	47.08
Nebraska	Nuckolls	31.39
Nebraska	Otoe	47.08
Nebraska	Pawnee	31.39
Nebraska	Perkins	31.39
Nebraska	Phelps	47.08
Nebraska	Pierce	31.39
Nebraska	Platte	47.08
Nebraska	Polk	47.08
Nebraska	Red Willow	15.69
Nebraska	Richardson	31.39
Nebraska	Rock	15.69
Nebraska	Saline	47.08
Nebraska	Sarpy	94.17
Nebraska	Saunders	62.78
Nebraska	Scotts Bluff	31.39
Nebraska	Seward	47.08
Nebraska	Sheridan	7.85
Nebraska	Sherman	15.69
Nebraska	Sioux	7.85
Nebraska	Stanton	47.08
Nebraska	Thayer	47.08
Nebraska	Thomas	7.85
Nebraska	Thurston	47.08
Nebraska	Valley	31.39
Nebraska	Washington	62.78
Nebraska	Wayne	47.08
Nebraska	Webster	31.39
Nebraska	Wheeler	15.69
Nebraska	York	62.78
Nevada	Carson City	94.17
Nevada	Churchill	47.08
Nevada	Clark	94.17
Nevada	Douglas	31.39
Nevada	Elko	7.85
Nevada	Esmeralda	31.39
Nevada	Eureka	7.85
Nevada	Humboldt	15.69
Nevada	Lander	7.85
Nevada	Lincoln	31.39
Nevada	Lyon	47.08
Nevada	Mineral	7.85
Nevada	Nye	31.39
Nevada	Pershing	31.39
Nevada	Storey	941.66
Nevada	Washoe	15.69
Nevada	White Pine	15.69
New Hampshire	Belknap	94.17
New Hampshire	Carroll	94.17
New Hampshire	Cheshire	94.17
New Hampshire	Coos	31.39
New Hampshire	Grafton	62.78
New Hampshire	Hillsborough	156.94

APPENDIX A TO PART 11—FEE SCHEDULE FOR FY 2010—Continued

State	County	(Fee/acre/YR)
New Hampshire	Merrimack	94.17
New Hampshire	Rockingham	313.89
New Hampshire	Strafford	94.17
New Hampshire	Sullivan	94.17
New Jersey	Atlantic	156.94
New Jersey	Bergen	1,569.43
New Jersey	Burlington	313.89
New Jersey	Camden	313.89
New Jersey	Cape May	313.89
New Jersey	Cumberland	156.94
New Jersey	Essex	1,569.43
New Jersey	Gloucester	313.89
New Jersey	Hudson *	313.89
New Jersey	Hunterdon	313.89
New Jersey	Mercer	627.77
New Jersey	Middlesex	627.77
New Jersey	Monmouth	627.77
New Jersey	Morris	941.66
New Jersey	Ocean	627.77
New Jersey	Passaic	941.66
New Jersey	Salem	156.94
New Jersey	Somerset	627.77
New Jersey	Sussex	313.89
New Jersey	Union	3,138.86
New Jersey	Warren	313.89
New Mexico	Bernalillo	15.69
New Mexico	Catron	7.85
New Mexico	Chaves	7.85
New Mexico	Cibola	7.85
New Mexico	Colfax	7.85
New Mexico	Curry	15.69
New Mexico	De Baca	7.85
New Mexico	Dona Ana	47.08
New Mexico	Eddy	7.85
New Mexico	Grant	7.85
New Mexico	Guadalupe	7.85
New Mexico	Harding *	7.85
New Mexico	Hidalgo	7.85
New Mexico	Lea	7.85
New Mexico	Lincoln	7.85
New Mexico	Los Alamos*	7.85
New Mexico	Luna	7.85
New Mexico	McKinley	7.85
New Mexico	Mora	7.85
New Mexico	Otero	7.85
New Mexico	Quay	7.85
New Mexico	Rio Arriba	15.69
New Mexico	Roosevelt	7.85
New Mexico	San Juan	15.69
New Mexico	San Miguel	7.85
New Mexico	Sandoval	7.85
New Mexico	Santa Fe	15.69
New Mexico	Sierra	7.85
New Mexico	Socorro	7.85
New Mexico	Taos	15.69
New Mexico	Torrance	7.85
New Mexico	Union	7.85
New Mexico	Valencia	31.39
New York	Albany	94.17
New York	Allegany	31.39
New York	Bronx *	47.08
New York	Broome	94.17
New York	Cattaraugus	47.08
New York	Cayuga	47.08
New York	Chautauqua	47.08
New York	Chemung	47.08
New York	Chenango	31.39
New York	Clinton	31.39
New York	Columbia	94.17
New York	Cortland	31.39
New York	Delaware	47.08
New York	Dutchess	313.89

APPENDIX A TO PART 11—FEE SCHEDULE FOR FY 2010—Continued

State	County	(Fee/acre/YR)
New York	Erie	47.08
New York	Essex	47.08
New York	Franklin	31.39
New York	Fulton	47.08
New York	Genesee	47.08
New York	Greene	62.78
New York	Hamilton *	47.08
New York	Herkimer	31.39
New York	Jefferson	31.39
New York	Kings *	47.08
New York	Lewis	31.39
New York	Livingston	47.08
New York	Madison	47.08
New York	Monroe	62.78
New York	Montgomery	47.08
New York	Nassau	941.66
New York	New York	313.89
New York	Niagara	47.08
New York	Oneida	31.39
New York	Onondaga	47.08
New York	Ontario	47.08
New York	Orange	156.94
New York	Orleans	31.39
New York	Oswego	62.78
New York	Otsego	47.08
New York	Putnam	313.89
New York	Queens	47.08
New York	Rensselaer	94.17
New York	Richmond	3,138.86
New York	Rockland	941.66
New York	Saratoga	94.17
New York	Schenectady	62.78
New York	Schoharie	47.08
New York	Schuyler	47.08
New York	Seneca	47.08
New York	St. Lawrence	31.39
New York	Steuben	31.39
New York	Suffolk	627.77
New York	Sullivan	94.17
New York	Tioga	47.08
New York	Tompkins	47.08
New York	Ulster	94.17
New York	Warren	94.17
New York	Washington	47.08
New York	Wayne	62.78
New York	Westchester	627.77
New York	Wyoming	47.08
New York	Yates	47.08
North Carolina	Alamance	156.94
North Carolina	Alexander	156.94
North Carolina	Alleghany	94.17
North Carolina	Anson	94.17
North Carolina	Ashe	156.94
North Carolina	Avery	156.94
North Carolina	Beaufort	62.78
North Carolina	Bertie	62.78
North Carolina	Bladen	94.17
North Carolina	Brunswick	94.17
North Carolina	Buncombe	156.94
North Carolina	Burke	156.94
North Carolina	Cabarrus	156.94
North Carolina	Caldwell	156.94
North Carolina	Camden	62.78
North Carolina	Carteret	62.78
North Carolina	Caswell	94.17
North Carolina	Catawba	94.17
North Carolina	Chatham	94.17
North Carolina	Cherokee	156.94
North Carolina	Chowan	62.78
North Carolina	Clay	156.94
North Carolina	Cleveland	94.17
North Carolina	Columbus	62.78

APPENDIX A TO PART 11—FEE SCHEDULE FOR FY 2010—Continued

State	County	(Fee/acre/YR)
North Carolina	Craven	62.78
North Carolina	Cumberland	94.17
North Carolina	Currituck	94.17
North Carolina	Dare	47.08
North Carolina	Davidson	156.94
North Carolina	Davie	156.94
North Carolina	Duplin	94.17
North Carolina	Durham	156.94
North Carolina	Edgecombe	62.78
North Carolina	Forsyth	156.94
North Carolina	Franklin	94.17
North Carolina	Gaston	156.94
North Carolina	Gates	47.08
North Carolina	Graham	94.17
North Carolina	Granville	94.17
North Carolina	Greene	94.17
North Carolina	Guilford	156.94
North Carolina	Halifax	47.08
North Carolina	Harnett	94.17
North Carolina	Haywood	156.94
North Carolina	Henderson	156.94
North Carolina	Hertford	62.78
North Carolina	Hoke	94.17
North Carolina	Hyde	47.08
North Carolina	Iredell	156.94
North Carolina	Jackson	156.94
North Carolina	Johnston	94.17
North Carolina	Jones	62.78
North Carolina	Lee	94.17
North Carolina	Lenoir	94.17
North Carolina	Lincoln	156.94
North Carolina	Macon	156.94
North Carolina	Madison	156.94
North Carolina	Martin	62.78
North Carolina	McDowell	94.17
North Carolina	Mecklenburg	313.89
North Carolina	Mitchell	156.94
North Carolina	Montgomery	94.17
North Carolina	Moore	94.17
North Carolina	Nash	94.17
North Carolina	New Hanover	313.89
North Carolina	Northampton	62.78
North Carolina	Onslow	94.17
North Carolina	Orange	156.94
North Carolina	Pamlico	62.78
North Carolina	Pasquotank	62.78
North Carolina	Pender	94.17
North Carolina	Perquimans	62.78
North Carolina	Person	62.78
North Carolina	Pitt	62.78
North Carolina	Polk	156.94
North Carolina	Randolph	156.94
North Carolina	Richmond	62.78
North Carolina	Robeson	62.78
North Carolina	Rockingham	94.17
North Carolina	Rowan	94.17
North Carolina	Rutherford	94.17
North Carolina	Sampson	94.17
North Carolina	Scotland	62.78
North Carolina	Stanly	94.17
North Carolina	Stokes	94.17
North Carolina	Surry	94.17
North Carolina	Swain	156.94
North Carolina	Transylvania	313.89
North Carolina	Tyrrell	47.08
North Carolina	Union	94.17
North Carolina	Vance	62.78
North Carolina	Wake	313.89
North Carolina	Warren	62.78
North Carolina	Washington	62.78
North Carolina	Watauga	156.94
North Carolina	Wayne	94.17

APPENDIX A TO PART 11—FEE SCHEDULE FOR FY 2010—Continued

State	County	(Fee/acre/YR)
North Carolina	Wilkes	94.17
North Carolina	Wilson	62.78
North Carolina	Yadkin	94.17
North Carolina	Yancey	156.94
North Dakota	Adams	7.85
North Dakota	Barnes	15.69
North Dakota	Benson	15.69
North Dakota	Billings	7.85
North Dakota	Bottineau	15.69
North Dakota	Bowman	7.85
North Dakota	Burke	7.85
North Dakota	Burleigh	15.69
North Dakota	Cass	31.39
North Dakota	Cavalier	15.69
North Dakota	Dickey	15.69
North Dakota	Divide	7.85
North Dakota	Dunn	7.85
North Dakota	Eddy	15.69
North Dakota	Emmons	7.85
North Dakota	Foster	15.69
North Dakota	Golden Valley	7.85
North Dakota	Grand Forks	31.39
North Dakota	Grant	7.85
North Dakota	Griggs	15.69
North Dakota	Hettinger	15.69
North Dakota	Kidder	7.85
North Dakota	LaMoure	15.69
North Dakota	Logan	7.85
North Dakota	McHenry	15.69
North Dakota	McIntosh	7.85
North Dakota	McKenzie	7.85
North Dakota	McLean	15.69
North Dakota	Mercer	7.85
North Dakota	Morton	7.85
North Dakota	Mountrail	7.85
North Dakota	Nelson	15.69
North Dakota	Oliver	7.85
North Dakota	Pembina	31.39
North Dakota	Pierce	15.69
North Dakota	Ramsey	15.69
North Dakota	Ransom	15.69
North Dakota	Renville	15.69
North Dakota	Richland	31.39
North Dakota	Rolette	15.69
North Dakota	Sargent	15.69
North Dakota	Sheridan	7.85
North Dakota	Sioux	7.85
North Dakota	Slope	7.85
North Dakota	Stark	15.69
North Dakota	Steele	15.69
North Dakota	Stutsman	15.69
North Dakota	Towner	15.69
North Dakota	Traill	31.39
North Dakota	Walsh	31.39
North Dakota	Ward	15.69
North Dakota	Wells	15.69
North Dakota	Williams	15.69
Ohio	Adams	62.78
Ohio	Allen	94.17
Ohio	Ashland	94.17
Ohio	Ashtabula	62.78
Ohio	Athens	47.08
Ohio	Auglaize	94.17
Ohio	Belmont	47.08
Ohio	Brown	62.78
Ohio	Butler	156.94
Ohio	Carroll	62.78
Ohio	Champaign	94.17
Ohio	Clark	94.17
Ohio	Clermont	94.17
Ohio	Clinton	94.17
Ohio	Columbiana	94.17

APPENDIX A TO PART 11—FEE SCHEDULE FOR FY 2010—Continued

State	County	(Fee/acre/YR)
Ohio	Coshocton	62.78
Ohio	Crawford	62.78
Ohio	Cuyahoga	627.77
Ohio	Darke	94.17
Ohio	Defiance	62.78
Ohio	Delaware	156.94
Ohio	Erie	94.17
Ohio	Fairfield	94.17
Ohio	Fayette	62.78
Ohio	Franklin	156.94
Ohio	Fulton	94.17
Ohio	Gallia	47.08
Ohio	Geauga	156.94
Ohio	Greene	94.17
Ohio	Guernsey	62.78
Ohio	Hamilton	156.94
Ohio	Hancock	62.78
Ohio	Hardin	62.78
Ohio	Harrison	31.39
Ohio	Henry	94.17
Ohio	Highland	62.78
Ohio	Hocking	94.17
Ohio	Holmes	94.17
Ohio	Huron	94.17
Ohio	Jackson	47.08
Ohio	Jefferson	47.08
Ohio	Knox	94.17
Ohio	Lake	313.89
Ohio	Lawrence	47.08
Ohio	Licking	94.17
Ohio	Logan	62.78
Ohio	Lorain	94.17
Ohio	Lucas	94.17
Ohio	Madison	94.17
Ohio	Mahoning	94.17
Ohio	Marion	62.78
Ohio	Medina	156.94
Ohio	Meigs	47.08
Ohio	Mercer	94.17
Ohio	Miami	94.17
Ohio	Monroe	47.08
Ohio	Montgomery	156.94
Ohio	Morgan	47.08
Ohio	Morrow	62.78
Ohio	Muskingum	62.78
Ohio	Noble	47.08
Ohio	Ottawa	62.78
Ohio	Paulding	62.78
Ohio	Perry	62.78
Ohio	Pickaway	94.17
Ohio	Pike	47.08
Ohio	Portage	156.94
Ohio	Preble	94.17
Ohio	Putnam	62.78
Ohio	Richland	94.17
Ohio	Ross	62.78
Ohio	Sandusky	62.78
Ohio	Scioto	47.08
Ohio	Seneca	62.78
Ohio	Shelby	94.17
Ohio	Stark	156.94
Ohio	Summit	156.94
Ohio	Trumbull	94.17
Ohio	Tuscarawas	94.17
Ohio	Union	94.17
Ohio	Van Wert	94.17
Ohio	Vinton	62.78
Ohio	Warren	156.94
Ohio	Washington	62.78
Ohio	Wayne	156.94
Ohio	Williams	62.78
Ohio	Wood	94.17

APPENDIX A TO PART 11—FEE SCHEDULE FOR FY 2010—Continued

State	County	(Fee/acre/YR)
Ohio	Wyandot	94.17
Oklahoma	Adair	31.39
Oklahoma	Alfalfa	31.39
Oklahoma	Atoka	31.39
Oklahoma	Beaver	15.69
Oklahoma	Beckham	15.69
Oklahoma	Blaine	15.69
Oklahoma	Bryan	31.39
Oklahoma	Caddo	15.69
Oklahoma	Canadian	31.39
Oklahoma	Carter	31.39
Oklahoma	Cherokee	31.39
Oklahoma	Choctaw	15.69
Oklahoma	Cimarron	7.85
Oklahoma	Cleveland	47.08
Oklahoma	Coal	31.39
Oklahoma	Comanche	31.39
Oklahoma	Cotton	15.69
Oklahoma	Craig	31.39
Oklahoma	Creek	31.39
Oklahoma	Custer	15.69
Oklahoma	Delaware	47.08
Oklahoma	Dewey	15.69
Oklahoma	Ellis	15.69
Oklahoma	Garfield	31.39
Oklahoma	Garvin	31.39
Oklahoma	Grady	31.39
Oklahoma	Grant	15.69
Oklahoma	Greer	15.69
Oklahoma	Harmon	15.69
Oklahoma	Harper	15.69
Oklahoma	Haskell	31.39
Oklahoma	Hughes	15.69
Oklahoma	Jackson	15.69
Oklahoma	Jefferson	15.69
Oklahoma	Johnston	31.39
Oklahoma	Kay	31.39
Oklahoma	Kingfisher	31.39
Oklahoma	Kiowa	15.69
Oklahoma	Latimer	31.39
Oklahoma	Le Flore	31.39
Oklahoma	Lincoln	31.39
Oklahoma	Logan	31.39
Oklahoma	Love	31.39
Oklahoma	Major	15.69
Oklahoma	Marshall	31.39
Oklahoma	Mayes	31.39
Oklahoma	McClain	31.39
Oklahoma	McCurtain	31.39
Oklahoma	McIntosh	31.39
Oklahoma	Murray	31.39
Oklahoma	Muskogee	31.39
Oklahoma	Noble	31.39
Oklahoma	Nowata	31.39
Oklahoma	Okfuskee	31.39
Oklahoma	Oklahoma	62.78
Oklahoma	Okmulgee	31.39
Oklahoma	Osage	15.69
Oklahoma	Ottawa	47.08
Oklahoma	Pawnee	15.69
Oklahoma	Payne	31.39
Oklahoma	Pittsburg	31.39
Oklahoma	Pontotoc	31.39
Oklahoma	Pottawatomie	31.39
Oklahoma	Pushmataha	15.69
Oklahoma	Roger Mills	15.69
Oklahoma	Rogers	47.08
Oklahoma	Seminole	31.39
Oklahoma	Sequoyah	47.08
Oklahoma	Stephens	31.39
Oklahoma	Texas	15.69
Oklahoma	Tillman	15.69

APPENDIX A TO PART 11—FEE SCHEDULE FOR FY 2010—Continued

State	County	(Fee/acre/YR)
Oklahoma	Tulsa	62.78
Oklahoma	Wagoner	47.08
Oklahoma	Washington	31.39
Oklahoma	Washita	15.69
Oklahoma	Woods	15.69
Oklahoma	Woodward	15.69
Oregon	Baker	15.69
Oregon	Benton	156.94
Oregon	Clackamas	313.89
Oregon	Clatsop	94.17
Oregon	Columbia	156.94
Oregon	Coos	94.17
Oregon	Crook	15.69
Oregon	Curry	62.78
Oregon	Deschutes	156.94
Oregon	Douglas	62.78
Oregon	Gilliam	7.85
Oregon	Grant	7.85
Oregon	Harney	7.85
Oregon	Hood River	313.89
Oregon	Jackson	94.17
Oregon	Jefferson	15.69
Oregon	Josephine	156.94
Oregon	Klamath	31.39
Oregon	Lake	15.69
Oregon	Lane	156.94
Oregon	Lincoln	94.17
Oregon	Linn	94.17
Oregon	Malheur	15.69
Oregon	Marion	156.94
Oregon	Morrow	15.69
Oregon	Multnomah	313.89
Oregon	Polk	156.94
Oregon	Sherman	15.69
Oregon	Tillamook	156.94
Oregon	Umatilla	31.39
Oregon	Union	31.39
Oregon	Wallowa	15.69
Oregon	Wasco	15.69
Oregon	Washington	313.89
Oregon	Wheeler	7.85
Oregon	Yamhill	313.89
Pennsylvania	Adams	156.94
Pennsylvania	Allegheny	156.94
Pennsylvania	Armstrong	62.78
Pennsylvania	Beaver	94.17
Pennsylvania	Bedford	62.78
Pennsylvania	Berks	156.94
Pennsylvania	Blair	94.17
Pennsylvania	Bradford	47.08
Pennsylvania	Bucks	313.89
Pennsylvania	Butler	156.94
Pennsylvania	Cambria	94.17
Pennsylvania	Cameron	62.78
Pennsylvania	Carbon	156.94
Pennsylvania	Centre	94.17
Pennsylvania	Chester	313.89
Pennsylvania	Clarion	47.08
Pennsylvania	Clearfield	47.08
Pennsylvania	Clinton	94.17
Pennsylvania	Columbia	94.17
Pennsylvania	Crawford	47.08
Pennsylvania	Cumberland	156.94
Pennsylvania	Dauphin	156.94
Pennsylvania	Delaware	627.77
Pennsylvania	Elk	94.17
Pennsylvania	Erie	62.78
Pennsylvania	Fayette	47.08
Pennsylvania	Forest	62.78
Pennsylvania	Franklin	156.94
Pennsylvania	Fulton	62.78
Pennsylvania	Greene	31.39

APPENDIX A TO PART 11—FEE SCHEDULE FOR FY 2010—Continued

State	County	(Fee/acre/YR)
Pennsylvania	Huntingdon	62.78
Pennsylvania	Indiana	62.78
Pennsylvania	Jefferson	47.08
Pennsylvania	Juniata	94.17
Pennsylvania	Lackawanna	94.17
Pennsylvania	Lancaster	313.89
Pennsylvania	Lawrence	62.78
Pennsylvania	Lebanon	156.94
Pennsylvania	Lehigh	156.94
Pennsylvania	Luzerne	94.17
Pennsylvania	Lycoming	62.78
Pennsylvania	McKean	31.39
Pennsylvania	Mercer	62.78
Pennsylvania	Mifflin	94.17
Pennsylvania	Monroe	156.94
Pennsylvania	Montgomery	627.77
Pennsylvania	Montour	94.17
Pennsylvania	Northampton	156.94
Pennsylvania	Northumberland	94.17
Pennsylvania	Perry	94.17
Pennsylvania	Philadelphia	941.66
Pennsylvania	Pike	94.17
Pennsylvania	Potter	47.08
Pennsylvania	Schuylkill	94.17
Pennsylvania	Snyder	94.17
Pennsylvania	Somerset	62.78
Pennsylvania	Sullivan	62.78
Pennsylvania	Susquehanna	62.78
Pennsylvania	Tioga	62.78
Pennsylvania	Union	156.94
Pennsylvania	Venango	47.08
Pennsylvania	Warren	47.08
Pennsylvania	Washington	62.78
Pennsylvania	Wayne	62.78
Pennsylvania	Westmoreland	94.17
Pennsylvania	Wyoming	62.78
Pennsylvania	York	156.94
Puerto Rico	All Areas	156.94
Rhode Island	Bristol	627.77
Rhode Island	Kent	313.89
Rhode Island	Newport	627.77
Rhode Island	Providence	313.89
Rhode Island	Washington	313.89
South Carolina	Abbeville	62.78
South Carolina	Aiken	62.78
South Carolina	Allendale	47.08
South Carolina	Anderson	94.17
South Carolina	Bamberg	47.08
South Carolina	Barnwell	47.08
South Carolina	Beaufort	62.78
South Carolina	Berkeley	94.17
South Carolina	Calhoun	47.08
South Carolina	Charleston	156.94
South Carolina	Cherokee	62.78
South Carolina	Chester	62.78
South Carolina	Chesterfield	47.08
South Carolina	Clarendon	47.08
South Carolina	Colleton	47.08
South Carolina	Darlington	31.39
South Carolina	Dillon	47.08
South Carolina	Dorchester	62.78
South Carolina	Edgefield	62.78
South Carolina	Fairfield	47.08
South Carolina	Florence	47.08
South Carolina	Georgetown	62.78
South Carolina	Greenville	94.17
South Carolina	Greenwood	47.08
South Carolina	Hampton	47.08
South Carolina	Horry	62.78
South Carolina	Jasper	47.08
South Carolina	Kershaw	62.78
South Carolina	Lancaster	62.78

APPENDIX A TO PART 11—FEE SCHEDULE FOR FY 2010—Continued

State	County	(Fee/acre/YR)
South Carolina	Laurens	62.78
South Carolina	Lee	47.08
South Carolina	Lexington	94.17
South Carolina	Marion	47.08
South Carolina	Marlboro	31.39
South Carolina	McCormick	94.17
South Carolina	Newberry	62.78
South Carolina	Oconee	156.94
South Carolina	Orangeburg	47.08
South Carolina	Pickens	156.94
South Carolina	Richland	94.17
South Carolina	Saluda	62.78
South Carolina	Spartanburg	156.94
South Carolina	Sumter	62.78
South Carolina	Union	47.08
South Carolina	Williamsburg	47.08
South Carolina	York	156.94
South Dakota	Aurora	15.69
South Dakota	Beadle	15.69
South Dakota	Bennett	7.85
South Dakota	Bon Homme	31.39
South Dakota	Brookings	31.39
South Dakota	Brown	31.39
South Dakota	Brule	15.69
South Dakota	Buffalo	7.85
South Dakota	Butte	7.85
South Dakota	Campbell	15.69
South Dakota	Charles Mix	15.69
South Dakota	Clark	31.39
South Dakota	Clay	47.08
South Dakota	Codington	31.39
South Dakota	Corson	7.85
South Dakota	Custer	15.69
South Dakota	Davison	31.39
South Dakota	Day	15.69
South Dakota	Deuel	31.39
South Dakota	Dewey	7.85
South Dakota	Douglas	31.39
South Dakota	Edmunds	15.69
South Dakota	Fall River	7.85
South Dakota	Faulk	15.69
South Dakota	Grant	31.39
South Dakota	Gregory	15.69
South Dakota	Haakon	7.85
South Dakota	Hamlin	31.39
South Dakota	Hand	15.69
South Dakota	Hanson	31.39
South Dakota	Harding	7.85
South Dakota	Hughes	15.69
South Dakota	Hutchinson	31.39
South Dakota	Hyde	7.85
South Dakota	Jackson	7.85
South Dakota	Jerauld	15.69
South Dakota	Jones	7.85
South Dakota	Kingsbury	31.39
South Dakota	Lake	31.39
South Dakota	Lawrence	31.39
South Dakota	Lincoln	47.08
South Dakota	Lyman	15.69
South Dakota	Marshall	15.69
South Dakota	McCook	31.39
South Dakota	McPherson	15.69
South Dakota	Meade	7.85
South Dakota	Mellette	7.85
South Dakota	Miner	31.39
South Dakota	Minnehaha	47.08
South Dakota	Moody	31.39
South Dakota	Pennington	15.69
South Dakota	Perkins	7.85
South Dakota	Potter	15.69
South Dakota	Roberts	31.39
South Dakota	Sanborn	15.69

APPENDIX A TO PART 11—FEE SCHEDULE FOR FY 2010—Continued

State	County	(Fee/acre/YR)
South Dakota	Shannon	7.85
South Dakota	Spink	15.69
South Dakota	Stanley	7.85
South Dakota	Sully	15.69
South Dakota	Todd	7.85
South Dakota	Tripp	15.69
South Dakota	Turner	47.08
South Dakota	Union	62.78
South Dakota	Walworth	15.69
South Dakota	Yankton	31.39
South Dakota	Ziebach	7.85
Tennessee	Anderson	156.94
Tennessee	Bedford	62.78
Tennessee	Benton	47.08
Tennessee	Bledsoe	62.78
Tennessee	Blount	156.94
Tennessee	Bradley	156.94
Tennessee	Campbell	62.78
Tennessee	Cannon	94.17
Tennessee	Carroll	47.08
Tennessee	Carter	94.17
Tennessee	Cheatham	94.17
Tennessee	Chester	47.08
Tennessee	Claiborne	47.08
Tennessee	Clay	47.08
Tennessee	Cocke	94.17
Tennessee	Coffee	94.17
Tennessee	Crockett	62.78
Tennessee	Cumberland	94.17
Tennessee	Davidson	313.89
Tennessee	Decatur	47.08
Tennessee	DeKalb	94.17
Tennessee	Dickson	94.17
Tennessee	Dyer	62.78
Tennessee	Fayette	62.78
Tennessee	Fentress	62.78
Tennessee	Franklin	94.17
Tennessee	Gibson	47.08
Tennessee	Giles	62.78
Tennessee	Grainger	62.78
Tennessee	Greene	94.17
Tennessee	Grundy	62.78
Tennessee	Hamblen	156.94
Tennessee	Hamilton	94.17
Tennessee	Hancock	62.78
Tennessee	Hardeman	31.39
Tennessee	Hardin	47.08
Tennessee	Hawkins	94.17
Tennessee	Haywood	47.08
Tennessee	Henderson	47.08
Tennessee	Henry	47.08
Tennessee	Hickman	47.08
Tennessee	Houston	47.08
Tennessee	Humphreys	47.08
Tennessee	Jackson	47.08
Tennessee	Jefferson	156.94
Tennessee	Johnson	94.17
Tennessee	Knox	156.94
Tennessee	Lake	47.08
Tennessee	Lauderdale	47.08
Tennessee	Lawrence	47.08
Tennessee	Lewis	62.78
Tennessee	Lincoln	62.78
Tennessee	Loudon	156.94
Tennessee	Macon	94.17
Tennessee	Madison	94.17
Tennessee	Marion	62.78
Tennessee	Marshall	62.78
Tennessee	Maury	94.17
Tennessee	McMinn	94.17
Tennessee	McNairy	31.39
Tennessee	Meigs	94.17

APPENDIX A TO PART 11—FEE SCHEDULE FOR FY 2010—Continued

State	County	(Fee/acre/YR)
Tennessee	Monroe	94.17
Tennessee	Montgomery	62.78
Tennessee	Moore	62.78
Tennessee	Morgan	62.78
Tennessee	Obion	47.08
Tennessee	Overton	62.78
Tennessee	Perry	47.08
Tennessee	Pickett	62.78
Tennessee	Polk	156.94
Tennessee	Putnam	94.17
Tennessee	Rhea	94.17
Tennessee	Roane	94.17
Tennessee	Robertson	94.17
Tennessee	Rutherford	94.17
Tennessee	Scott	62.78
Tennessee	Sequatchie	62.78
Tennessee	Sevier	156.94
Tennessee	Shelby	156.94
Tennessee	Smith	62.78
Tennessee	Stewart	62.78
Tennessee	Sullivan	94.17
Tennessee	Sumner	94.17
Tennessee	Tipton	62.78
Tennessee	Trousdale	94.17
Tennessee	Unicoi	313.89
Tennessee	Union	94.17
Tennessee	Van Buren	62.78
Tennessee	Warren	62.78
Tennessee	Washington	156.94
Tennessee	Wayne	47.08
Tennessee	Weakley	47.08
Tennessee	White	94.17
Tennessee	Williamson	156.94
Tennessee	Wilson	94.17
Texas	Anderson	31.39
Texas	Andrews	7.85
Texas	Angelina	62.78
Texas	Aransas	31.39
Texas	Archer	15.69
Texas	Armstrong	15.69
Texas	Atascosa	31.39
Texas	Austin	62.78
Texas	Bailey	15.69
Texas	Bandera	47.08
Texas	Bastrop	47.08
Texas	Baylor	15.69
Texas	Bee	31.39
Texas	Bell	47.08
Texas	Bexar	62.78
Texas	Blanco	62.78
Texas	Borden	15.69
Texas	Bosque	47.08
Texas	Bowie	47.08
Texas	Brazoria	47.08
Texas	Brazos	47.08
Texas	Brewster	7.85
Texas	Briscoe	7.85
Texas	Brooks	15.69
Texas	Brown	31.39
Texas	Burleson	47.08
Texas	Burnet	47.08
Texas	Caldwell	47.08
Texas	Calhoun	31.39
Texas	Callahan	15.69
Texas	Cameron	47.08
Texas	Camp	62.78
Texas	Carson	15.69
Texas	Cass	47.08
Texas	Castro	31.39
Texas	Chambers	31.39
Texas	Cherokee	47.08
Texas	Childress	15.69

APPENDIX A TO PART 11—FEE SCHEDULE FOR FY 2010—Continued

State	County	(Fee/acre/YR)
Texas	Clay	31.39
Texas	Cochran	15.69
Texas	Coke	15.69
Texas	Coleman	15.69
Texas	Collin	94.17
Texas	Collingsworth	15.69
Texas	Colorado	47.08
Texas	Comal	62.78
Texas	Comanche	31.39
Texas	Concho	15.69
Texas	Cooke	47.08
Texas	Coryell	31.39
Texas	Cottle	7.85
Texas	Crane	7.85
Texas	Crockett	7.85
Texas	Crosby	15.69
Texas	Culberson	7.85
Texas	Dallam	15.69
Texas	Dallas	94.17
Texas	Dawson	15.69
Texas	Deaf Smith	15.69
Texas	Delta	31.39
Texas	Denton	94.17
Texas	DeWitt	31.39
Texas	Dickens	7.85
Texas	Dimmit	15.69
Texas	Donley	15.69
Texas	Duval	31.39
Texas	Eastland	31.39
Texas	Ector	7.85
Texas	Edwards	15.69
Texas	El Paso	62.78
Texas	Ellis	47.08
Texas	Erath	47.08
Texas	Falls	31.39
Texas	Fannin	31.39
Texas	Fayette	62.78
Texas	Fisher	15.69
Texas	Floyd	15.69
Texas	Foard	15.69
Texas	Fort Bend	62.78
Texas	Franklin	31.39
Texas	Freestone	31.39
Texas	Frio	31.39
Texas	Gaines	15.69
Texas	Galveston	47.08
Texas	Garza	7.85
Texas	Gillespie	62.78
Texas	Glasscock	15.69
Texas	Goliad	31.39
Texas	Gonzales	31.39
Texas	Gray	15.69
Texas	Grayson	62.78
Texas	Gregg	47.08
Texas	Grimes	47.08
Texas	Guadalupe	62.78
Texas	Hale	15.69
Texas	Hall	7.85
Texas	Hamilton	31.39
Texas	Hansford	15.69
Texas	Hardeman	15.69
Texas	Hardin	47.08
Texas	Harris	94.17
Texas	Harrison	31.39
Texas	Hartley	15.69
Texas	Haskell	15.69
Texas	Hays	94.17
Texas	Hemphill	7.85
Texas	Henderson	47.08
Texas	Hidalgo	62.78
Texas	Hill	31.39
Texas	Hockley	15.69

APPENDIX A TO PART 11—FEE SCHEDULE FOR FY 2010—Continued

State	County	(Fee/acre/YR)
Texas	Hood	62.78
Texas	Hopkins	47.08
Texas	Houston	31.39
Texas	Howard	15.69
Texas	Hudspeth	7.85
Texas	Hunt	47.08
Texas	Hutchinson	7.85
Texas	Irion	7.85
Texas	Jack	31.39
Texas	Jackson	31.39
Texas	Jasper	47.08
Texas	Jeff Davis	7.85
Texas	Jefferson	31.39
Texas	Jim Hogg	15.69
Texas	Jim Wells	15.69
Texas	Johnson	62.78
Texas	Jones	15.69
Texas	Karnes	31.39
Texas	Kaufman	47.08
Texas	Kendall	62.78
Texas	Kenedy	15.69
Texas	Kent	7.85
Texas	Kerr	31.39
Texas	Kimble	31.39
Texas	King	7.85
Texas	Kinney	15.69
Texas	Kleberg	15.69
Texas	Knox	7.85
Texas	La Salle	15.69
Texas	Lamar	31.39
Texas	Lamb	15.69
Texas	Lampasas	31.39
Texas	Lavaca	47.08
Texas	Lee	47.08
Texas	Leon	31.39
Texas	Liberty	47.08
Texas	Limestone	31.39
Texas	Lipscomb	15.69
Texas	Live Oak	31.39
Texas	Llano	47.08
Texas	Loving	7.85
Texas	Lubbock	31.39
Texas	Lynn	15.69
Texas	Madison	31.39
Texas	Marion	31.39
Texas	Martin	15.69
Texas	Mason	31.39
Texas	Matagorda	31.39
Texas	Maverick	7.85
Texas	McCulloch	31.39
Texas	McLennan	31.39
Texas	McMullen	31.39
Texas	Medina	31.39
Texas	Menard	15.69
Texas	Midland	15.69
Texas	Milam	31.39
Texas	Mills	31.39
Texas	Mitchell	15.69
Texas	Montague	47.08
Texas	Montgomery	94.17
Texas	Moore	15.69
Texas	Morris	31.39
Texas	Motley	7.85
Texas	Nacogdoches	47.08
Texas	Navarro	31.39
Texas	Newton	31.39
Texas	Nolan	15.69
Texas	Nueces	31.39
Texas	Ochiltree	15.69
Texas	Oldham	7.85
Texas	Orange	47.08
Texas	Palo Pinto	31.39

APPENDIX A TO PART 11—FEE SCHEDULE FOR FY 2010—Continued

State	County	(Fee/acre/YR)
Texas	Panola	31.39
Texas	Parker	62.78
Texas	Parmer	15.69
Texas	Pecos	7.85
Texas	Polk	47.08
Texas	Potter	15.69
Texas	Presidio	15.69
Texas	Rains	47.08
Texas	Randall	15.69
Texas	Reagan	7.85
Texas	Real	15.69
Texas	Red River	31.39
Texas	Reeves	7.85
Texas	Refugio	15.69
Texas	Roberts	7.85
Texas	Robertson	31.39
Texas	Rockwall	94.17
Texas	Runnels	15.69
Texas	Rusk	47.08
Texas	Sabine	62.78
Texas	San Augustine	47.08
Texas	San Jacinto	62.78
Texas	San Patricio	31.39
Texas	San Saba	31.39
Texas	Schleicher	15.69
Texas	Scurry	15.69
Texas	Shackelford	15.69
Texas	Shelby	47.08
Texas	Sherman	15.69
Texas	Smith	47.08
Texas	Somervell	47.08
Texas	Starr	31.39
Texas	Stephens	15.69
Texas	Sterling	7.85
Texas	Stonewall	7.85
Texas	Sutton	15.69
Texas	Swisher	15.69
Texas	Tarrant	94.17
Texas	Taylor	31.39
Texas	Terrell	7.85
Texas	Terry	15.69
Texas	Throckmorton	15.69
Texas	Titus	47.08
Texas	Tom Green	31.39
Texas	Travis	47.08
Texas	Trinity	31.39
Texas	Tyler	62.78
Texas	Upshur	47.08
Texas	Upton	7.85
Texas	Uvalde	31.39
Texas	Val Verde	7.85
Texas	Van Zandt	47.08
Texas	Victoria	31.39
Texas	Walker	62.78
Texas	Waller	94.17
Texas	Ward	7.85
Texas	Washington	62.78
Texas	Webb	15.69
Texas	Wharton	31.39
Texas	Wheeler	15.69
Texas	Wichita	31.39
Texas	Wilbarger	15.69
Texas	Willacy	31.39
Texas	Williamson	62.78
Texas	Wilson	47.08
Texas	Winkler	7.85
Texas	Wise	62.78
Texas	Wood	47.08
Texas	Yoakum	15.69
Texas	Young	15.69
Texas	Zapata	31.39
Texas	Zavala	31.39

APPENDIX A TO PART 11—FEE SCHEDULE FOR FY 2010—Continued

State	County	(Fee/acre/YR)
Utah	Beaver	62.78
Utah	Box Elder	15.69
Utah	Cache	62.78
Utah	Carbon	15.69
Utah	Daggett	31.39
Utah	Davis	156.94
Utah	Duchesne	15.69
Utah	Emery	31.39
Utah	Garfield	47.08
Utah	Grand	31.39
Utah	Iron	31.39
Utah	Juab	15.69
Utah	Kane	15.69
Utah	Millard	31.39
Utah	Morgan	31.39
Utah	Piute	47.08
Utah	Rich	15.69
Utah	Salt Lake	156.94
Utah	San Juan	7.85
Utah	Sanpete	31.39
Utah	Sevier	47.08
Utah	Summit	31.39
Utah	Tooele	15.69
Utah	Uintah	7.85
Utah	Utah	94.17
Utah	Wasatch	94.17
Utah	Washington	47.08
Utah	Wayne	47.08
Utah	Weber	156.94
Vermont	Addison	47.08
Vermont	Bennington	47.08
Vermont	Caledonia	62.78
Vermont	Chittenden	62.78
Vermont	Essex	47.08
Vermont	Franklin	47.08
Vermont	Grand Isle	94.17
Vermont	Lamoille	62.78
Vermont	Orange	47.08
Vermont	Orleans	47.08
Vermont	Rutland	94.17
Vermont	Washington	62.78
Vermont	Windham	62.78
Vermont	Windsor	94.17
Virginia	Accomack	62.78
Virginia	Albemarle	156.94
Virginia	Alleghany	62.78
Virginia	Amelia	62.78
Virginia	Amherst	62.78
Virginia	Appomattox	47.08
Virginia	Arlington	94.17
Virginia	Augusta	94.17
Virginia	Bath	62.78
Virginia	Bedford	94.17
Virginia	Bland	47.08
Virginia	Botetourt	94.17
Virginia	Brunswick	47.08
Virginia	Buchanan	94.17
Virginia	Buckingham	62.78
Virginia	Campbell	47.08
Virginia	Caroline	62.78
Virginia	Carroll	94.17
Virginia	Charles City	94.17
Virginia	Charlotte	47.08
Virginia	Chesapeake City	94.17
Virginia	Chesterfield	156.94
Virginia	Clarke	156.94
Virginia	Craig	62.78
Virginia	Culpeper	156.94
Virginia	Cumberland	62.78
Virginia	Dickenson	47.08
Virginia	Dinwiddie	47.08
Virginia	Essex	62.78

APPENDIX A TO PART 11—FEE SCHEDULE FOR FY 2010—Continued

State	County	(Fee/acre/YR)
Virginia	Fairfax	313.89
Virginia	Fauquier	156.94
Virginia	Floyd	62.78
Virginia	Fluvanna	62.78
Virginia	Franklin	62.78
Virginia	Frederick	94.17
Virginia	Giles	62.78
Virginia	Gloucester	94.17
Virginia	Goochland	94.17
Virginia	Grayson	94.17
Virginia	Greene	156.94
Virginia	Greensville	47.08
Virginia	Halifax	47.08
Virginia	Hanover	156.94
Virginia	Henrico	156.94
Virginia	Henry	47.08
Virginia	Highland	62.78
Virginia	Isle of Wight	62.78
Virginia	James City	156.94
Virginia	King and Queen	62.78
Virginia	King George	94.17
Virginia	King William	62.78
Virginia	Lancaster	62.78
Virginia	Lee	47.08
Virginia	Loudoun	313.89
Virginia	Louisa	62.78
Virginia	Lunenburg	47.08
Virginia	Madison	94.17
Virginia	Mathews	94.17
Virginia	Mecklenburg	47.08
Virginia	Middlesex	94.17
Virginia	Montgomery	94.17
Virginia	Nelson	62.78
Virginia	New Kent	94.17
Virginia	Northampton	62.78
Virginia	Northumberland	62.78
Virginia	Nottoway	62.78
Virginia	Orange	94.17
Virginia	Page	156.94
Virginia	Patrick	47.08
Virginia	Pittsylvania	47.08
Virginia	Powhatan	94.17
Virginia	Prince Edward	47.08
Virginia	Prince George	62.78
Virginia	Prince William	313.89
Virginia	Pulaski	62.78
Virginia	Rappahannock	94.17
Virginia	Richmond	47.08
Virginia	Roanoke	94.17
Virginia	Rockbridge	94.17
Virginia	Rockingham	156.94
Virginia	Russell	47.08
Virginia	Scott	47.08
Virginia	Shenandoah	94.17
Virginia	Smyth	47.08
Virginia	Southampton	62.78
Virginia	Spotsylvania	156.94
Virginia	Stafford	156.94
Virginia	Suffolk	62.78
Virginia	Surry	62.78
Virginia	Sussex	47.08
Virginia	Tazewell	47.08
Virginia	Virginia Beach City	94.17
Virginia	Warren	156.94
Virginia	Washington	62.78
Virginia	Westmoreland	62.78
Virginia	Wise	62.78
Virginia	Wythe	62.78
Virginia	York	1,569.43
Washington	Adams	31.39
Washington	Asotin	15.69
Washington	Benton	47.08

APPENDIX A TO PART 11—FEE SCHEDULE FOR FY 2010—Continued

State	County	(Fee/acre/YR)
Washington	Chelan	313.89
Washington	Clallam	313.89
Washington	Clark	313.89
Washington	Columbia	31.39
Washington	Cowlitz	156.94
Washington	Douglas	31.39
Washington	Ferry	15.69
Washington	Franklin	47.08
Washington	Garfield	15.69
Washington	Grant	62.78
Washington	Grays Harbor	62.78
Washington	Island	313.89
Washington	Jefferson	156.94
Washington	King	627.77
Washington	Kitsap	627.77
Washington	Kittitas	94.17
Washington	Klickitat	31.39
Washington	Lewis	94.17
Washington	Lincoln	15.69
Washington	Mason	156.94
Washington	Okanogan	31.39
Washington	Pacific	62.78
Washington	Pend Oreille	47.08
Washington	Pierce	313.89
Washington	San Juan	313.89
Washington	Skagit	156.94
Washington	Skamania	156.94
Washington	Snohomish	313.89
Washington	Spokane	62.78
Washington	Stevens	31.39
Washington	Thurston	313.89
Washington	Wahkiakum	94.17
Washington	Walla Walla	47.08
Washington	Whatcom	156.94
Washington	Whitman	31.39
Washington	Yakima	47.08
West Virginia	Barbour	31.39
West Virginia	Berkeley	94.17
West Virginia	Boone	31.39
West Virginia	Braxton	31.39
West Virginia	Brooke	31.39
West Virginia	Cabell	47.08
West Virginia	Calhoun	31.39
West Virginia	Clay	31.39
West Virginia	Doddridge	31.39
West Virginia	Fayette	47.08
West Virginia	Gilmer	31.39
West Virginia	Grant	47.08
West Virginia	Greenbrier	47.08
West Virginia	Hampshire	47.08
West Virginia	Hancock	62.78
West Virginia	Hardy	47.08
West Virginia	Harrison	31.39
West Virginia	Jackson	47.08
West Virginia	Jefferson	94.17
West Virginia	Kanawha	47.08
West Virginia	Lewis	31.39
West Virginia	Lincoln	31.39
West Virginia	Logan	62.78
West Virginia	Marion	47.08
West Virginia	Marshall	31.39
West Virginia	Mason	47.08
West Virginia	McDowell	31.39
West Virginia	Mercer	47.08
West Virginia	Mineral	47.08
West Virginia	Mingo	31.39
West Virginia	Monongalia	47.08
West Virginia	Monroe	47.08
West Virginia	Morgan	62.78
West Virginia	Nicholas	47.08
West Virginia	Ohio	31.39
West Virginia	Pendleton	31.39

APPENDIX A TO PART 11—FEE SCHEDULE FOR FY 2010—Continued

State	County	(Fee/acre/YR)
West Virginia	Pleasants	31.39
West Virginia	Pocahontas	31.39
West Virginia	Preston	47.08
West Virginia	Putnam	47.08
West Virginia	Raleigh	47.08
West Virginia	Randolph	31.39
West Virginia	Ritchie	31.39
West Virginia	Roane	31.39
West Virginia	Summers	31.39
West Virginia	Taylor	47.08
West Virginia	Tucker	31.39
West Virginia	Tyler	31.39
West Virginia	Upshur	31.39
West Virginia	Wayne	31.39
West Virginia	Webster	31.39
West Virginia	Wetzel	31.39
West Virginia	Wirt	31.39
West Virginia	Wood	47.08
West Virginia	Wyoming	31.39
Wisconsin	Adams	62.78
Wisconsin	Ashland	31.39
Wisconsin	Barron	47.08
Wisconsin	Bayfield	31.39
Wisconsin	Brown	94.17
Wisconsin	Buffalo	47.08
Wisconsin	Burnett	47.08
Wisconsin	Calumet	94.17
Wisconsin	Chippewa	47.08
Wisconsin	Clark	47.08
Wisconsin	Columbia	94.17
Wisconsin	Crawford	47.08
Wisconsin	Dane	94.17
Wisconsin	Dodge	62.78
Wisconsin	Door	62.78
Wisconsin	Douglas	31.39
Wisconsin	Dunn	47.08
Wisconsin	Eau Claire	47.08
Wisconsin	Florence	47.08
Wisconsin	Fond du Lac	62.78
Wisconsin	Forest	47.08
Wisconsin	Grant	62.78
Wisconsin	Green	62.78
Wisconsin	Green Lake	62.78
Wisconsin	Iowa	62.78
Wisconsin	Iron	31.39
Wisconsin	Jackson	47.08
Wisconsin	Jefferson	94.17
Wisconsin	Juneau	47.08
Wisconsin	Kenosha	156.94
Wisconsin	Kewaunee	94.17
Wisconsin	La Crosse	62.78
Wisconsin	Lafayette	62.78
Wisconsin	Langlade	47.08
Wisconsin	Lincoln	47.08
Wisconsin	Manitowoc	94.17
Wisconsin	Marathon	47.08
Wisconsin	Marinette	47.08
Wisconsin	Marquette	62.78
Wisconsin	Menominee	31.39
Wisconsin	Milwaukee	313.89
Wisconsin	Monroe	62.78
Wisconsin	Oconto	62.78
Wisconsin	Oneida	62.78
Wisconsin	Outagamie	94.17
Wisconsin	Ozaukee	156.94
Wisconsin	Pepin	47.08
Wisconsin	Pierce	62.78
Wisconsin	Polk	62.78
Wisconsin	Portage	94.17
Wisconsin	Price	47.08
Wisconsin	Racine	156.94
Wisconsin	Richland	62.78

APPENDIX A TO PART 11—FEE SCHEDULE FOR FY 2010—Continued

State	County	(Fee/acre/YR)
Wisconsin	Rock	94.17
Wisconsin	Rusk	62.78
Wisconsin	Sauk	94.17
Wisconsin	Sawyer	62.78
Wisconsin	Shawano	94.17
Wisconsin	Sheboygan	94.17
Wisconsin	St. Croix	94.17
Wisconsin	Taylor	47.08
Wisconsin	Trempealeau	47.08
Wisconsin	Vernon	47.08
Wisconsin	Vilas	94.17
Wisconsin	Walworth	156.94
Wisconsin	Washburn	47.08
Wisconsin	Washington	156.94
Wisconsin	Waukesha	156.94
Wisconsin	Waupaca	62.78
Wisconsin	Waushara	94.17
Wisconsin	Winnebago	94.17
Wisconsin	Wood	47.08
Wyoming	Albany	7.85
Wyoming	Big Horn	31.39
Wyoming	Campbell	7.85
Wyoming	Carbon	7.85
Wyoming	Converse	7.85
Wyoming	Crook	15.69
Wyoming	Fremont	7.85
Wyoming	Goshen	15.69
Wyoming	Hot Springs	7.85
Wyoming	Johnson	7.85
Wyoming	Laramie	7.85
Wyoming	Lincoln	31.39
Wyoming	Natrona	7.85
Wyoming	Niobrara	7.85
Wyoming	Park	31.39
Wyoming	Platte	15.69
Wyoming	Sheridan	15.69
Wyoming	Sublette	31.39
Wyoming	Sweetwater	7.85
Wyoming	Teton	94.17
Wyoming	Uinta	15.69
Wyoming	Washakie	15.69
Wyoming	Weston	7.85

[FR Doc. 2010–18201 Filed 7–27–10; 8:45 am]

BILLING CODE 6717–01–P

SOCIAL SECURITY ADMINISTRATION

20 CFR Part 408

[Docket No. SSA–2009–0062]

RIN 0960–AH16

Technical Amendment Language Change From "Wholly" to "Fully"; Correction

AGENCY: Social Security Administration.

ACTION: Correcting amendment.

SUMMARY: In the **Federal Register** of June 11, 2010, we published a final rules document replacing the word "wholly" with the word "fully" in a number of sections of our regulations when we describe the favorable and unfavorable nature of determinations or decisions we make on claims on benefits. We inadvertently amended § 408.1070 incorrectly. This document corrects the wording in this section.

DATES: Effective on July 28, 2010.

FOR FURTHER INFORMATION CONTACT: Brian J. Rudick, Office of Regulations, Social Security Administration, 6401 Security Boulevard, Baltimore, MD 21235–6401, (410) 965–7102. For information on eligibility or filing for benefits, call our national toll-free number, 1–800–772–1213, or TTY 1–800–325–0778, or visit our Internet site, Social Security Online, at *http://www.socialsecurity.gov.*

SUPPLEMENTARY INFORMATION: We published a final rules document in the **Federal Register** of June 11, 2010, (75 FR 33167) replacing the word "wholly" with the word "fully" in a number of sections of our regulations. In those final rules, we incorrectly stated and amended § 408.1070 (b)(1) when the introductory text was amended by removing the words "wholly or partially favorable" and adding in their place the words "fully or partially favorable". This correction changes the language of paragraph (b)(1) by removing the word "favorable" and adding in its place the word "unfavorable".

List of Subjects in 20 CFR Part 408

Administrative practice and procedure, Aged, Reporting and recordkeeping requirements, Social security, Supplemental Security Income (SSI), Veterans.

■ Accordingly, 20 CFR part 408 is amended by making the following correcting amendment:

PART 408—SPECIAL BENEFITS FOR CERTAIN WORLD WAR II VETERANS

Subpart J—[Amended]

■ 1. The authority citation for subpart J of part 408 continues to read as follows:

Authority: Secs. 702(a)(5) and 809 of the Social Security Act (42 U.S.C. 902(a)(5) and 1009).

§ 408.1070 [Corrected]

■ 2. In § 408.1070, amend paragraph (b)(1) introductory text by removing the words "wholly or partially unfavorable" and adding in its place the words "fully or partially unfavorable".

Martin Sussman,

Senior Advisor for Regulations.

[FR Doc. 2010–18426 Filed 7–27–10; 8:45 am]

BILLING CODE 4191–02–P

DEPARTMENT OF THE TREASURY

Internal Revenue Service

26 CFR Part 1

[TD 9487]

RIN 1545–BG03

Build-In Gains and Losses Under Section 382(h); Correction

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Correcting amendment.

SUMMARY: This document contains correcting amends to IRS' regulations providing guidance regarding the treatment of prepaid income under the built-in gain provisions of section 382(h). These errors were made when the agency published final regulations (TD 9487) in the **Federal Register** on Wednesday, June 16, 2010 (75 FR 33990).

DATES: This correction is effective on July 28, 2010, and is applicable on June 16, 2010.

FOR FURTHER INFORMATION CONTACT: Keith E. Stanley, (202) 622–7750 (not a toll-free number).

SUPPLEMENTARY INFORMATION:

Background

The final regulations (TD 9487) that are the subject of this document are under section 382 of the Internal Revenue Code.

Need for Correction

As published, the final regulations (TD 9487) contain errors that may prove to be misleading and are 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 amendments:

PART 1—INCOME TAXES

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

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

■ **Par. 2.** Section 1.382–2T is amended by revising the headings of paragraph (h)(4)(vii)(A) and paragraph (h)(4)(x)(J) to read as follows:

§ 1.382–2T Definition of ownership change under section 382, as amended by the tax Reform Act of 1986 (temporary).

* * * * *

(h) * * *

(4) * * *

(vii) * * *

(A) Right or obligation to issue stock.

* * *

* * * * *

(x) * * *

(J) Title 11 or similar case. * * *

* * * * *

LaNita Van Dyke,

Chief, Publications and Regulations Branch, Legal Processing Division, Associate Chief Counsel, (Procedure and Administration).

[FR Doc. 2010–18270 Filed 7–27–10; 8:45 am]

BILLING CODE 4830–01–P

POSTAL REGULATORY COMMISSION

30 CFR Part 3020

[Docket Nos. MC2010–21; CP2010–36 and MC2010–20]

New Postal Products

AGENCY: Postal Regulatory Commission.

ACTION: Final rule.

SUMMARY: The Commission is updating postal product lists. This action reflects the disposition of recent dockets, as set out in two Commission orders, and adoption of a publication policy. The publication policy assumes periodic updates. The updates are identified in the body of this document. The product lists, which are re-published in their entirety, include these updates.

DATES: *Effective Date:* July 28, 2010.

Applicability Date: April 22, 2010 (GREPS 1) and June 17, 2010 (Post Office Box Service).

FOR FURTHER INFORMATION CONTACT: Stephen L. Sharfman, General Counsel, at *stephen.sharfman@prc.gov* or 202–789–6820.

SUPPLEMENTARY INFORMATION: This document identifies recent updates to the product lists, which appear as 39 CFR Appendix A to Subpart A of Part 3020–Mail Classification Schedule. Publication of updated product lists in the **Federal Register** is required by the Postal Accountability and Enhancement Act (PAEA) of 2006.

Authorization. The Commission process for periodic publication of updates was established in Order No. 445, April 22, 2010.

Changes. Since publication of the product lists in the **Federal Register** on March 16, 2010 (75 FR 12445), the following additions to the competitive product list have been made:

- Reseller Expedited Package Services 1 (MC2010–21 and CP2010–36), added April 22, 2010 (Order No. 445); and
- Post Office Box Service (MC2010–20), added June 17, 2010 (Order No. 473).

Updated product lists. The referenced changes to the product lists are included in the product lists following the Secretary's signature.

List of Subjects in 39 CFR Part 3020

Administrative practice and procedure; Postal Service.

By the Commission.

Shoshana M. Grove,

Secretary.

■ For the reasons discussed in the preamble, the Postal Regulatory Commissin amends chapter III of title 39 of the Code of Federal Regulations as follows:

■ 1. The authority citation for part 3020 continues to read as follows:

Authority: 39 U.S.C. 503; 3622; 3631; 3642; 3682.

■ 2. Revise Appendix A to Subpart A of Part 3020–Mail Classification Schedule to read as follows:

Appendix A to Subpart A of Part 3020—Mail Classification Schedule

Part A—Market Dominant Products

1000 Market Dominant Product List

First-Class Mail

- Single-Piece Letters/Postcards
- Bulk Letters/Postcards
- Flats
- Parcels
- Outbound Single-Piece First-Class Mail International
- Inbound Single-Piece First-Class Mail International

Standard Mail (Regular and Nonprofit)

- High Density and Saturation Letters
- High Density and Saturation Flats/Parcels
- Carrier Route

- Letters
- Flats
- Not Flat-Machinables (NFMs)/Parcels
- Periodicals
  - Within County Periodicals
  - Outside County Periodicals
- Package Services
  - Single-Piece Parcel Post
  - Inbound Surface Parcel Post (at UPU rates)
  - Bound Printed Matter Flats
  - Bound Printed Matter Parcels
  - Media Mail/Library Mail
- Special Services
  - Ancillary Services
  - International Ancillary Services
  - Address Management Services
  - Caller Service
  - Change-of-Address Credit Card Authentication
  - Confirm
  - Customized Postage
  - International Reply Coupon Service
  - International Business Reply Mail Service
  - Money Orders
  - Post Office Box Service
- Negotiated Service Agreements
  - HSBC North America Holdings Inc. Negotiated Service Agreement
  - Bookspan Negotiated Service Agreement
  - Bank of America Corporation Negotiated Service Agreement
  - The Bradford Group Negotiated Service Agreement
  - Inbound International
    - Canada Post—United States Postal Service Contractual Bilateral Agreement for Inbound Market Dominant Services (MC2010-12 and R2010-2)
- Market Dominant Product Descriptions
- First-Class Mail
  - Single-Piece Letters/Postcards
  - Bulk Letters/Postcards
  - Flats
  - Parcels
  - Outbound Single-Piece First-Class Mail International
  - Inbound Single-Piece First-Class Mail International
- Standard Mail (Regular and Nonprofit)
  - High Density and Saturation Letters
  - High Density and Saturation Flats/Parcels
  - Carrier Route
  - Letters
  - Flats
  - Not Flat-Machinables (NFMs)/Parcels
- Periodicals
  - Within County Periodicals
  - Outside County Periodicals
- Package Services
  - Single-Piece Parcel Post
  - Inbound Surface Parcel Post (at UPU rates)
  - Bound Printed Matter Flats
  - Bound Printed Matter Parcels
  - Media Mail/Library Mail
- Special Services
  - Ancillary Services
  - Address Correction Service
  - Applications and Mailing Permits
  - Business Reply Mail
  - Bulk Parcel Return Service
  - Certified Mail
  - Certificate of Mailing
  - Collect on Delivery
  - Delivery Confirmation
  - Insurance
  - Merchandise Return Service
  - Parcel Airlift (PAL)
  - Registered Mail
  - Return Receipt
  - Return Receipt for Merchandise
  - Restricted Delivery
  - Shipper-Paid Forward
  - Signature Confirmation
  - Special Handling
  - Stamped Envelopes
  - Stamped Cards
  - Premium Stamped Stationery
  - Premium Stamped Cards
  - International Ancillary Services
  - International Certificate of Mailing
  - International Registered Mail
  - International Return Receipt
  - International Restricted Delivery
  - Address List Services
  - Caller Service
  - Change-of-Address Credit Card Authentication
  - Confirm
  - International Reply Coupon Service
  - International Business Reply Mail Service
  - Money Orders
  - Post Office Box Service
- Negotiated Service Agreements
  - HSBC North America Holdings Inc. Negotiated Service Agreement
  - Bookspan Negotiated Service Agreement
  - Bank of America Corporation Negotiated Service Agreement
  - The Bradford Group Negotiated Service Agreement
- Part B—Competitive Products
- 2000 Competitive Product List
- Express Mail
  - Express Mail
  - Outbound International Expedited Services
  - Inbound International Expedited Services
    - Inbound International Expedited Services 1 (CP2008–7)
    - Inbound International Expedited Services 2 (MC2009–10 and CP2009–12)
    - Inbound International Expedited Services 3 (MC2010–13 and CP2010–12)
- Priority Mail
  - Priority Mail
  - Outbound Priority Mail International
  - Inbound Air Parcel Post (at non-UPU rates)
    - Royal Mail Group Inbound Air Parcel Post Agreement
  - Inbound Air Parcel Post (at UPU rates)
- Parcel Select
- Parcel Return Service
- International
  - International Priority Airlift (IPA)
  - International Surface Airlift (ISAL)
  - International Direct Sacks—M—Bags
  - Global Customized Shipping Services
  - Inbound Surface Parcel Post (at non-UPU rates)
    - Canada Post—United States Postal Service Contractual Bilateral Agreement for Inbound Competitive Services (MC2010–14 and CP2010–13—Inbound Surface Parcel post at Non-UPU Rates and Xpresspost-USA)
  - International Money Transfer Service—Outbound
  - International Money Transfer Service—Inbound
  - International Ancillary Services
- Special Services
  - Address Enhancement Service
  - Greeting Cards and Stationery
  - Premium Forwarding Service
  - Shipping and Mailing Services
- Negotiated Service Agreements
  - Domestic
    - Express Mail Contract 1 (MC2008–5)
    - Express Mail Contract 2 (MC2009–3 and CP2009–4)
    - Express Mail Contract 3 (MC2009–15 and CP2009–21)
    - Express Mail Contract 4 (MC2009–34 and CP2009–45)
    - Express Mail Contract 5 (MC2010–5 and CP2010–5)
    - Express Mail Contract 6 (MC2010–6 and CP2010–6)
    - Express Mail Contract 7 (MC2010–7 and CP2010–7)
    - Express Mail Contract 8 (MC2010–16 and CP2010–16)
    - Express Mail & Priority Mail Contract 1 (MC2009–6 and CP2009–7)
    - Express Mail & Priority Mail Contract 2 (MC2009–12 and CP2009–14)
    - Express Mail & Priority Mail Contract 3 (MC2009–13 and CP2009–17)
    - Express Mail & Priority Mail Contract 4 (MC2009–17 and CP2009–24)
    - Express Mail & Priority Mail Contract 5 (MC2009–18 and CP2009–25)
    - Express Mail & Priority Mail Contract 6 (MC2009–31 and CP2009–42)
    - Express Mail & Priority Mail Contract 7 (MC2009–32 and CP2009–43)
    - Express Mail & Priority Mail Contract 8 (MC2009–33 and CP2009–44)
    - Parcel Select & Parcel Return Service Contract 1 (MC2009–11 and CP2009–13)
    - Parcel Select & Parcel Return Service Contract 2 (MC2009–40 and CP2009–61)
    - Parcel Return Service Contract 1 (MC2009–1 and CP2009–2)
    - Priority Mail Contract 1 (MC2008–8 and CP2008–26)
    - Priority Mail Contract 2 (MC2009–2 and CP2009–3)
    - Priority Mail Contract 3 (MC2009–4 and CP2009–5)
    - Priority Mail Contract 4 (MC2009–5 and CP2009–6)

Priority Mail Contract 5 (MC2009–21 and CP2009–26)
Priority Mail Contract 6 (MC2009–25 and CP2009–30)
Priority Mail Contract 7 (MC2009–25 and CP2009–31)
Priority Mail Contract 8 (MC2009–25 and CP2009–32)
Priority Mail Contract 9 (MC2009–25 and CP2009–33)
Priority Mail Contract 10 (MC2009–25 and CP2009–34)
Priority Mail Contract 11 (MC2009–27 and CP2009–37)
Priority Mail Contract 12 (MC2009–28 and CP2009–38)
Priority Mail Contract 13 (MC2009–29 and CP2009–39)
Priority Mail Contract 14 (MC2009–30 and CP2009–40)
Priority Mail Contract 15 (MC2009–35 and CP2009–54)
Priority Mail Contract 16 (MC2009–36 and CP2009–55)
Priority Mail Contract 17 (MC2009–37 and CP2009–56)
Priority Mail Contract 18 (MC2009–42 and CP2009–63)
Priority Mail Contract 19 (MC2010–1 and CP2010–1)
Priority Mail Contract 20 (MC2010–2 and CP2010–2)
Priority Mail Contract 21 (MC2010–3 and CP2010–3)
Priority Mail Contract 22 (MC2010–4 and CP2010–4)
Priority Mail Contract 23 (MC2010–9 and CP2010–9)
Priority Mail Contract 24 (MC2010–15 and CP2010–15)
Outbound International
Direct Entry Parcels Contracts
Direct Entry Parcels 1 (MC2009–26 and CP2009–36)
Global Direct Contracts (MC2009–9, CP2009–10, and CP2009–11)
Global Direct Contracts 1 (MC2010–17 and CP2010–18)
Global Expedited Package Services (GEPS) Contracts
GEPS 1 (CP2008–5, CP2008–11, CP2008–12, CP2008–13, CP2008–18, CP2008–19, CP2008–20, CP2008–21, CP2008–22, CP2008–23, and CP2008–24)
Global Expedited Package Services 2 (CP2009–50)
Global Plus Contracts
Global Plus 1 (CP2008–8, CP2008–46 and CP2009–47)
Global Plus 2 (MC2008–7, CP2008–48 and CP2008–49)
Global Reseller Expedited Package Services 1 (MC2010-21 and CP2010-36)
Inbound International
Inbound Direct Entry Contracts with Foreign Postal Administrations
Inbound Direct Entry Contracts with Foreign Postal Administrations (MC2008–6, CP2008–14 and MC2008–15)
Inbound Direct Entry Contracts with Foreign Postal Administrations 1 (MC2008–6 and CP2009–62)
International Business Reply Service Competitive Contract 1 (MC2009–14 and CP2009–20)
International Business Reply Service Competitive Contract 2 (MC2010–18, CP2010–21 and CP2010–22)
Competitive Product Descriptions
Express Mail
Express Mail
Outbound International Expedited Services
Inbound International Expedited Services
Priority
Priority Mail
Outbound Priority Mail International
Inbound Air Parcel Post
Parcel Select
Parcel Return Service
International
International Priority Airlift (IPA)
International Surface Airlift (ISAL)
International Direct Sacks—M–Bags
Global Customized Shipping Services
International Money Transfer Service
Inbound Surface Parcel Post (at non-UPU rates)
International Ancillary Services
International Certificate of Mailing
International Registered Mail
International Return Receipt
International Restricted Delivery
International Insurance
Negotiated Service Agreements
Domestic
Outbound International
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Part D—Country Price Lists for International Mail [Reserved]

[FR Doc. 2010–18407 Filed 7–27–10; 8:45 am]
BILLING CODE 7710–FW–S

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 165

[Docket No. USCG–2010–0648]

RIN 1625–AA00

Safety Zone; Chicago Harbor, Navy Pier Southeast, Chicago, IL

AGENCY: Coast Guard, DHS.

ACTION: Notice of enforcement of regulation.

SUMMARY: The Coast Guard will enforce the Navy Pier Southeast Safety Zone in Chicago Harbor during August 4, 2010 through August 29, 2010. This action is necessary and intended to ensure safety of life on the navigable waters immediately prior to, during, and immediately after fireworks events. This rule will establish restrictions upon, and control movement of, vessels in a specified area immediately prior to, during, and immediately after fireworks events. During the enforcement period, no person or vessel may enter the safety zones without permission of the Captain of the Port, Sector Lake Michigan.

DATES: The regulations in 33 CFR 165.931 will be enforced as detailed below from 9:15 p.m. on August 4, 2010, to 9:45 p.m. on August 29, 2010.

FOR FURTHER INFORMATION CONTACT: If you have questions on this notice, call or e-mail BM1 Adam Kraft, Prevention Department, Coast Guard Sector Lake Michigan, Milwaukee, WI at 414–747–7154, e-mail *Adam.D.Kraft@uscg.mil.*

SUPPLEMENTARY INFORMATION:

The Coast Guard will enforce the safety zone; Chicago Harbor, Navy Pier Southeast, Chicago, IL, 33 CFR 165.931 for the following events:

(1) *Navy Pier Fireworks;* on August 4, 2010 from 9:15 p.m. through 9:45 p.m.; on August 07, 2010 from 10 p.m. through 10:30 p.m.; on August 11, 2010 from 9:15 p.m. through 9:45 p.m.; on August 14, 2010 from 10 p.m. through 10:30 p.m.; on August 18, 2010 from 9:15 p.m. through 9:45 p.m.; on August 21, 2010 from 10 p.m. through 10:30 p.m.; on August 24, 2010 from 9:15 p.m. through 9:45 p.m.; on August 25, 2010 from 9:15 p.m. through 9:45 p.m.; on August 26, 2010 from 9:15 p.m. through 9:45 p.m.; on August 27, 2010 from 10 p.m. through 10:30 p.m.; on August 28, 2010 from 10 p.m. through 10:30 p.m.; on August 29, 2010 from 9:15 p.m. through 9:45 p.m.

All vessels must obtain permission from the Captain of the Port, Sector Lake Michigan, or his or her on-scene representative to enter, move within or exit the safety zone. Vessels and persons granted permission to enter the safety zone shall obey all lawful orders or directions of the Captain of the Port, Sector Lake Michigan, or his or her on-scene representative. While within a safety zone, all vessels shall operate at the minimum speed necessary to maintain a safe course.

This notice is issued under authority of 33 CFR 165.931 Safety Zone, Chicago Harbor, Navy Pier Southeast, Chicago IL and 5 U.S.C. 552(a). In addition to this notice in the **Federal Register**, the Coast Guard will provide the maritime community with advance notification of these enforcement periods via Broadcast Notice to Mariners or Local Notice to Mariners. The Captain of the Port,

Sector Lake Michigan, will issue a Broadcast Notice to Mariners notifying the public when enforcement of the safety zone established by this section is suspended. If the Captain of the Port, Sector Lake Michigan, determines that the safety zone need not be enforced for the full duration stated in this notice, he or she may use a Broadcast Notice to Mariners to grant general permission to enter the safety zone. The Captain of the Port, Sector Lake Michigan, or his or her on-scene representative may be contacted via VHF Channel 16.

Dated: July 6, 2010.

L. Barndt,

Captain, U.S. Coast Guard, Captain of the Port, Sector Lake Michigan.

[FR Doc. 2010–18519 Filed 7–27–10; 8:45 am]

BILLING CODE 9110–04–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 165

[USCG–2010–0647]

RIN 1625–AA00

Safety Zone; Milwaukee Harbor, Milwaukee, WI

AGENCY: Coast Guard, DHS.

ACTION: Notice of enforcement of regulation.

SUMMARY: The Coast Guard will enforce the safety zones for annual fireworks events in the Captain of the Port Sector Lake Michigan zone from 9:15 p.m. on August 7, 2010, through 10:00 p.m. on August 22, 2010. This action is necessary and intended to ensure safety of life on the navigable waters immediately prior to, during, and immediately after fireworks events. This safety zone imposes restrictions upon, and control movement of, vessels in a specified area immediately prior to, during, and immediately after firework events. During the enforcement period, no person or vessel may enter the safety zones without permission of the Captain of the Port, Sector Lake Michigan.

DATES: The regulations in 33 CFR 165.935 will be enforced as detailed below from 9:15 p.m. on August 7, 2010, through 10 p.m. on August 22, 2010.

FOR FURTHER INFORMATION CONTACT: If you have questions on this notice, call or e-mail BM1 Adam Kraft, Prevention Department, Coast Guard Sector Lake Michigan, Milwaukee, WI at 414–747–7154, e-mail *Adam.D.Kraft@uscg.mil.*

SUPPLEMENTARY INFORMATION: The Coast Guard will enforce the safety zone listed in 33 CFR 165.935, Safety Zone, Milwaukee Harbor, Milwaukee, WI, for the following events:

(1) *Arab World Festival fireworks display* on August 7, 2010 from 9:15 p.m. through 10 p.m.

(2) *Irish Festival fireworks display* on August 22, 2010 from 9:15 p.m. through 10 p.m.

All vessels must obtain permission from the Captain of the Port or his or her on-scene representative to enter, move within or exit the safety zone. Vessels and persons granted permission to enter the safety zone shall obey all lawful orders or directions of the Captain of the Port or a designated representative. While within a safety zone, all vessels shall operate at the minimum speed necessary to maintain a safe course.

This notice is issued under authority of 33 CFR 165.935 Safety Zone, Milwaukee Harbor, Milwaukee, WI and 5 U.S.C. 552(a). In addition to this notice in the **Federal Register**, the Coast Guard will provide the maritime community with advance notification of these enforcement periods via Broadcast Notice to Mariners or Local Notice to Mariners. The Captain of the Port, Sector Lake Michigan will issue a Broadcast Notice to Mariners notifying the public when enforcement of the safety zone established by this section is suspended. If the Captain of the Port, Sector Lake Michigan, determines that the safety zone need not be enforced for the full duration stated in this notice, he or she may use a Broadcast Notice to Mariners to grant general permission to enter the safety zone. The Captain of the Port, Sector Lake Michigan, or his or her on-scene representative may be contacted via VHF Channel 16.

Dated: July 6, 2010.

L. Barndt,

Captain, U.S. Coast Guard, Captain of the Port, Sector Lake Michigan.

[FR Doc. 2010–18521 Filed 7–27–10; 8:45 am]

BILLING CODE 9110–04–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[EPA–R09–OAR–2010–0277; FRL–9180–1]

Revisions to the Arizona State Implementation Plan, Maricopa County Air Quality Department

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: EPA is finalizing approval of revisions to the Maricopa County Air Quality Department (MCAQD) portion of the Arizona State Implementation Plan (SIP). These revisions were proposed in the **Federal Register** on April 16, 2010 and concern opacity standards related to multiple pollutants, including particulate matter (PM) emissions from several different types of sources, ranging from fugitive dust to diesel generators. We are approving a local rule that regulates these emission sources under the Clean Air Act as amended in 1990 (CAA or the Act).

DATES: *Effective Date:* This rule is effective on August 27, 2010.

ADDRESSES: EPA has established docket number EPA–R09–OAR–2010–0277 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: Joanne Wells, EPA Region IX, (415) 947–4118, *wells.joanne@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 April 16, 2010 (75 FR 19921), EPA proposed to approve the following rule into the Arizona SIP.

Local agency	Rule No.	Rule title	Amended	Submitted
MCAQD	300	Visible Emissions	03/12/08	07/10/08

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

II. Public Comments and EPA Responses

EPA's proposed action provided a 30-day public comment period. During this period, we received no comments.

III. EPA Action

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

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

Under section 307(b)(1) of the Clean Air Act, petitions for judicial review of this action must be filed in the United States Court of Appeals for the appropriate circuit by September 27, 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, Particulate matter, Reporting and recordkeeping requirements.

Dated: July 7, 2010.

Keith Takata,

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 D—Arizona

■ 2. Section 52.120 is amended by adding paragraph (c)(141)(i)(B)(*3*) to read as follows:

§ 52.120 Identification of plan.

* * * * *

(c) * * *

(141) * * *

(i) * * *

(B) * * *

(*3*) Rule 300, "Visible Emissions," amended March 12, 2008.

* * * * *

[FR Doc. 2010–18561 Filed 7–27–10; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 81

[EPA–R10–OAR–2008–0391; FRL–9180–2]

Determination of Attainment for PM–10; Fort Hall PM–10 Nonattainment Area, Idaho

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: EPA is finalizing its determination that the Fort Hall PM–10 nonattainment area on the Fort Hall Indian Reservation in Idaho has attained the National Ambient Air Quality Standard for particulate matter with an aerodynamic diameter of less than or equal to 10 microns (PM–10) under the

Clean Air Act. EPA's final determination that the Fort Hall PM–10 nonattainment area has attained the 24-hour PM–10 National Ambient Air Quality Standard is based on EPA's review of complete, quality-assured air quality data for the three-year period ending December 31, 2009. Currently available preliminary data for 2010 indicate that the area continues to attain the standard.

EPA's determination of attainment is not equivalent to a redesignation to attainment under Clean Air Act section 107(d)(3). The Fort Hall PM–10 nonattainment area's designation for PM–10 will remain moderate nonattainment until such time as the area is redesignated to attainment as provided in Clean Air Act section 107(d)(3).

DATES: This action is effective on August 27, 2010.

ADDRESSES: Copies of the information supporting this action are available for inspection at EPA Region 10, Office of Air, Waste, and Toxics (AWT–107), 1200 Sixth Avenue, Suite 900, Seattle, Washington 98101.

FOR FURTHER INFORMATION CONTACT: Donna Deneen, EPA Region 10, Office of Air, Waste, and Toxics (AWT–107), 1200 Sixth Avenue, Seattle, Washington 98101, or at (206) 553–6706.

SUPPLEMENTARY INFORMATION: Throughout this document wherever "we", "us" or "our" are used, we mean EPA. Information is organized as follows:

Table of Contents

I. What is the background for this action?
II. What comments did we receive on the proposed action?
III. What is our final action?
IV. Statutory and Executive Order Reviews

I. What is the background for this action?

On May 13, 2010, EPA proposed to determine that the Fort Hall PM–10 nonattainment area on the Fort Hall Indian Reservation in Idaho has attained the 24-hour PM–10 National Ambient Air Quality Standard (NAAQS) under the Clean Air Act. 75 FR 26898. We proposed this determination of attainment based upon three years of complete, quality-assured ambient air monitoring data that showed the area monitored attainment of the PM–10 NAAQS for the 2007–2009 monitoring period. Preliminary data available for 2010 indicate that the area continues to attain the standard and show no exceedances of the standard in 2010. Additional background and our rationale for this determination can be found in the proposed rule.

II. What comments did we receive on the proposed action?

We received one comment letter on the proposed action, which supported our proposed action.

III. What is our final action?

We are finalizing our determination that the Fort Hall PM–10 nonattainment area on the Fort Hall Indian Reservation in Idaho has attained the 24-hour PM–10 standard, based on complete, quality-assured air monitoring data for 2007–2009, and currently available preliminary data for 2010. This determination of attainment is not a redesignation to attainment under CAA section 107(d)(3). The designation status in 40 CFR part 81 for the Fort Hall PM–10 nonattainment area will remain moderate nonattainment until such time as the area is redesignated to attainment as provided in CAA section 107(d)(3). If in the future EPA determines, after notice- and- comment rulemaking, that the area is no longer attaining the PM–10 NAAQS, EPA will publish such determination in the **Federal Register**.

IV. Statutory and Executive Order Reviews

This action merely makes a determination of attainment based upon air quality and does not impose additional requirements. 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, this rule does not have tribal implications as specified by Executive Order 13175 (65 FR 67249, November 9, 2000), because the rule merely makes a required determination based on air quality data and neither imposes substantial direct compliance costs on tribal governments, nor preempts tribal law. Therefore, the requirements of section 5(b) and 5(c) of the Executive Order do not apply to this rule. Consistent with EPA policy, EPA nonetheless provided a consultation opportunity to the Shoshone-Bannock Tribes in a letter to the Chairman of the Fort Hall Business Council, dated January 25, 2010, offering the Tribes the opportunity to consult on this determination and have meaningful and timely input into the proposed decision. EPA received no request from the Tribes for consultation on this determination.

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 rules 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 September 27, 2010. Filing a petition for reconsideration by the Administrator of this final action 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 81

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

Dated: July 15, 2010.

Michael A. Bussell,

Acting Regional Administrator, Region 10.

[FR Doc. 2010–18564 Filed 7–27–10; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 271

[EPA–R10–RCRA 2010–0251; FRL–9181–8]

Washington: Final Authorization of State Hazardous Waste Management Program Revisions

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: Washington has applied to EPA for final authorization of certain changes to its hazardous waste management program under the Resource Conservation and Recovery Act, as amended, (RCRA). On June 18, 2010, EPA published a proposed rule to authorize the changes and opened a public comment period under Docket ID No. EPA–R10–RCRA–2010–0251. The comment period closed on July 19, 2010. EPA has decided that the revisions to the Washington hazardous waste management program satisfy all of the requirements necessary to qualify for final authorization and EPA is authorizing these revisions to Washington's authorized hazardous waste management program in this Final rule.

DATES: *Effective Date:* Final authorization for the revisions to the hazardous waste management program in Washington shall be effective at 1 p.m. EST on July 28, 2010.

ADDRESSES: EPA established a docket for this action under Docket ID No. EPA–R10–RCRA–2010–0251. All documents in the docket are available electronically on the Web site *http://www.regulations.gov.* A hard copy of the authorization revision application is also available for viewing, during normal business hours at the U.S. Environmental Protection Agency, Region 10, Office of Air, Waste and Toxics, 1200 Sixth Avenue (AWT–122), Suite 900, Seattle, Washington 98101, contact: Nina Kocourek, phone number (206) 553–6502; or from the Washington State Department of Ecology, 300 Desmond Drive, Lacey, Washington 98503, *contact:* Robert Rieck, phone number (360) 407–6751.

FOR FURTHER INFORMATION CONTACT: Nina Kocourek, U.S. Environmental Protection Agency, Region 10, Office of Air, Waste & Toxics (AWT–122), 1200 Sixth Avenue, Suite 900, Seattle, Washington 98101, *phone number:* (206) 553–6502, *e-mail: kocourek.nina@epa.gov.*

SUPPLEMENTARY INFORMATION:

A. Why are revisions to State programs necessary?

States which have received final authorization from EPA under RCRA section 3006(b), 42 U.S.C. 6926(b), must maintain a hazardous waste management program that is equivalent to, consistent with, and no less stringent than the Federal program. As the Federal program changes, States must change their programs and ask EPA to authorize the changes. Changes to State programs may be necessary when Federal or State statutory or regulatory authority is modified or when certain other changes occur. Most commonly, States must change their programs because of changes to EPA's regulations in Title 40 of the Code of Federal Regulations (CFR) parts 124, 260 through 266, 268, 270, 273, and 279.

B. What decisions have we made in this rule?

EPA has made a final determination that Washington's application to revise its authorized program meets all of the statutory and regulatory requirements established by RCRA. Therefore, we are granting Washington final authorization to operate its hazardous waste management program for the changes described in its revised program application. Washington will have responsibility for permitting treatment, storage, and disposal facilities (TSDFs) within its borders, except in Indian country (18 U.S.C. 1151), and for carrying out the aspects of the RCRA program described in its revised program application, subject to the limitations of the Hazardous and Solid Waste Amendments of 1984 (HSWA). New Federal requirements and prohibitions imposed by Federal regulations that EPA promulgates under the authority of HSWA, which are more stringent than existing requirements, take effect in authorized States before the State is authorized for these requirements. Thus, EPA will implement those requirements and prohibitions in Washington, including issuing permits, until the State is granted authorization to do so.

C. What is the effect of this authorization decision?

The effect of this action is that a facility in Washington subject to RCRA will have to comply with the authorized State requirements instead of the corresponding Federal requirements in order to comply with RCRA. Additionally, such persons will have to comply with any applicable Federal requirements, such as, HSWA regulations issued by EPA for which the State has not received authorization, and RCRA requirements that are not supplanted by authorized State-issued requirements. Washington has enforcement responsibilities under its State hazardous waste management program for violations of its currently authorized program and will have enforcement responsibilities for the revisions which are the subject of this final rule. EPA continues to have independent enforcement authority under RCRA sections 3007, 3008, 3013, and 7003, which include,, among others, authority to:

- Conduct inspections; require monitoring, tests, analyses, or reports;
- Enforce RCRA requirements; suspend, terminate, modify or revoke permits; and
- Take enforcement actions regardless of whether the State has taken its own actions.

This action to approve these revisions would not impose additional requirements on the regulated community because the regulations for which Washington will be authorized are already effective under State law and are not changed by the act of authorization.

D. What were the comments on EPA's proposed rule?

On June 18, 2010 (75 FR 34674), EPA published a proposed rule to grant authorization of changes to Washington's hazardous waste management program subject to public comment. The public comment period opened on June 18, 2010 and ended on July 19, 2010. The Agency did not receive any comments on the proposed rule.

E. What has Washington previously been authorized for?

Washington initially received final authorization on January 30, 1986, effective January 31, 1986 (51 FR 3782), to implement the State's dangerous

waste management program. EPA granted authorization for changes to Washington's program on September 22, 1987, effective on November 23, 1987 (52 FR 35556); August 17, 1990, effective October 16, 1990 (55 FR 33695); November 4, 1994, effective November 4, 1994 (59 FR 55322); February 29, 1996, effective April 29, 1996 (61 FR 7736); September 22, 1998, effective October 22, 1998 (63 FR 50531); October 12, 1999, effective January 11, 2000 (64 FR 55142); April 11, 2002, effective April 11, 2002 (67 FR 17636); April 14, 2006, effective June 13, 2006 (71 FR 19442) and on October 30, 2006 effective December 29, 2006 (71 FR 63253).

F. What changes are we authorizing with this action?

On May 18, 2010, Washington submitted a hazardous waste management program revision application seeking authorization of its changes in accordance with 40 CFR 271.21. On May 28, 2010 we determined that Washington's program revision application was complete. EPA has determined that Washington's hazardous waste management program revisions, as described in the State's authorization revision application dated May 18, 2010 satisfy the requirements necessary to qualify for final authorization. The following program changes as identified in Table 1 and Table 2 below will be authorized with this action. The State is authorized for those federal rules as published in 40 CFR parts 260 through 265, 268, 270, and 279 that the State incorporated by reference as of July 1, 2007, unless otherwise noted; and all of the referenced analogous State authorities were legally adopted and effective State rules as of July 31, 2009.

TABLE 1—EQUIVALENT AND MORE STRINGENT ANALOGUES TO THE FEDERAL PROGRAM

Regulatory checklist [1]	Federal requirements	Federal Register	Analogous state authority—Washington's Administrative Code (WAC) (WAC 173–303–* * *)
17S	HSWA Codification Rule-Exposure Information.	50 FR 28702, 7/15/85	800(8); 800(12).
117B [2]	Toxicity Characteristic Amendment.	57 FR 23062, 6/1/92	070(3) except 070(3)(a)(iii) and 070(3)(c).
203 [2]	Recycled Used Oil Management Standards; Clarification.	68 FR 44659, 7/30/03	070(8)(c); 515(3) Incorporated by Reference (IBR) 045(1); 515(11) IBR 045(1).
205	NESHAP: Surface Coating of Automobiles and Light-Duty Trucks.	69 FR 22601, 4/26/04	691(1)(g); 400(3)(a).
207 [2] and 207.1 [2]	Uniform Hazardous Waste Manifest Rule and Amendment.	70 FR 10766, 3/4/05 as amended on 6/16/05 at 70 FR 35034.	040 "designated facility" definition; 040 "manifest" definition; 040 "manifest tracking number" definition; 160(2)(a), 160(2)(a)(ii), 160(2)(a)(iii); 180, 180(1), 180(7), 180(7)(a) IBR 045(1), 180(7)(b), 180(7)(b)(i), 180(7)(b)(ii), 180(7)(b)(iii), 180(7)(b)(iv), 180(7)(c), 180(8), 180(8)(a), 180(8)(b); 190(3), 190(3)(b), 190(4); 200, 200(6), 200(6)(a), 200(6)(b); 230 IBR 045(1), 230(2), 230(2)(c), 230(2)(d), 230(2)(e); 180(1) IBR 045(1); 250, 250(1)(a), 250(1)(b), 250(9), 250(9)(a), 250(9)(b), 250(9)(c), 250(9)(d), 250(5), 250(6), 250(6)(a), 250(6)(b), 250(6)(b)(i), 250(6)(b)(ii); 370, 370(1); 370(2), 370(2)(a), 370(2)(b), 370(2)(c), 370(2)(d), 370(2)(e), 370(3), 370(4)(d), 370(8), 370(5), 370(5)(a), 370(5)(a)(i), 370(5)(a)(ii), 370(5)(a)(iii), 370(5)(b), 370(5)(c), 370(5)(d)(i), 370(5)(d)(ii), 370(5)(e), 370(5)(e)(i), 370(5)(e)(ii), 370(5)(e)(iii), 370(5)(e)(iv), 370(5)(e)(v), 370(5)(e)(vi), 370(5)(e)(vii), 370(5)(f), 370(5)(f)(i), 370(5)(f)(ii), 370(5)(f)(iii), 370(5)(f)(iv), 370(5)(f)(v), 370(5)(f)(vi), 370(5)(f)(vii), 370(5)(g); 390(1), 390(1)(a), 390(1)(b), 390(1)(c), 390(1)(d), 390(1)(e), 390(1)(f), 390(1)(g).
209 [2]	Universal Waste Rule: Specific Provisions for Mercury Containing Equipment.	70 FR 45508, 8/5/05	040 "mercury-containing equipment" definition; 040 "universal waste" definition; 077(2); 600(3)(o)(ii); 400(2)(c)(xi)(B); 140(2)(a) IBR 045(1); 800(7)(c)(iii)(B); 573(1)(a)(ii), 573(3)(a), 573(3)(b), 573(3)(b)(i), 573(3)(b)(ii), 573(3)(b)(iii), 573(3)(c)(i), 573(3)(c)(ii); 040 "ampule" definition; 040 "large quantity handler of universal waste" definition; 040 "mercury containing equipment" definition; 040 "small quantity handler of universal waste" definition; 040 "universal waste" definition; 573(9)(b), 573(9)(b)(i), 573(9)(b)(ii), 573(9)(b)(ii)(A), 573(9)(b)(ii)(B), 573(9)(b)(ii)(C), 573(9)(b)(ii)(D), 573(9)(b)(ii)(E), 573(9)(b)(ii)(F), 573(9)(b)(ii)(G), 573(9)(b)(ii)(H), 573(9)(b)(iii), 573(9)(b)(iii)(A), 573(9)(b)(iii)(B), 573(9)(b)(iv)(A), 573(9)(b)(iv)(A)(I), 573(9)(b)(iv)(A)(II), 573(9)(b)(iv)(B), 573(9)(b)(iv)(C), 573(10)(b)(i), 573(10)(b)(ii), 573(19)(b)(iv), 573(19)(b)(v), 573(20)(b), 573(20(b)(i), 573(20)(b)(ii), 573(20)(b)(ii)(A), 573(20)(b)(ii)(B), 573(20)(b)(ii)(C), 573(20)(b)(ii)(D), 573(20)(b)(ii)(E), 573(20)(b)(ii)(F), 573(20)(b)(ii)(G), 573(20)(b)(ii)(H), 573(20)(b)(iii), 573(20)(b)(iii)(A), 573(20)(b)(iii)(B), 573(20)(b)(iv)(A), 573(20)(b)(iv)(A)(I), 573(20)(b)(iv)(A)(II), 573(20)(b)(iv)(B), 573(20)(b)(iv)(C), 573(21)(b)(i), 573(21)(b)(ii).

TABLE 1—EQUIVALENT AND MORE STRINGENT ANALOGUES TO THE FEDERAL PROGRAM—Continued

Regulatory checklist [1]	Federal requirements	Federal Register	Analogous state authority—Washington's Administrative Code (WAC) (WAC 173–303–* * *)
212	NESHAP: Final Standards for Hazardous Waste Combustors (Phase I Final Replacement Standards and Phase II).	70 FR 59402, 10/12/05	110(1), 110(3)(g)(viii); 670(1)(b)(i), 670(1)(b)(v); 400(3)(a) IBR 045(1); 110(1), 110(3), 110(3)(g)(viii); 806 (17), 806(17)(a), 806(17)(a)(i), 806(17)(a)(ii), 806(17)(a)(iii), 806(17)(a)(iv), 806(17)(a)(v), 806(17)(a)(vi), 806(17)(a)(vii), 806(17)(a)(viii), 806(17)(a)(ix), 806(17)(b), 806(4)(f)(v), 806(4)(n), 806(4)(j)(iv)(C), 806(4)(k)(v)(C); 815(2)(b)(iii); 830(4)(j)(i), 830(4)(j)(ii), 830(4)(j)(iii), 830(4)(k), 830(4)(k)(i), 830(4)(k)(i)(A), 830(4)(k)(i)(B), 830(4)(k)(i)(C), 830(4)(k)(i)(D), 830(4)(k)(ii), 830(4)(k)(ii)(A), 830(4)(k)(ii)(B), 830 Appendix L 10; 807 introductory text; 811 IBR 045(1), 841 IBR 045(1).
213 [2]	Burden Reduction Initiative.	71 FR 16862, 4/4/06	040 "performance track member facility" definition; 017(5)(b)(ii)(B), 017(5)(b)(ii)(C), 017(5)(b)(ii)(D), 017(5)(b)(ii)(E), 017(5)(b)(ii)(F), 017(5)(b)(ii)(G); 071(3)(w)(iii)(E), 071(3)(s)(ix); 320(2)(c); 330(i); 350(2); 360(2)(j); 380(1), 380(1)(a), 380(1)(b), 380(1)(f), 380(1)(g), 380(1)(i); 645(9)(d), 645(9)(g)(ii), 645(9)(g)(iii), 645(10)(f), 645(10)(g), 645(10)(h)(iii)(A), 645(10)(h)(iii)(B), 645(11)(g); 610(4)(e)(v), 610(6), 610(11); 620(4)(b), 620(6)(b), 620(8)(e); 630(6); 640(2)(a); 640(2)(c)(v)(B), 640(3)(a), 640(3)(c), 640(4)(a)(i), 640(4)(a)(ii), 640(6)(b), 640(6)(b)(ii), 640(6)(b)(i), 640(6)(b)(iii), 640(4)(f), 640(6)(c), 640(6)(d), 640(7)(f); 660(2)(j); 655(8)(b); 140(4)(b)(i), 140(4)(b)(ii), 140(4)(b)(iii), 140(4)(b)(iv), 140(4)(b)(v), 140(4)(b)(v)(A), 140(4)(b)(v)(B); 670(4)(a)(ii), 670(7)(c); 64690 IBR 045(1); 675(2)(a), 675(2)(b), 675(2)(c), 675(4)(a)(iv)(B), 675(4)(g), 675(5)(a); 691(2) IBR 045(1); 695 IBR 045(1); 400(3)(a) IBR 045(1), 400(3)(c)(v)(A), 400(3)(c)(v)(B), 400(3)(c)(v)(D), 400(3)(c)(v)(E), 400(3)(c)(vi)(C), 400(3)(c)(vi)(D), 400(3)(c)(vi)(E), 400(3)(c)(vii)(C), 400(3)(c)(vii)(D), 400(3)(c)(vii)(E), 400(3)(c)(viii)(A), 400(3)(c)(ix)(B), 400(3)(c)(ix)(C), 400(3)(c)(ix)(D), 400(3)(c)(ix)(E), 400(3)(c)(ix)(G), 400(3)(c)(ix)(H), 400(3)(c)(ix)(I), 400(3)(c)(ix)(J), 400(3)(c)(ix)(K), 400(3)(c)(ix)(L), 400(3)(c)(x), 400(3)(c)(xi)(A), 400(3)(c)(xii)(B), 400(3)(a)(xiii), 400(3)(a)(xiii)(B); 140(4)(b)(i), 140(4)(b)(ii), 140(4)(b)(iii), 140(4)(b)(iv), 140(4)(b)(v), 140(4)(b)(v)(A), 140(4)(b)(v)(B); 400(3)(c)(xviii)(A), 400(3)(c)(xviii)(B), 400(3)(c)(xviii)(C), 400(3)(c)(xviii)(D), 400(3)(c)(xviii)(E), 400(3)(c)(xviii)(F), 400(3)(c)(xx)(B), 400(3)(c)(xx)(A), 400(3)(c)(xx)(C), 400(3)(c)(xxii)(A), 400(3)(c)(xxii)(B); 140(2)(c) IBR 045(1), 140(2)(d) IBR 045(1), 140(2)(e) IBR 045(1), 140(2)(a) IBR 045(1), 140(2)(f) IBR 045(1); 806(4)(a), 806(4)(c)(i), 806(4)(l)(iii)(O); 830(1).

TABLE 1—EQUIVALENT AND MORE STRINGENT ANALOGUES TO THE FEDERAL PROGRAM—Continued

Regulatory checklist [1]	Federal requirements	Federal Register	Analogous state authority—Washington's Administrative Code (WAC) (WAC 173–303–* * *)
214 [2]	Corrections to Errors in the Code of Federal Regulations.	71 FR 40254, 7/14/06	040 "incompatible waste" definition; 040 "personnel or facility personnel" definition; 040 "universal waste" definition; 040 "used oil" definition; 525(2), 525(3) introductory paragraph; 016(5)(a); 070(3); 016(5)(a)(i)(B); 071(3)(aa)(i)(B), 071(3)(aa)(ii), 071(3)(aa)(ii)(A), 071(3)(aa)(ii)(B), 071(3)(aa)(ii)(C), 071(3)(aa)(ii)(D), 071(3)(aa)(ii)(E), 071(3)(aa)(ii)(F), 071(3)(g)(i), 071(3)(r)(ii)(F), 071(3)(r)(iii)(A); 120(3)(b), 120(3)(d), 120(3)(g), 120(3)(f), 120(4)(c); 090(5)(a)(iii), 090(5)(a)(iii)(A), 090(5)(a)(iii)(B), 090(5)(a)(iii)(B)(I), 090(5)(a)(iii)(B)(II), 090(5)(a)(iii)(B)(III), 090(5)(a)(iii)(B)(IV), 090(5)(a)(iv), 090(5)(a)(iv)(A), 090(5)(a)(iv)(B), 090(5)(a)(iv)(C), 090(5)(a)(iv)(D), 090(5)(a) Note 1, 090(5)(a) Note 2, 090(5)(a) Note 3, 090(5)(a) Note 4, 090(8)(b); 9904 Footnote; 081(2)(a), 81(2)(a)(i); 9903 Introductory, 9903; 081(1); 082(4) IBR 045(1); 9905; 200(1)(b)(i), 200(1)(b)(ii), 200(1)(b)(iii), 200(1)(b)(iv), 200(1)(b)(v); 230(1) IBR 045(1); 600(3)(f), 600(5); 280(2); 300(5)(h)(iii)(B); 395(1)(a); 282(3)(g), 282(6)(c)(i)(A); 645(8)(a)(i), 645(8)(a)(i)(A), 645(8)(i)(v), 645(9)(a)(ii), 645(9)(g)(iv)(A), 645(10)(h)(ii); 64610(3); 610(2)(b), 610(3)(a)(ix), 610(6), 610(9), 610(8)(c), 610(10)(b)(i)(B); 620(1)(d)(i), 620(3)(c)(ii), 620(4)(b) IBR 045(1), 620(6)(b) IBR 045(1), 620(8)(b) IBR 045(1), 620(10) IBR 045(1); 630(7)(a)(i); 640(4)(c)(iv), 630(4)(d)(iv), 640(4)(e)(ii)(B), 640(4)(e)(ii)(C), 640(4)(e)(ii)(E)(I), 640(4)(e)(ii)(E)(II), 640(4)(e)(iii)(A), 640(4)(e)(iii)(B), 640(4)(g)(i)(C), 640(4)(g)(i)(D), 640(4)(g)(ii)(A)(I); 650(2)(j)(i)(B), 650(2)(j)(iii)(B), 650(2)(l)(i), 650(2)(l)(ii)(B), 650(2)(l)(ii)(C), 650(11)(b)(i), 650(4)(a)(ii); 660(2)(a)(ii)(A)(I), 660(3)(a), 630(3)(b), 660(10)(b); 655(8)(a)(vii), 655(8)(d), 655(12)(a); 665(2)(h)(ii), 665(2)(j)(ii)(B), 665(8)(a), 665(8)(b), 665(9)(b)(i); 140(4)(b)(v)(B); 665(11)(a); 670(5)(b); 64660(3)(d)(iii), 64660(3)(d)(iv)(F), 64660(3)(f)(ii)(E); 64680(5); 64690 IBR 045(1); 646910(5)(f); 675(4)(a)(i), 675(4)(a)(iv)(A), 675(4)(a)(v), 675(4)(b), 675(4)(m)(ii), 675(4)(m)(iii); 680(1), 680(2)(a), 680(2)(b)(xi), 680(2)(c)(iv); 690(1)(c), 690(2) IBR 045(1); 691(1)(f), 691(2) IBR 045(1); 692(1)(a), 692(1)(c), 692(2) IBR 045(1); 695 IBR 045(1); 380(2)(c), 380(2)(d); 400(2)(c)(ii); 290(1)(a); 310(2)(b); 330(1)(c)(ii); 400(3)(a) IBR 045(1); 360(2)(b); 400(3)(c)(viii), 400(3)(c)(ix)(G), 400(3)(c)(ix)(K), 400(3)(c)(xviii)(C); 380(2)(c), 380(2)(d); 525(1)(a); 140(2)(a) IBR 045(1); 803(2); 800(2); 802(2); 800(7)(c)(i); 040 "on-site" definition, 040 "publicly owned treatment works (POTW)"; 806(12); 810(13)(a); 803(3)(k)(vii); 806(4)(a); 282(6)(a)(i); 806(4)(a)(xviii)(C), 806(4)(a)(xxvi), 806(4)(d)(vii), 806(4)(e)(ii), 806(4)(e)(viii), 806(4)(g)(viii)(B)(vii)(A), 806(4)(g)(viii)(B)(vii)(B), 806(4)(g)(viii)(B)(vii)(C), 806(4)(g)(viii)(B)(vii)(D), 806(4)(l)(iii)(O); 815(3)(b); 282(2)(i); 830(4)(d)(ii)(A), 830 Appendix I; 805(1)(b), 805(7)(b)(ii); 040 "Universal Waste" definition; 573(10)(a), 573(21)(a); 515(2) IBR 045(1), 515(5)(e), 515(4) IBR 045(1), 515(4) Table 1, 515(8) IBR 045(1), 515(9) IBR 045(1), 515(10) IBR 045(1), 515(11) IBR 045(1).
215 [2]	Cathode Ray Tubes Rule	71 FR 42928, 7/28/06	040 "cathode ray tube" definition; 040 "CRT collector" definition; 040 "CRT glass manufacturer" definition; 040 "CRT processing" definition; 071(3)(oo)(i), 071(3)(oo)(ii), 071(3)(oo)(iii), 071(3)(oo)(iv).
217 [2]	NESHAP: Final Standards for Hazardous Waste Combustors (Phase I Final Replacement Standards and Phase II) Amendments.	73 FR 18970, 4/8/08	670(1), 670(1)(b)(i), 670(1)(b)(iii), 670(1)(b)(v).

[1] Regulatory Checklist is a document that addresses specific changes made to the Federal regulations by one or more related final rules published in the **Federal Register.** EPA develops these checklists as tools to assist States in developing their authorization application and in documenting specific State regulations analogous to the Federal regulations. For more information on EPA's RCRA State Authorization Guidance see *http://www.epa.gov/epawaste/osw/laws-regs/State/index.htm.*

[2] State rule contains more stringent provisions. For identification of the more stringent State provisions refer the Docket ID Number EPA–R10–RCRA–2010–0251 for this action.

TABLE 2—STATE INITIATED CHANGES

State Citation—Washington's Administrative Code (WAC) (WAC 173–303–* * *)	Reason for change	Analogous Federal 40 CFR citation
030	Clarification—Add acronyms (PODC, DRE, APTI, MACT, TEQ, CAMU, TU).	260 related.
040	Clarify definition for Closure—update to clarify closure applies to recyclers, some generators and some transporters.	262.10.
040	Compliance Procedure—removed the cited dates and added RCW title.	260 related.
040	Person definition—Updated to match Federal rule	260.10.
040	Staging Pile definition—Updated to match Federal rule	260.10.
040	Surface Impoundment definition—Change language to reflect Federal definition by deleting the word "dangerous".	260.10.
045	Incorporation by reference updated to July 2007	260–280 related.
070(7)(c)	Clarify that counting exclusion applies to permit-by-rule (PBR), not to treatment by generator activity.	261/5(c) Intro.
070(8)(d)	Citations corrected for used oil burned for energy recovery.	261.5 related.
071(3)(cc)(ii)	Deletion of incorrect NAICS codes—487110, 722310, 425110.	261.4(a)(12)(i), 261.4(a)(12)(ii).
081(1), 081(1)(a) and 082(1).	Clarification on appropriate commercial chemical product waste code.	261.33, 261.31(a).
*083(2)(b)(iii)(A) & (B)	Clarification—SW–846 is incorporated by reference at 110(3)(a).	261.35(b)(2)(iii)(A), 261.35(b)(2)(iii)(B).
*090(5)(a)(i) and (6)(a)(i), & (iii).	Clarification—SW–846 test method is incorporated by reference at 110(3).	261.21(a)(1), 261.22(a)(1), 261.22(a)(2).
	Updates to ASTM and NACE procedures	
090(6)(a)(ii)	Clarify that the NACE test method is the same as SW–846 Method 1110A.	261.22(a)(1) and (2).
110 title	First sentence revised by adding word "analytes"	260.1, 270.6 related.
110(2)(a)(vi), (2)(b)	Clarification on selection of sampling device	260.11, 261 (Appendix I, Index).
	Reference to AC&D liquid sample removed	
*110(3)(a)	Added "IIIB Update" and "Final Update IV" to SW 846 reference.	260.11(a) through (g), related.
110(3)(c)	Chemical Testing Methods guidance revisions and updates.	Previously authorized as and currently related to 40 CFR 261 Appendix 1—Test Methods.
*110(3)(f)	Clarification—Use test methods in SW–846 Chapter 2 for identifying toxic constituents.	260.11 Appendix III.
110(3)(e) through (h)	Updated referenced test methods to latest revision date	260.11.
110(3)(g)(x)	Duplicate deleted [*see* 110(3)(g)(vii)]	260.11(15).
110(5)	Citation correction from "to approve" to "approval for the use of" an equivalent testing method by submitting a petition.	260.21.
110(6)	Clarification—Test method results need to be reported on a dry weight basis.	Technical clarification, consistent with and no less stringent than the Federal program, related to 260.21.
110(7)	"Ground-Water Monitoring List" Appendix IX to 40 CFR Part 264 is replaced with the version in Appendix 5 of the State's "Chemical Testing Methods for Designating Dangerous Waste, Publication #97–407, June 2009" which is incorporated by reference into the WAC at 173–303–110(1).	264 Appendix IX.
120(4)(c)	Correct second repeated (c)(vii) by renumbering as (c)(ix).	261.6(c)(2).
*140(2)(a)	Clarify that section 110 test methods must be used	268 related, conforming change to reflect retention of use of SW–846 methods.
140(4)(b)(iv)(B)(I)	ASTM Test method update	264.314(e).
200(1)(b)(ii) & (iii), 200(4)(a)(iv)(A)(II)	Delete "stress of installation" phrase and insert in 640 and 675.	262.34(a)(1)Intro, 262.34(a)(1)(ii), 262.34(a)(1)(iii).
200(1)(b)(iv)	Correct the Federal references by substituting State citations for closure and financial assurance.	262.34(a)(1)(iv).
	The word "shall" was changed to "must"	
270(3)	49 CFR 171.16 reference—updated transporter spill reporting address and method.	263.30(c)(2).
281(4)	Citations corrected from WAC 173–303–840 to WAC 173–303–830.	124.31(a).
*300(5)(f)	Clarify that section 110 test methods must be where specific WAC citations are referenced.	264.13(b)(6); 265.13(b)(6); 264.73(b)(3); 265.73(b)(3), conforming change to reflect retention of use of SW–846 methods.
310(1)	Reworded to be consistent with Federal rule	264.14; 265.14.

TABLE 2—STATE INITIATED CHANGES—Continued

State Citation—Washington's Administrative Code (WAC) (WAC 173–303–* * *)	Reason for change	Analogous Federal 40 CFR citation
*380(1)(c)	Clarify that section 110 test methods must be used where specific 40 CFR citations are referenced.	264.73(b)(3); 265.73(b)(3); conforming change to reflect retention of use of SW–846 methods.
*380(1)(f)	Add "incorporated by reference" for clarity and clarified that section 110 test methods must be used where specific WAC citations are referenced.	264.73(b)(6); 265.73(b)(6), conforming change to reflect retention of use of SW–846 methods.
380(2)(c)	Add "tons (2000 lbs)" to unit of measure Table 1	264 Appendix I (2) Table 1; 265 Appendix I (2) Table 1.
400(2)(c)(xiv)	Language added for equivalence with Federal rule	265.1(c)(5).
400(2)(c)(xv)		
400(3)(c)	Added the word "qualified" to the description of an independent registered professional engineer. This occurs nineteen times in the sub subsection.	265 related—more stringent State requirement.
*400(3)(c)(iii)	Clarify that section 110 test methods must be used where specific 40 CFR 265 subparts are referenced.	265 related, conforming change to reflect retention of use of SW–846 methods.
400(3)(c)(iv) Moved from (3)(c)(x).	Reference regarding Subpart B is changed because the only part of Subpart B that is incorporated by reference is 265.19.	265.19.
400(3)(c)(xiii)(A)	Correction—the word carbonaceous replaces carcinogen.	265.300 Subpart N—Landfills, related.
505(1)(b)(iv)	Citation corrected	266.20.
506(3)(vii)	Deleted CFC recycling exception from closure and financial responsibility requirements.	264.110, 265.110 Subpart G related; 264.140, 265.140 Subpart H related.
510(1)(b)(i)(B)	Correct internal citation	260.30(b) Introduction, 260.30(b)(1), 266.100(b)(1).
*515(3)	Clarify that section 110(3) test methods must be used	279.10, conforming change to reflect retention of use of SW–846 methods.
*515(4)	Clarify that section 110(3) test methods must be used	279.11, conforming change to reflect retention of use of SW–846 methods.
*515(8), (9), (10) and (13)(b).	Clarify that section 110(3) test methods must be used	279.40–47, 279.50–59, 279.60–67, 279.10, conforming change to reflect retention of use of SW–846 methods.
610(3)(a)(ix), (3)(b)(ii)(D), (8)(b)(iv), and (8)(d)(ii)(D).	Citation corrected	264.112 related.
610(6) & (11)	Add "qualified" to PE description	264.115; 264.120—more stringent State requirement.
610(12)(e), 620(1)(e)(ii)	Correction—change "resource reclamation units" to "recycling units".	264.143.
620(4)(d)(iv)	Clarification that corporate guarantors are also subject to a minimum net worth criteria.	264.143.
620(4)(c), 620(4)(e)(i), 620(4)(f).	New financial instrument option—"assigned security deposit" for used oil processors and recyclers.	264.143.
620(4)(d)(i)	Clarification that used oil processors may use partially funded trust funds.	264.143.
620(4)(d)(iv)	Clarification that corporate guarantors are also subject to a minimum net worth criteria.	264.143.
620(5)(c), 620(5)(d), 620(7)	Edit—add hyphen to post-closure	264.143.
*640(1)(b)	Provide title for test method	264.190.
	Clarification that SW–846 is incorporated by reference	
*645(4)(a) and (b)	Note that the 40 CFR 264 Appendix IX Ground-Water monitoring list is included as Appendix 5 in the "Chemical Testing Methods for Dangerous Waste, Publication #97–407, June 2009", which is incorporated by reference at WAC 173–303–110(1).	264 Appendix IX.
*645(9)(g)(ii), (iii) and (iv)(A)		
645(10)(g)		
64610(4)		
806(4)(a)(xx)(D)(II)		
645(8)(c)	Update reference to Chapter 173–160 WAC	264.97(c).
640(4)(c)(i) & 675(4)(a)(v)	Relocate "stress of installation" phrase from 200	264.573. 264.193.
64660(3)(d)(iv)(F)	Correct "SW846" to read "SW–846"	264.552 related (CAMU).
665(13)	New subsection	264.314.
	Added a reference to the liquid waste disposal provision in 140(4)(b).	
*690	Deleted proposed language requiring use of 110(3)(a) test methods.	264.1030, 264.1050 (Air Emissions for Vents, and Equipment Leaks).
*691		
806(2)(a)	Citation corrected	270.10.
*806(4)(f)(iii)(A)(III)	Clarification that equivalent analytical techniques must be approved by ecology.	270.19.
806(8)	Updated permit application requirements for consistency with Federal rule and clarified that facilities must consult with Ecology about submittal of exposure information.	270.10(c).
*807(2)(a)(iii)	Clarification that equivalent analytical techniques must be approved by Ecology.	270.62.
810(11)(c)	Duplicate provision deleted	270.30(j)(2).
810(16)	Citation corrected	270.30(m).

TABLE 2—STATE INITIATED CHANGES—Continued

State Citation—Washington's Administrative Code (WAC) (WAC 173–303–* * *)	Reason for change	Analogous Federal 40 CFR citation
830(4)(b)(vii)	Citation corrected	270.42(b) related.
*910(2)(d)	Clarify that approved equivalent test methods will be incorporated at 110(3).	260.20(a), 260.21(d).
910(3)	Clarify that exemption petitions also go to EPA for Federal listed wastes.	260.22(d)(1)(i).
9901; 9902	Delete obsolete title	260 Appendix I, related.

*These State citations were amended to clarify that SW–846 test methods must be used, or in some cases requiring the use of test methods specifically called out in WAC 173–303–110.

G. Where are the revised State rules different from the Federal rules?

This section does not discuss all the program differences, because in most instances Washington writes its own version of the Federal hazardous waste rules. This section highlights those more notable differences between the revised State rules and the Federal rules. The State regulations that EPA is authorizing are located in Tables 1 and 2 above, and by viewing the Docket. There are certain portions of the Federal program which are not delegable to the States because of the Federal government's special role in foreign policy matters and because of national concerns that arise with certain decisions. For example, EPA does not delegate import/export functions. Under RCRA regulations found in 40 CFR part 262, EPA will continue to implement requirements for import/export functions. However, the State rules found at WAC 173–303–230 reference EPA's export and import requirements and the State has amended these references to include those changes promulgated in the Federal rule "Corrections to Errors in the Code of Federal Regulation, (71 FR 40254, 7/14/06)".

The State did not adopt the Federal Methods Innovation Rule (70 FR 34537, 6/14/05) which amended a variety of testing and monitoring requirements found in RCRA and removed from the Federal regulations a requirement to use the methods found in "EPA's Test Methods for Evaluating Solid Waste, Physical/Chemical Methods," also known as "SW–846" in conducting various testing and monitoring. The State retained the RCRA-related sampling and analysis requirement to use the testing methods found in "SW–846," and EPA considers these changes to be state-initiated changes within the scope of Ecology's existing authorization that are consistent with and no less stringent than the Federal program. (**Note:** The State does have an existing state-only petition process for deviating from "SW–846" for equivalent testing methods, found at WAC 173–303–110(5) which is not part of its state-only rule and isn't part of the federally-authorized program. Additionally, in Table 2, above, those State citations identified with an asterisk (*) indicate those state provisions where "SW–846" testing methods must be used.)

The State's definition of "Designated facility", found at WAC 173–303–040, is equivalent to the Federal definition, found at 40 CFR 260.10, with the exception of one broader in scope phrase that is a state-only requirement. The broader in scope phrase that is not authorized is: "The following are designated facilities only for receipt of State-only waste; they cannot receive federal hazardous waste from off-site: Facilities operating under WAC 173–303–500(2)(c)."

States are allowed to seek authorization for more stringent requirements than the Federal program. EPA has the authority to authorize and enforce those parts of a State's program EPA finds to be more stringent than the Federal program. The State revised its previous federally authorized mercury-containing equipment requirements with the adoption of the Federal Rule for Mercury-Containing Equipment Universal Waste (70 FR 45508, 8/5/06). The State's revised mercury-containing equipment universal waste rule is more stringent than the Federal rule as the State regulates lamps at a lower accumulation limit than the Federal rule. Specifically, the State's definitions of small and large quantity handlers of universal waste found at WAC 173–303–040 are more stringent than the Federal definitions found at 40 CFR 273.9; and the State's large quantity handlers of universal waste notification standards found at WAC 173–303–573(19)(b)(v) are more stringent than the Federal notification standards found at 40 CFR 273.32(b)(5). Additionally, the State adopted some portions of the Federal Burden Reduction Initiative Rule (70 FR 16862, 4/4/06). The State's rule retains many of the Federal requirements that were reduced by the Federal Burden Reduction Initiative Rule, and as a result those requirements retained by the State are more stringent than their Federal counterparts. The State's definitions of "Cathode ray tubes (CRT) and CRT collector" found at WAC 173–303–040 are more stringent than the Federal CRT definitions found at 40 CFR 260.10, because the State defines a CRT to mean all categories of CRTs (intact, used and broken) and requires that all CRTs be managed (WAC 173–303–071(3)(oo)(i)–(iv)) under the same standards used in the federal program for used and broken CRTs (40 CFR 261.39).

H. Who handles permits after this authorization takes effect?

After authorization, Washington will continue to issue permits for all the provisions for which it is authorized and will administer the permits it issues. If EPA issued permits prior to authorizing Washington for these revisions, these permits would continue in force according to the terms of such permits until the effective date of the State's issuance or denial of a State hazardous waste management permit, at which time, EPA would modify the existing EPA permit to expire at an earlier date, terminate the existing EPA permit for cause, or allow the existing EPA permit to otherwise expire by its terms, except for those facilities located in Indian Country. EPA will not issue any new permits, permit components, or new portions of permits for the provisions listed in Section G after the effective date of this authorization. EPA will continue to implement and issue permits for HSWA requirements for which Washington is not yet authorized.

I. What is codification and is EPA codifying Washington's hazardous waste program as authorized in this final rule?

Codification is the process of placing the State's statutes and regulations that

comprise the State's authorized hazardous waste program into the Code of Federal Regulations. This is done by referencing the authorized State rules in 40 CFR part 272. EPA is reserving the amendment of 40 CFR part 272, subpart WW for this authorization of Washington's program revisions until a later date.

J. How does today's action affect Indian Country (18 U.S.C. 1151) in Washington?

EPA's decision to authorize the Washington hazardous waste management program does not include any land that is, or becomes after the date of authorization, "Indian Country," as defined in 18 U.S.C. 1151, with the exception of the non-trust lands within the exterior boundaries of the Puyallup Indian Reservation (also referred to as the "1873 Survey Area" or "Survey Area") located in Tacoma, Washington. EPA retains jurisdiction over "Indian Country". Effective October 22, 1998 (63 FR 50531, 9/22/98) the State of Washington was authorized to implement the State's federally-authorized hazardous waste management program on the non-trust lands within the 1873 Survey Area of the Puyallup Indian Reservation. The authorization did not extend to trust lands within the reservation. EPA retains its authority to implement RCRA on trust lands and over Indians and Indian activities within the 1873 Survey Area.

K. Statutory and Executive Order Reviews

This final rule revises the State of Washington's authorized hazardous waste management program pursuant to section 3006 of RCRA and imposes no requirements other than those currently imposed by State law. This final rule complies with applicable executive orders and statutory provisions as follows:

1. Executive Order 12866

Under Executive Order 12866 (58 FR 51735, October 4, 1993), the Agency must determine whether the regulatory action is "significant", and therefore subject to OMB review and the requirements of the Executive Order. The Executive Order defines "significant regulatory action" as one that is likely to result in a rule that may: (1) Have an annual effect on the economy of $100 million or more, or adversely affect in a material way, the economy, a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or State, local, or tribal governments or communities; (2) create a serious inconsistency or otherwise interfere with an action taken or planned by another agency; (3) materially alter the budgetary impact of entitlements, grants, user fees, or loan programs, or the rights and obligations of recipients thereof; or (4) raise novel legal or policy issues arising out of legal mandates, the President's priorities, or the principles set forth in the Executive Order. EPA has determined that this final rule is not a "significant regulatory action" under the terms of Executive Order 12866 and is therefore not subject to OMB review.

2. 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.,* because this final rule does not establish or modify any information or recordkeeping requirements for the regulated community and only seeks to authorize the pre-existing requirements under State law and imposes no additional requirements beyond those imposed by State law. Burden means the total time, effort, or financial resources expended by persons to generate, maintain, retain, or disclose or provide information to or for a Federal agency. This includes the time needed to review instructions; develop, acquire, install, and utilize technology and systems for the purposes of collecting, validating, and verifying information, processing, and maintaining information, and disclosing and providing information; adjust the existing ways to comply with any previously applicable instructions and requirements; train personnel to be able to respond to a collection of information; search data sources; complete and review the collection of information; and transmit or otherwise disclose the information. An Agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. The OMB control numbers for EPA's regulations in Title 40 of the CFR are listed in 40 CFR part 9.

3. Regulatory Flexibility Act

The Regulatory Flexibility Act (RFA) generally requires Federal agencies to prepare a regulatory flexibility analysis of any rule subject to notice and comment rulemaking requirements under the Administrative Procedure Act or any other statute unless the agency certifies that the rule will not have a significant economic impact on a substantial number of small entities. Small entities include small businesses, small organizations, and small governmental jurisdictions. For purposes of assessing the impacts of today's final rule on small entities, small entity is defined as: (1) A small business defined by the Small Business Administration's size regulations at 13 CFR Part 121.201; (2) a small governmental jurisdiction that is a government of a city, county, town, school district, or special district with a population of less than 50,000; and (3) a small organization that is any not-for-profit enterprise which is independently owned and operated and is not dominant in its field. I certify that this final rule will not have a significant economic impact on a substantial number of small entities because the final rule will only have the effect of authorizing pre-existing requirements under State law and imposes no additional requirements beyond those imposed by State law.

4. Unfunded Mandates Reform Act

Title II of the Unfunded Mandates Reform Act (UMRA) of 1995 (Pub. L. 104–4) establishes requirements for Federal agencies to assess the effects of their regulatory actions on State, local, and tribal governments and the private sector. Under section 202 of the UMRA, EPA generally must prepare a written Statement, including a cost-benefit analysis, for proposed and final rules with "Federal mandates" that may result in expenditures and final rules with "Federal mandates" that may result in expenditures to State, local, and tribal governments, in the aggregate, or to the private sector, of $100 million or more in any one year. Before promulgating an EPA rule for which a written Statement is needed section 205 of the UMRA generally requires EPA to identify and consider a reasonable number of regulatory alternatives and adopt the least costly, most cost-effective or least burdensome alternative that achieves the objectives of the rule. The provisions of section 205 do not apply when they are inconsistent with applicable law. Moreover, section 205 allows EPA to adopt an alternative other than the least costly, most cost-effective, or least burdensome alternative if the Administrator publishes with the rule an explanation why the alternative was not adopted. Before EPA establishes any regulatory requirements that may significantly or uniquely affect small governments, including tribal governments, it must have developed under section 203 of the UMRA a small government agency plan. The plan must provide for notifying potentially affected small governments, enabling officials of affected small governments to have meaningful and timely input in

the development of EPA regulatory proposals with significant Federal intergovernmental mandates, and informing, educating, and advising small governments on compliance with the regulatory requirements. Today's final rule contains no Federal mandates (under the regulatory provisions of Title II of the UMRA) for State, local, or tribal governments or the private sector. It imposes no new enforceable duty on any State, local or tribal governments or the private sector. Similarly, EPA has also determined that this final rule contains no regulatory requirements that might significantly or uniquely affect small government entities. Thus, today's final rule is not subject to the requirements of sections 202 and 203 of the UMRA.

5. Executive Order 13132: Federalism

This final rule does not have Federalism implications. It will not have substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among various levels of government, as specified in Executive Order 13132 (64 FR 43255, August 10, 1999). This final rule authorizes pre-existing State rules. Therefore, Executive Order 13132 does not apply to this final rule.

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

Executive Order 13175, entitled "Consultation and Coordination with Indian Tribal Governments" (59 FR 22951, 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 because EPA retains its authority over Indian Country. Therefore, Executive Order 13175 does not apply to this final rule.

7. Executive Order 13045: Protection of Children From Environmental Health 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 action is not subject to Executive Order 13045 because it approves a State program.

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

This final 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" as defined under Executive Order 12866.

9. National Technology Transfer and Advancement Act

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

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

Executive Order 12898 (59 FR 7629, February 16, 1994) establishes Federal executive policy on environmental justice. Its main provision directs Federal agencies, to the greatest extent practicable and permitted by law, to make environmental justice part of their mission by identifying and addressing, as appropriate, disproportionately high and adverse human health or environmental effects of their programs, policies, and activities on minority populations and low-income populations in the United States. EPA has determined that this final rule will not have disproportionately high and adverse human health or environmental effects on minority or low-income populations. This final rule does not affect the level of protection provided to human health or the environment because this rule authorizes pre-existing State rules which are equivalent to, and no less stringent than existing Federal requirements.

List of Subjects in 40 CFR Part 271

Environmental protection, Administrative practice and procedure, Confidential business information, Hazardous materials transportation, Hazardous waste, Indians—lands, Intergovernmental relations, Penalties, Reporting and recordkeeping requirements.

Authority: This final action is issued under the authority of sections 2002(a), 3006 and 7004(b) of the Solid Waste Disposal Act, as amended, 42 U.S.C. 6912(a), 6926, 6974(b).

Dated: July 21, 2010.

Dennis J. McLerran,

Regional Administrator, Region 10.

[FR Doc. 2010–18566 Filed 7–27–10; 8:45 am]

BILLING CODE 6560–50–P

DEPARTMENT OF HOMELAND SECURITY

Federal Emergency Management Agency

44 CFR Part 64

[Docket ID FEMA–2010–0003; Internal Agency Docket No. FEMA–8139]

Suspension of Community Eligibility

AGENCY: Federal Emergency Management Agency, DHS.

ACTION: Final rule.

SUMMARY: This rule identifies communities, where the sale of flood insurance has been authorized under the National Flood Insurance Program (NFIP), that are scheduled for suspension on the effective dates listed within this rule because of noncompliance with the floodplain management requirements of the program. If the Federal Emergency Management Agency (FEMA) receives documentation that the community has adopted the required floodplain management measures prior to the effective suspension date given in this rule, the suspension will not occur and a notice of this will be provided by publication in the **Federal Register** on a subsequent date.

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

FOR FURTHER INFORMATION CONTACT: If you want to determine whether a particular community was suspended on the suspension date or for further information, contact David Stearrett, Mitigation Directorate, Federal Emergency Management Agency, 500 C

Street, SW., Washington, DC 20472, (202) 646–2953.

SUPPLEMENTARY INFORMATION: The NFIP enables property owners to purchase flood insurance which is generally not otherwise available. In return, communities agree to adopt and administer local floodplain management aimed at protecting lives and new construction from future flooding. Section 1315 of the National Flood Insurance Act of 1968, as amended, 42 U.S.C. 4022, prohibits flood insurance coverage as authorized under the NFIP, 42 U.S.C. 4001 *et seq.;* unless an appropriate public body adopts adequate floodplain management measures with effective enforcement measures. The communities listed in this document no longer meet that statutory requirement for compliance with program regulations, 44 CFR part 59. Accordingly, the communities will be suspended on the effective date in the third column. As of that date, flood insurance will no longer be available in the community. However, some of these communities may adopt and submit the required documentation of legally enforceable floodplain management measures after this rule is published but prior to the actual suspension date. These communities will not be suspended and will continue their eligibility for the sale of insurance. A notice withdrawing the suspension of the communities will be published in the **Federal Register**.

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

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

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

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

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

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

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

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

List of Subjects in 44 CFR Part 64

Flood insurance, Floodplains.

■ Accordingly, 44 CFR part 64 is amended as follows:

PART 64—[AMENDED]

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

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

§ 64.6 [Amended]

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

State and location	Community No.	Effective date authorization/cancellation of sale of flood insurance in community	Current effective map date	Date certain Federal assistance no longer available in SFHAs
Region IV				
Alabama:				
Eutaw, City of, Greene County	010093	July 23, 1974, Emerg; August 19, 1985, Reg; August 5, 2010, Susp.	Aug. 5, 2010	Aug. 5, 2010
Greene County, Unincorporated Areas	010091	April 5, 1976, Emerg; April 16, 1990, Reg; August 5, 2010, Susp.	*do	Do.
Georgia:				
Brooklet, Town of, Bulloch County	130020	September 10, 1975, Emerg; July 3, 1986, Reg; August 5, 2010, Susp.	do	Do.
Jenkins County, Unincorporated Areas	130118	January 16, 1976, Emerg; September 29, 1989, Reg; August 5, 2010, Susp.	do	Do.
Statesboro, City of, Bulloch County	130021	January 20, 1975, Emerg; May 15, 1980, Reg; August 5, 2010, Susp.	do	Do.
Unified Government of Georgetown, Quitman County.	130379	October 17, 1986, Emerg; September 1, 1987, Reg; August 5, 2010, Susp.	do	Do.
Kentucky:				
Elliott County, Unincorporated Areas	210372	May 8, 1996, Emerg; August 5, 2010, Reg; August 5, 2010, Susp.	do	Do.

State and location	Community No.	Effective date authorization/cancellation of sale of flood insurance in community	Current effective map date	Date certain Federal assistance no longer available in SFHAs
Inez, City of, Martin County	210362	May 19, 1988, Emerg; May 19, 1988, Reg; August 5, 2010, Susp.	.....do	Do.
Martin County, Unincorporated Areas	210166	April 14, 1977, Emerg; February 19, 1986, Reg; August 5, 2010, Susp.	.....do	Do.
Nicholas County, Unincorporated Areas	210181	April 17, 1975, Emerg; September 27, 1985, Reg; August 5, 2010, Susp.	.....do	Do.
Warfield, Town of, Martin County	210364	N/A, Emerg; September 4, 1986, Reg; August 5, 2010, Susp.	.....do	Do.
Region V				
Illinois:				
Browning, Village of, Schuyler County	170606	June 12, 1974, Emerg; August 16, 1982, Reg; August 5, 2010, Susp.	.....do	Do.
DuQuoin, City of, Perry County	170539	June 13, 1975, Emerg; July 2, 1987, Reg; August 5, 2010, Susp.	.....do	Do.
Perry County, Unincorporated Areas	170538	September 13, 1996, Emerg; August 5, 2010, Reg; August 5, 2010, Susp.	.....do	Do.
Pinckneyville, City of, Perry County	170540	July 2, 1975, Emerg; September 16, 1982, Reg; August 5, 2010, Susp.	.....do	Do.
Region VI				
Louisiana:				
Arnaudville, Town of, St. Landry and St. Martin Parishes.	220166	March 4, 1974, Emerg; November 1, 1985, Reg; August 5, 2010, Susp.	.....do	Do.
Cankton, Village of, St. Landry Parish	220167	March 5, 1975, Emerg; June 25, 1976, Reg; August 5, 2010, Susp.	.....do	Do.
Eunice, City of, Acadia and St. Landry Parishes.	220168	June 5, 1975, Emerg; June 1, 1981, Reg; August 5, 2010, Susp.	.....do	Do.
Grand Coteau, Town of, St. Landry Parish.	220169	September 26, 1975, Emerg; June 30, 1976, Reg; August 5, 2010, Susp.	.....do	Do.
Krotz Springs, Town of, St. Landry Parish.	220170	May 30, 1973, Emerg; January 15, 1988, Reg; August 5, 2010, Susp.	.....do	Do.
Leonville, Town of, St. Landry Parish	220171	May 28, 1975, Emerg; November 9, 1982, Reg; August 5, 2010, Susp.	.....do	Do.
Melville, Town of, St. Landry Parish	220172	May 31, 1973, Emerg; July 3, 1978, Reg; August 5, 2010, Susp.	.....do	Do.
Opelousas, City of, St. Landry Parish	220173	December 12, 1974, Emerg; August 3, 1981, Reg; August 5, 2010, Susp.	.....do	Do.
Palmetto, Village of, St. Landry Parish	220174	April 12, 1974, Emerg; April 15, 1986, Reg; August 5, 2010, Susp.	.....do	Do.
Port Barre, Town of, St. Landry Parish	220175	February 28, 1974, Emerg; April 15, 1981, Reg; August 5, 2010, Susp.	.....do	Do.
St. Landry Parish, Unincorporated Areas.	220165	May 15, 1973, Emerg; May 3, 1982, Reg; August 5, 2010, Susp.	.....do	Do.
Sunset, Town of, St. Landry Parish	220176	April 24, 1975, Emerg; March 30, 1982, Reg; August 5, 2010, Susp.	.....do	Do.
Washington, Town of, St. Landry Parish	220177	May 1, 1975, Emerg; May 1, 1985, Reg; August 5, 2010, Susp.	.....do	Do.
New Mexico:				
Aztec, City of, San Juan County	350065	May 9, 1974, Emerg; July 15, 1988, Reg; August 5, 2010, Susp.	.....do	Do.
Bloomfield, City of, San Juan County	350066	June 19, 1975, Emerg; August 8, 1978, Reg; August 5, 2010, Susp.	.....do	Do.
Clovis, City of, Curry County	350010	May 1, 1974, Emerg; February 4, 1981, Reg; August 5, 2010, Susp.	.....do	Do.
Curry County, Unincorporated Areas	350127	February 11, 2005, Emerg; August 5, 2010, Reg; August 5, 2010, Susp.	.....do	Do.
Farmington, City of, San Juan County	350067	August 30, 1974, Emerg; September 29, 1978, Reg; August 5, 2010, Susp.	.....do	Do.
Oklahoma:				
Afton, Town of, Ottawa County	400155	March 30, 1976, Emerg; January 3, 1986, Reg; August 5, 2010, Susp.	.....do	Do.
Commerce, City of, Ottawa County	400156	February 7, 1983, Emerg; July 18, 1985, Reg; August 5, 2010, Susp.	.....do	Do.
Delaware County, Unincorporated Areas.	400502	August 2, 1988, Emerg; March 1, 1990, Reg; August 5, 2010, Susp.	.....do	Do.
Fairland, Town of, Ottawa County	400377	June 29, 1990, Emerg; January 1, 1992, Reg; August 5, 2010, Susp.	.....do	Do.
Grove, City of, Delaware County	400385	April 12, 1976, Emerg; February 18, 1981, Reg; August 5, 2010, Susp.	.....do	Do.
Jay, Town of, Delaware County	400057	August 5, 1976, Emerg; July 5, 1978, Reg; August 5, 2010, Susp.	.....do	Do.

State and location	Community No.	Effective date authorization/cancellation of sale of flood insurance in community	Current effective map date	Date certain Federal assistance no longer available in SFHAs
Miami, City of, Ottawa County	400157	November 29, 1974, Emerg; December 16, 1980, Reg; August 5, 2010, Susp.	.....do	Do.
Ottawa County, Unincorporated Areas	400154	November 19, 1980, Emerg; December 2, 1988, Reg; August 5, 2010, Susp.	.....do	Do.
Picher, City of, Ottawa County	400159	May 25, 1976, Emerg; September 21, 1982, Reg; August 5, 2010, Susp.	.....do	Do.
Wyandotte, Town of, Ottawa County	400161	July 12, 1976, Emerg; December 17, 1987, Reg; August 5, 2010, Susp.	.....do	Do.
Region VII				
Kansas:				
Baldwin City, City of, Douglas County	200088	June 23, 1975, Emerg; January 2, 1980, Reg; August 5, 2010, Susp.	.....do	Do.
Douglas County, Unincorporated Areas	200087	May 30, 1975, Emerg; March 2, 1981, Reg; August 5, 2010, Susp.	.....do	Do.
Region VIII				
South Dakota:				
Clay County, Unincorporated Areas	460259	May 16, 1986, Emerg; April 1, 1987, Reg; August 5, 2010, Susp.	.....do	Do.
Vermillion, City of, Clay County	460015	June 24, 1975, Emerg; January 30, 1984, Reg; August 5, 2010, Susp.	.....do	Do.
Wyoming:				
Jackson, Town of, Teton County	560052	August 8, 1975, Emerg; May 4, 1989, Reg; August 5, 2010, Susp.	.....do	Do.
Teton County, Unincorporated Areas	560094	April 19, 1978, Emerg; May 4, 1989, Reg; August 5, 2010, Susp.	.....do	Do.
Region IX				
Nevada:				
Caliente, City of, Lincoln County	320015	August 22, 1975, Emerg; June 1, 1982, Reg; August 5, 2010, Susp.	.....do	Do.
Lincoln County, Unincorporated Areas	320014	December 12, 1983, Emerg; March 1, 1984, Reg; August 5, 2010, Susp.	.....do	Do.

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

Dated: July 15, 2010.

Sandra K. Knight,

Deputy Federal Insurance and Mitigation Administrator, Mitigation.

[FR Doc. 2010–18449 Filed 7–27–10; 8:45 am]

BILLING CODE 9110–12–P

DEPARTMENT OF HOMELAND SECURITY

Federal Emergency Management Agency

44 CFR Part 67

[Docket ID FEMA–2010–0003]

Final Flood Elevation Determinations

AGENCY: Federal Emergency Management Agency, DHS.

ACTION: Final rule.

SUMMARY: Base (1% annual-chance) Flood Elevations (BFEs) and modified BFEs are made final for the communities listed below. The BFEs and modified BFEs are the basis for the floodplain management measures that each community is required either to adopt or to show evidence of being already in effect in order to qualify or remain qualified for participation in the National Flood Insurance Program (NFIP).

DATES: The date of issuance of the Flood Insurance Rate Map (FIRM) showing BFEs and modified BFEs for each community. This date may be obtained by contacting the office where the maps are available for inspection as indicated in the table below.

ADDRESSES: The final BFEs for each community are available for inspection at the office of the Chief Executive Officer of each community. The respective addresses are listed in the table below.

FOR FURTHER INFORMATION CONTACT: Kevin C. Long, Acting Chief, Engineering Management Branch, Federal Insurance and Mitigation Administration, Federal Emergency Management Agency, 500 C Street, SW., Washington, DC 20472, (202) 646–2820, or (e-mail) *kevin.long@dhs.gov.*

SUPPLEMENTARY INFORMATION: The Federal Emergency Management Agency (FEMA) makes the final determinations listed below for the modified BFEs for each community listed. These modified elevations have been published in newspapers of local circulation and ninety (90) days have elapsed since that publication. The Deputy Federal Insurance and Mitigation Administrator has resolved any appeals resulting from this notification.

This final rule is issued in accordance with section 110 of the Flood Disaster Protection Act of 1973, 42 U.S.C. 4104, and 44 CFR part 67. FEMA has developed criteria for floodplain management in floodprone areas in accordance with 44 CFR part 60.

Interested lessees and owners of real property are encouraged to review the proof Flood Insurance Study and FIRM available at the address cited below for each community. The BFEs and modified BFEs are made final in the communities listed below. Elevations at selected locations in each community are shown.

National Environmental Policy Act. This final rule is categorically excluded from the requirements of 44 CFR part 10, Environmental Consideration. An environmental impact assessment has not been prepared.

Regulatory Flexibility Act. As flood elevation determinations are not within

the scope of the Regulatory Flexibility Act, 5 U.S.C. 601–612, a regulatory flexibility analysis is not required.

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

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

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

List of Subjects in 44 CFR Part 67

Administrative practice and procedure, Flood insurance, Reporting and recordkeeping requirements.

■ Accordingly, 44 CFR part 67 is amended as follows:

PART 67—[AMENDED]

■ 1. The authority citation for part 67 continues to read as follows:

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

§ 67.11 [Amended]

■ 2. The tables published under the authority of § 67.11 are amended as follows:

Flooding source(s)	Location of referenced elevation	* Elevation in feet (NGVD) + Elevation in feet (NAVD) # Depth in feet above ground ∧ Elevation in meters (MSL) Modified	Communities affected
Coffee County, Alabama, and Incorporated Areas Docket No.: FEMA–B–1053			
Beaverdam Creek	Approximately 3,492 feet upstream of the confluence with the Pea River.	+199	City of Elba.
	Approximately 6,718 feet upstream of the confluence with the Pea River.	+204	
Pea River	Approximately 3,160 feet downstream of the intersection of County Road 404 and Reese Avenue.	+192	City of Elba, Unincorporated Areas of Coffee County.
	Approximately 13,918 feet upstream of the confluence with the Pea River.	+206	
Whitewater Creek	Approximately 2,000 feet upstream of State Route 203	+205	City of Elba, Unincorporated Areas of Coffee County.
	Approximately 14,458 feet upstream of State Route 203	+206	
Wilkerson Creek	At the Geneva County boundary	+135	Unincorporated Areas of Coffee County.
	Approximately 2,140 feet upstream of the Geneva County boundary.	+138	
Wilson Mill Creek	Approximately 390 feet downstream of County Road 45	+135	Unincorporated Areas of Coffee County.
	Just downstream of County Road 45	+137	

* National Geodetic Vertical Datum.
+ North American Vertical Datum.
# Depth in feet above ground.
∧ Mean Sea Level, rounded to the nearest 0.1 meter.

ADDRESSES

City of Elba
Maps are available for inspection at 200 Buford Street, Elba, AL 36323.

Unincorporated Areas of Coffee County
Maps are available for inspection at 1065 East McKinnon Street, New Brockton, AL 36351.

La Plata County, Colorado, and Incorporated Areas Docket No.: FEMA–B–1051			
Grimes Creek	Approximately 0.5 mile downstream of County Road 501	+7674	Unincorporated Areas of La Plata County.
	Approximately 1,400 feet upstream of West Grimes Creek Road.	+7776	
Junction Creek	At Pleasant Drive in Durango County	+6659	Unincorporated Areas of La Plata County.
	Approximately 0.2 mile upstream of the San Juan National Forest boundary.	+6996	
Los Pinos River	Approximately 1.2 mile downstream of U.S. Route 160B	+6826	Town of Bayfield, Unincorporated Areas of La Plata County.
	At the Vallecito Reservoir Dam	+7533	

Flooding source(s)	Location of referenced elevation	* Elevation in feet (NGVD) + Elevation in feet (NAVD) # Depth in feet above ground ∧ Elevation in meters (MSL) Modified	Communities affected
Middle Creek	Approximately 0.6 mile downstream of County Road 501	+7674	Unincorporated Areas of La Plata County.
	At West Grimes Creek Road	+7717	
Vallecito Creek	Approximately 0.5 mile downstream of County Road 501	+7674	Unincorporated Areas of La Plata County.
	At the Vallecito Campground/San Juan National Forest boundary.	+7918	

* National Geodetic Vertical Datum.
+ North American Vertical Datum.
# Depth in feet above ground.
∧ Mean Sea Level, rounded to the nearest 0.1 meter.

ADDRESSES

Town of Bayfield
Maps are available for inspection at P.O. Box 80, Bayfield, CO 81122.

Unincorporated Areas of La Plata County
Maps are available for inspection at 1060 East 2nd Avenue, Durango, CO 81301.

Russell County, Kentucky, and Incorporated Areas
Docket No.: FEMA–B–1040

Cumberland River	Approximately 3,700 feet downstream of the confluence with Lester Creek.	+565	Unincorporated Areas of Russell County.
	Just downstream of the Wolf Creek Dam	+577	
Lake Cumberland	Just upstream of the Wolf Creek Dam	+760	City of Jamestown, Unincorporated Areas of Russell County.
	Just downstream of the confluence with Thomas Branch	+760	

* National Geodetic Vertical Datum.
+ North American Vertical Datum.
# Depth in feet above ground.
∧ Mean Sea Level, rounded to the nearest 0.1 meter.

ADDRESSES

City of Jamestown
Maps are available for inspection at 202 Monument Square, Jamestown, KY 42629.

Unincorporated Areas of Russell County
Maps are available for inspection at 1 Public Square, Jamestown, KY 42629.

Valencia County, New Mexico, and Incorporated Areas
Docket No.: FEMA–B–1022

Rancho Cielo Arroyo 3	At the Belen Highline Canal	+4876	Unincorporated Areas of Valencia County.
	Approximately 7,900 feet upstream of I–25	+5018	
Rancho Cielo Arroyo 3, Tributary #1.	At the confluence with Rancho Cielo Arroyo 3	+4840	Unincorporated Areas of Valencia County.
	Approximately 2,260 feet upstream of the confluence with Rancho Cielo Arroyo 3.	+4987	
Rancho Cielo Arroyo 5	At the Belen Highline Canal	+4870	Unincorporated Areas of Valencia County.
	Approximately 16,700 feet upstream of I–25	+5056	
Rancho Cielo Arroyo 5, Tributary #1.	At the confluence with Rancho Cielo Arroyo 5	+4931	Unincorporated Areas of Valencia County.
	Approximately 5,370 feet upstream of the confluence with Rancho Cielo Arroyo 5.	+5056	
Rancho Cielo Arroyo 6	At the Belen Highline Canal	+4873	Unincorporated Areas of Valencia County.
	Approximately 31,900 feet upstream of I–25	+4873	
Rancho Cielo Arroyo 8	At the Belen Highline Canal	+4880	Unincorporated Areas of Valencia County.
	Approximately 32,700 feet upstream of I–25	+5274	

Flooding source(s)	Location of referenced elevation	* Elevation in feet (NGVD) + Elevation in feet (NAVD) # Depth in feet above ground ∧ Elevation in meters (MSL) Modified	Communities affected
Rancho Cielo Arroyo 9	At the Belen Highline Canal	+4877	Unincorporated Areas of Valencia County.
	Approximately 14,200 feet upstream of I–25	+5145	
Rancho Cielo Arroyo 9, Tributary #1.	At the confluence with Rancho Cielo Arroyo 9	+5018	Unincorporated Areas of Valencia County.
	Approximately 6,150 feet upstream of the confluence with Rancho Cielo Arroyo 9.	+5176	

* National Geodetic Vertical Datum.
+ North American Vertical Datum.
# Depth in feet above ground.
∧ Mean Sea Level, rounded to the nearest 0.1 meter.

ADDRESSES

Unincorporated Areas of Valencia County

Maps are available for inspection at 444 Los Lunas Avenue, Los Lunas, NM 87031.

Pepin County, Wisconsin, and Incorporated Areas
Docket No.: FEMA–B–1012

Chippewa River	Approximately 7,000 feet downstream of the new U.S. Route 10 bridge.	+712	City of Durand, Unincorporated Areas of Pepin County.
	Approximately 6,000 feet upstream of the confluence with Bear Creek.	+717	
Mississippi River	Approximately at the intersection of Lakeport Road and State Highway 35.	+681	Unincorporated Areas of Pepin County, Village of Stockholm.
	At the Pierce County boundary	+681	

* National Geodetic Vertical Datum.
+ North American Vertical Datum.
# Depth in feet above ground.
∧ Mean Sea Level, rounded to the nearest 0.1 meter.

ADDRESSES

City of Durand

Maps are available for inspection at City Hall, 104 East Main Street, Durand, WI 54736.

Unincorporated Areas of Pepin County

Maps are available for inspection at the Pepin County Government Center, 740 7th Avenue West, Pepin, WI 54736.

Village of Stockholm

Maps are available for inspection at the Village Hall, 2041 Spring Street, Stockholm, WI 54769.

(Catalog of Federal Domestic Assistance No. 97.022, "Flood Insurance.")

Dated: July 19, 2010.

Sandra K. Knight,

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

[FR Doc. 2010–18453 Filed 7–27–10; 8:45 am]

BILLING CODE 9110–12–P

DEPARTMENT OF TRANSPORTATION

Surface Transportation Board

49 CFR Part 1002

[Docket No. EP 542 (Sub-No. 17)]

Regulations Governing Fees for Services Performed in Connection With Licensing and Related Services—2010 Update

AGENCY: Surface Transportation Board, DOT.

ACTION: Final rules.

SUMMARY: The Board adopts its 2010 User-Fee Update and revises its fee schedule to reflect increased costs associated with the January 2010 government salary increases, to reflect government fringe benefits, and to consider changes to the Board's overhead costs.

DATES: *Effective Date:* These rules are effective on August 27, 2010.

FOR FURTHER INFORMATION CONTACT: David T. Groves, (202) 245–0327, or Anne Quinlan, (202) 245–0309. [TDD for the hearing impaired: 1–800–877–8339.]

SUPPLEMENTARY INFORMATION: The Board's regulations at 49 CFR 1002.3 provide for annual updates of the Board's User-Fee schedule. Fees are generally revised based on the cost-study formula set forth at 49 CFR

1002.3(d). The fee changes adopted here, which reflect a combination of the increased wage costs plus changes to various Board overhead costs (mainly decreases from their comparable 2009 levels), result from the mechanical application of the update formula in 49 CFR 1002.3(d). Application of the formula generally results in fee amounts in this 2010 update that either remain unchanged or decrease from their respective 2009 update levels. No new fees are proposed in this proceeding. Therefore, the Board finds that notice and comment are unnecessary for this proceeding. *See Regulations Governing Fees For Services—1990 Update,* 7 I.C.C.2d 3 (1990); *Regulations Governing Fees For Services—1991 Update,* 8 I.C.C.2d 13 (1991); and *Regulations Governing Fees For Services—1993 Update,* 9 I.C.C.2d 855 (1993).

The Board concludes that the fee changes adopted here will not have a significant economic impact on a substantial number of small entities because the Board's regulations provide for waiver of filing fees for those entities that can make the required showing of financial hardship.

Additional information is contained in the Board's decision. To obtain a free copy of the full decision, visit the Board's Web site at *http://www.stb.dot.gov* or call the Board's Information Officer at (202) 245–0245. [Assistance for the hearing impaired is available through Federal Information Relay Services (FIRS): (800) 877–8339.]

List of Subjects in 49 CFR Part 1002

Administrative practice and procedure, Common carriers, and Freedom of information.

Decided: July 22, 2010.

By the Board, Chairman Elliott, Vice Chairman Mulvey, and Comissioner Nottingham.

Jeffrey Herzig,

Clearance Clerk.

■ For the reasons set forth in the preamble, title 49, chapter X, part 1002, of the Code of Federal Regulations is amended as follows:

PART 1002—FEES

■ 1. The authority citation for part 1002 continues to read as follows:

Authority: 5 U.S.C. 552(a)(4)(A) and 553; 31 U.S.C. 9701 and 49 U.S.C. 721(a).

■ 2. Section 1002.1 is amended by revising paragraphs (b) and (c); paragraph (f)(1); the table in paragraph (g)(6); to read as follows:

§ 1002.1 Fees for record search, review, copying, certification, and related services.

* * * * *

(b) Service involved in examination of tariffs or schedules for preparation of certified copies of tariffs or schedules or extracts therefrom at the rate of $41.00 per hour.

(c) Service involved in checking records to be certified to determine authenticity, including clerical work, etc., identical thereto, at the rate of $28.00 per hour.

* * * * *

(f) * * *

(1) A fee of $71.00 per hour for professional staff time will be charged when it is required to fulfill a request for ADP data.

* * * * *

(g) * * *

(6) * * *

Grade	Rate	Grade	Rate
GS–1	$12.01	GS–9	$28.04
GS–2	13.07	GS–10	30.88
GS–3	14.73	GS–11	33.92
GS–4	16.54	GS–12	40.66
GS–5	18.50	GS–13	48.21
GS–6	20.63	GS–14	57.13
GS–7	22.92	GS–15 and over	67.21
GS–8	25.38		

* * * * *

■ 3. In § 1002.2, paragraph (f) is revised as follows:

§ 1002.2 Filing fees.

(a) * * *

(f) *Schedule of filing fees.*

Type of proceeding	Fee
PART I: Non-Rail Applications or Proceedings to Enter Upon a Particular Financial Transaction or Joint Arrangement	
(1) An application for the pooling or division of traffic	$4,400.
(2)(i) An application involving the purchase, lease, consolidation, merger, or acquisition of control of a motor carrier of passengers under 49 U.S.C. 14303.	$2,000.
(ii) A petition for exemption under 49 U.S.C. 13541 (other than a rulemaking) filed by a non-rail carrier not otherwise covered.	$3,200.
(iii) A petition to revoke an exemption filed under 49 U.S.C. 13541(d)	$2,600.
(3) An application for approval of a non-rail rate association agreement. 49 U.S.C. 13703.	$27,600.
(4) An application for approval of an amendment to a non-rail rate association agreement:	
(i) Significant amendment	$4,600.
(ii) Minor amendment	$100.
(5) An application for temporary authority to operate a motor carrier of passengers. 49 U.S.C. 14303(i)	$500.
(6) A notice of exemption for transaction within a motor passenger corporate family that does not result in adverse changes in service levels, significant operational changes, or a change in the competitive balance with motor passenger carriers outside the corporate family.	$1,700.
(7)–(10) [Reserved]	
PART II: Rail Licensing Proceedings other than Abandonment or Discontinuance Proceedings	
(11) (i) An application for a certificate authorizing the extension, acquisition, or operation of lines of railroad. 49 U.S.C. 10901.	$7,200.

Type of proceeding	Fee
(ii) Notice of exemption under 49 CFR 1150.31–1150.35	$1,800.
(iii) Petition for exemption under 49 U.S.C. 10502	$12,500.
(12) (i) An application involving the construction of a rail line	$74,500.
(ii) A notice of exemption involving construction of a rail line under 49 CFR 1150.36	$1,800.
(iii) A petition for exemption under 49 U.S.C. 10502 involving construction of a rail line	$74,500.
(iv) A request for determination of a dispute involving a rail construction that crosses the line of another carrier under 49 U.S.C. 10902(d).	$250.
(13) A Feeder Line Development Program application filed under 49 U.S.C. 10907(b)(1)(A)(i) or 10907(b)(1)(A)(ii)	$2,600.
(14)(i) An application of a class II or class III carrier to acquire an extended or additional rail line under 49 U.S.C. 10902.	$6,200.
(ii) Notice of exemption under 49 CFR 1150.41–1150.45	$1,800.
(iii) Petition for exemption under 49 U.S.C. 10502 relating to an exemption from the provisions of 49 U.S.C. 10902.	$6,600.
(15) A notice of a modified certificate of public convenience and necessity under 49 CFR 1150.21–1150.24	$1,700.
(16) An application for a land-use-exemption permit for a facility existing as of October 16, 2008 under 49 U.S.C. 10909.	$6,000.
(17) An application for a land-use-exemption permit for a facility not existing as of October 16, 2008 under 49 U.S.C. 10909.	$21,100.
(18)–(20) [Reserved]	
PART III: Rail Abandonment or Discontinuance of Transportation Services Proceedings	
(21)(i) An application for authority to abandon all or a portion of a line of railroad or discontinue operation thereof filed by a railroad (except applications filed by Consolidated Rail Corporation pursuant to the Northeast Rail Service Act [Subtitle E of Title XI of Pub. L. 97–35], bankrupt railroads, or exempt abandonments).	$22,100.
(ii) Notice of an exempt abandonment or discontinuance under 49 CFR 1152.50	$3,600.
(iii) A petition for exemption under 49 U.S.C. 10502	$6,300.
(22) An application for authority to abandon all or a portion of a line of a railroad or operation thereof filed by Consolidated Rail Corporation pursuant to Northeast Rail Service Act.	$450.
(23) Abandonments filed by bankrupt railroads	$1,800.
(24) A request for waiver of filing requirements for abandonment application proceedings	$1,800.
(25) An offer of financial assistance under 49 U.S.C. 10904 relating to the purchase of or subsidy for a rail line proposed for abandonment.	$1,500.
(26) A request to set terms and conditions for the sale of or subsidy for a rail line proposed to be abandoned	$22,600.
(27) (i) A request for a trail use condition in an abandonment proceeding under 16 U.S.C.1247(d)	$250.
(ii) A request to extend the period to negotiate a trail use agreement	$450.
(28)–(35) [Reserved]	
PART IV: Rail Applications to Enter Upon a Particular Financial Transaction or Joint Arrangement	
(36) An application for use of terminal facilities or other applications under 49 U.S.C. 11102	$18,900.
(37) An application for the pooling or division of traffic. 49 U.S.C. 11322	$10,200.
(38) An application for two or more carriers to consolidate or merge their properties or franchises (or a part thereof) into one corporation for ownership, management, and operation of the properties previously in separate ownership. 49 U.S.C. 11324:	
(i) Major transaction	$1,489,900.
(ii) Significant transaction	$298,000.
(iii) Minor transaction	$7,500.
(iv) Notice of an exempt transaction under 49 CFR 1180.2(d)	$1,700.
(v) Responsive application	$7,500.
(vi) Petition for exemption under 49 U.S.C. 10502	$9,300.
(vii) A request for waiver or clarification of regulations filed in a major financial proceeding as defined at 49 CFR 1180.2(a).	$5,500.
(39) An application of a non-carrier to acquire control of two or more carriers through ownership of stock or otherwise. 49 U.S.C. 11324:	
(i) Major transaction	$1,489,900.
(ii) Significant transaction	$298,000.
(iii) Minor transaction	$7,500.
(iv) A notice of an exempt transaction under 49 CFR 1180.2(d)	$1,300.
(v) Responsive application	$7,500.
(vi) Petition for exemption under 49 U.S.C. 10502	$9,300.
(vii) A request for waiver or clarification of regulations filed in a major financial proceeding as defined at 49 CFR 1180.2(a).	$5,500.
(40) An application to acquire trackage rights over, joint ownership in, or joint use of any railroad lines owned and operated by any other carrier and terminals incidental thereto. 49 U.S.C. 11324:	
(i) Major transaction	$1,489,900.
(ii) Significant transaction	$298,000.
(iii) Minor transaction	$7,500.
(iv) Notice of an exempt transaction under 49 CFR 1180.2(d)	$1,200.
(v) Responsive application	$7,500.
(vi) Petition for exemption under 49 U.S.C. 10502	$9,300.
(vii) A request for waiver or clarification of regulations filed in a major financial proceeding as defined at 49 CFR 1180.2(a).	$5,500.

Type of proceeding	Fee
(41) An application of a carrier or carriers to purchase, lease, or contract to operate the properties of another, or to acquire control of another by purchase of stock or otherwise. 49 U.S.C. 11324:	
(i) Major transaction	$1,489,900.
(ii) Significant transaction	$298,000.
(iii) Minor transaction	$7,500.
(iv) Notice of an exempt transaction under 49 CFR 1180.2(d)	$1,400.
(v) Responsive application	$7,500.
(vi) Petition for exemption under 49 U.S.C. 10502	$6,600.
(vii) A request for waiver or clarification of regulations filed in a major financial proceeding as defined at 49 CFR 1180.2(a).	$5,500.
(42) Notice of a joint project involving relocation of a rail line under 49 CFR 1180.2(d)(5)	$2,400.
(43) An application for approval of a rail rate association agreement. 49 U.S.C. 10706	$69,700.
(44) An application for approval of an amendment to a rail rate association agreement. 49 U.S.C. 10706:	
(i) Significant amendment	$12,900.
(ii) Minor amendment	$100.
(45) An application for authority to hold a position as officer or director under 49 U.S.C. 11328	$750.
(46) A petition for exemption under 49 U.S.C. 10502 (other than a rulemaking) filed by rail carrier not otherwise covered.	$8,000.
(47) National Railroad Passenger Corporation (Amtrak) conveyance proceeding under 45 U.S.C. 562	$250.
(48) National Railroad Passenger Corporation (Amtrak) compensation proceeding under Section 402(a) of the Rail Passenger Service Act.	$250.
(49)–(55) [Reserved]	
PART V: Formal Proceedings	
(56) A formal complaint alleging unlawful rates or practices of carriers:	
(i) A formal complaint filed under the coal rate guidelines (Stand-Alone Cost Methodology) alleging unlawful rates and/or practices of rail carriers under 49 U.S.C. 10704(c)(1).	$350.
(ii) A formal complaint involving rail maximum rates filed under the Simplified-SAC methodology	$350.
(iii) A formal complaint involving rail maximum rates filed under the Three Benchmark methodology	$150.
(iv) All other formal complaints (except competitive access complaints)	$20,600.
(v) Competitive access complaints	$150.
(vi) A request for an order compelling a rail carrier to establish a common carrier rate	$250.
(57) A complaint seeking or a petition requesting institution of an investigation seeking the prescription or division of joint rates or charges. 49 U.S.C. 10705.	$8,800.
(58) A petition for declaratory order:	
(i) A petition for declaratory order involving a dispute over an existing rate or practice which is comparable to a complaint proceeding.	$1,000.
(ii) All other petitions for declaratory order	$1,400.
(59) An application for shipper antitrust immunity. 49 U.S.C. 10706(a)(5)(A)	$7,000.
(60) Labor arbitration proceedings	$250.
(61)(i) An appeal of a Surface Transportation Board decision on the merits or petition to revoke an exemption pursuant to 49 U.S.C. 10502(d).	$250.
(ii) An appeal of a Surface Transportation Board decision on procedural matters except discovery rulings	$350.
(62) Motor carrier undercharge proceedings	$250.
(63)(i) Expedited relief for service inadequacies: A request for expedited relief under 49 U.S.C. 11123 and 49 CFR part 1146 for service emergency.	$250.
(ii) Expedited relief for service inadequacies: A request for temporary relief under 49 U.S.C. 10705 and 11102, and 49 CFR part 1147 for service inadequacy.	$250.
(64) A request for waiver or clarification of regulations except one filed in an abandonment or discontinuance proceeding, or in a major financial proceeding as defined at 49 CFR 1180.2(a).	$550.
(65)–(75) [Reserved]	
PART VI: Informal Proceedings	
(76) An application for authority to establish released value rates or ratings for motor carriers and freight forwarders of household goods under 49 U.S.C. 14706.	$1,200.
(77) An application for special permission for short notice or the waiver of other tariff publishing requirements	$100.
(78) The filing of tariffs, including supplements, or contract summaries	$1 per page. ($24 minimum charge.)
(79) Special docket applications from rail and water carriers:	
(i) Applications involving $25,000 or less	$75.
(ii) Applications involving over $25,000	$150.
(80) Informal complaint about rail rate applications	$600.
(81) Tariff reconciliation petitions from motor common carriers:	
(i) Petitions involving $25,000 or less	$75.
(ii) Petitions involving over $25,000	$150.
(82) Request for a determination of the applicability or reasonableness of motor carrier rates under 49 U.S.C. 13710(a)(2) and (3).	$200.
(83) Filing of documents for recordation. 49 U.S.C. 11301 and 49 CFR 1177.3(c)	$41 per document.
(84) Informal opinions about rate applications (all modes)	$250.
(85) A railroad accounting interpretation	$1,100.
(86) (i) A request for an informal opinion not otherwise covered	$1,400.

Type of proceeding	Fee
(ii) A proposal to use on a voting trust agreement pursuant to 49 CFR 1013 and 49 CFR 1180.4(b)(4)(iv) in connection with a major control proceeding as defined at 49 CFR 1180.2(a).	$5,100.
(iii) A request for an informal opinion on a voting trust agreement pursuant to 49 CFR 1013.3(a) not otherwise covered.	$500.
(87) Arbitration of Certain Disputes Subject to the Statutory Jurisdiction of the Surface Transportation Board under 49 CFR 1108:	
(i) Complaint	$75.
(ii) Answer (per defendant), Unless Declining to Submit to Any Arbitration	$75.
(iii) Third Party Complaint	$75.
(iv) Third Party Answer (per defendant), Unless Declining to Submit to Any Arbitration	$75.
(v) Appeals of Arbitration Decisions or Petitions to Modify or Vacate an Arbitration Award	$150.
(88) Basic fee for STB adjudicatory services not otherwise covered	$250.
(89)–(95) [Reserved]	
PART VII: Services	
(96) Messenger delivery of decision to a railroad carrier's Washington, DC, agent	$32 per delivery.
(97) Request for service or pleading list for proceedings	$24 per list.
(98) Processing the paperwork related to a request for the Carload Waybill Sample to be used in a Surface Transportation Board or State proceeding that:	
(i) Does not require a **Federal Register** notice:	
(a) Set cost portion	$150.
(b) Sliding cost portion	$47 per party.
(ii) Does require a **Federal Register** notice:	
(a) Set cost portion	$400.
(b) Sliding cost portion	$47 per party.
(99)(i) Application fee for the Surface Transportation Board's Practitioners' Exam	$150.
(ii) Practitioners' Exam Information Package	$25.
(100) Carload Waybill Sample data:	
(i) Requests for Public Use File for all years prior to the most current year Carload Waybill Sample data available, provided on CD–R.	$250 per year.
(ii) Specialized programming for Waybill requests to the Board	$112 per hour.

* * * * *

[FR Doc. 2010–18460 Filed 7–27–10; 8:45 am]

BILLING CODE 4915–01–P

Proposed Rules

Federal Register
Vol. 75, No. 144
Wednesday, July 28, 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

Grain Inspection, Packers and Stockyards Administration

9 CFR Part 201

RIN 0580–AB07

Implementation of Regulations Required Under Title XI of the Food, Conservation and Energy Act of 2008; Conduct in Violation of the Act

AGENCY: Grain Inspection, Packers and Stockyards Administration, USDA.

ACTION: Proposed rule; extension of comment period.

SUMMARY: The Department of Agriculture (USDA), Grain Inspection, Packers and Stockyards Administration (GIPSA) is proposing to add several new sections to the regulations under the Packers and Stockyards Act, 1921, as amended and supplemented (P&S Act). The new regulations that GIPSA is proposing would describe and clarify conduct that violates the P&S Act and allow for more effective and efficient enforcement by GIPSA. The proposed regulations would clarify conditions for industry compliance with the P&S Act and provide for a fairer market place.

DATES: We will consider comments we receive by November 22, 2010.

ADDRESSES: We invite you to submit comments on this proposed rule. You may submit comments by any of the following methods:

- *E-mail: comments.gipsa@usda.gov.*
- *Mail:* Tess Butler, GIPSA, USDA, 1400 Independence Avenue, SW., Room 1643–S, Washington, DC 20250–3604.
- *Fax:* (202) 690–2173.
- *Hand Delivery or Courier:* Tess Butler, GIPSA, USDA, 1400 Independence Avenue, SW., Room 1643–S, Washington, DC 20250–3604.
- *Federal e-Rulemaking Portal: http://www.regulation.gov.* Follow the on-line instructions for submitting comments.

Instructions: All comments will become a matter of public record and should be identified as "Farm Bill Comments," making reference to the date and page number of this issue of the **Federal Register.** Comments will be available for public inspection at *http://www.regulations.gov* and in the above office during regular business hours (7 CFR 1.27(b)). Please call GIPSA Management Support Services staff at (202) 720–7486 to arrange a public inspection of comments.

FOR FURTHER INFORMATION CONTACT: S. Brett Offutt, Director, Policy and Litigation Division, P&SP, GIPSA, 1400 Independence Ave., SW., Washington, DC 20250, (202) 720–7363, *s.brett.offutt@usda.gov.*

SUPPLEMENTARY INFORMATION:

Background

The Department of Agriculture, Grain Inspection, Packers and Stockyards Administration (GIPSA) published a proposed rule in the **Federal Register** on June 22, 2010 (75 FR 35338) proposing to add several new sections to the regulations under the Packers and Stockyards Act of 1921, as amended and supplemented (P&S Act). The new regulations that GIPSA is proposing would describe and clarify conduct that violates the P&S Act and allow for more effective and efficient enforcement by GIPSA. The proposed regulations would clarify conditions for industry compliance with the P&S Act and provide for a fairer market place. We have received comments asking for an extension of the comment period, and others asking that the comment not be extended. After review, we have decided to extend the comment period until November 22, 2010.

Authority: 7 U.S.C. 181–229, 229c.

Alan R. Christian,

Acting Administrator, Grain Inspection, Packers and Stockyards Administration.

[FR Doc. 2010–18458 Filed 7–26–10; 11:15 am]

BILLING CODE 3410–KD–P

DEPARTMENT OF COMMERCE

International Trade Administration

19 CFR Part 351

[Docket No. 100614263–0263–01]

RIN 06–25–AA84

Antidumping and Countervailing Duty Proceedings: Electronic Filing Procedures; Administrative Protective Order Procedures

AGENCY: Import Administration, International Trade Administration, Department of Commerce.

ACTION: Proposed Rule; Request for Comments.

SUMMARY: The Department of Commerce ("the Department") proposes to amend its regulations governing the submission of information to the Department in antidumping duty ("AD") and countervailing duty ("CVD") proceedings to adopt rules of practice and procedure that will incorporate changes resulting from the Department's implementation of an electronic filing and documents management program. More detailed procedures for electronic filing will be set forth in a document separate from the regulations that will be entitled "IA ACCESS Handbook On Electronic Filing Procedures" ("IA ACCESS Handbook"), which the Department intends to publish on its Web site at *http://www.trade.gov/ia* by the effective date of the Final Rule.

DATES: To be assured of consideration, written comments must be received no later than September 27, 2010.

ADDRESSES: Written comments should be submitted by using the Federal eRulemaking Portal at *http://www.Regulations.gov.* All comments must be submitted into Docket Number ITA–2010–0003. All comments should refer to RIN 0625–AA84. If a submitter is unable to submit comments online, the Department will accept hardcopy comments by mail or hand delivery/courier. Please submit the original and two copies of hardcopy comments to the Secretary of Commerce, Attn: Import Administration, APO/Dockets Unit, Room 1870, U.S. Department of Commerce, Constitution Avenue and 14th Street NW., Washington, DC 20230.

FOR FURTHER INFORMATION CONTACT: Evangeline Keenan at (202) 482–3354,

Mykhaylo Gryzlov at (202) 482–0833 or Brian Soiset at (202) 482–1284.

SUPPLEMENTARY INFORMATION:

Background

The Department proposes to amend its regulations governing the submission of information to the Department in antidumping and countervailing duty proceedings to adopt rules of practice and procedure that will incorporate changes resulting from the Department's implementation of an electronic filing and documents management program named Import Administration Antidumping and Countervailing Duty Centralized Electronic Service System, or IA ACCESS. The goal of this system is to expand the public's access to information in antidumping and countervailing duty proceedings by making all publicly filed documents available on the Internet. It will also allow interested parties to file all submissions (both public and business proprietary) with the Department using an internet connection. The Department envisions that such a system will create efficiencies in both the process and costs associated with filing and maintaining the documents. The ease of document submission will increase accessibility of submission to the Department by interested parties located within and outside the Washington, DC area. The Department is currently conducting a pilot program to test IA ACCESS. *See Import Administration IA ACCESS Pilot Program, Public Notice and Request For Comments,* 75 FR 32341 (June 8, 2010); *Import Administration IA ACCESS Pilot Program, Public Notice and Request For Comments; Correction,* 75 FR 34960 (June 21, 2010).

Explanation of Particular Provisions

Sections 351.103(a), 351.103(b), 351.103(c), and 351.103(d). Electronic and Manual Filing of Documents and Service Lists

Sections 351.103(a) and 351.103(b) describe the functions of Import Administration's Central Records Unit (CRU) and Administrative Protective Order and Dockets Unit (APO/Dockets Unit), as well as their location and office hours. The current regulations state that one function of the CRU is to maintain the Subsidies Library. However, CRU no longer maintains the Subsidies Library, which is now maintained by Import Administration's Subsidies Enforcement Office. Therefore, the Department proposes deleting the language referring to this function. The Department also proposes amending these sections to specify that the office hours pertain to Eastern Time and to clarify that the Department's official address is 14th Street and Constitution Avenue, NW, not Pennsylvania Avenue and 14th Street, NW. Additionally, the Department proposes deleting an extraneous period in "NW" in the addresses of the CRU and the APO/Dockets Unit.

Section 351.103(c) currently provides that while a party is free to provide the Department with a courtesy copy of a document, a document is not considered to be officially received by the Department unless it is submitted to the Import Administration's APO/Dockets Unit in Room 1870 and stamped with the date and, where necessary, the time of the receipt. To implement electronic filing procedures, the Department proposes amending the regulations so that the Department will consider a document to be officially received by the Department only when it is filed electronically in accordance with section 351.303(b)(2) unless a relevant exception applies.

The Department also proposes deleting the language stating that a party is free to provide the Department with a courtesy copy of a document. It has been the Department's experience that Import Administration staff will often accept electronic and/or hardcopy courtesy copies of documents from the submitter rather than wait for the official copy to be delivered via intra-Department mail to expedite review of the document. Because the Department will now require that documents be filed electronically, Import Administration staff will have faster access to filed submissions, thus reducing the need for courtesy copies.

The Department intends to require all documents to be filed electronically unless the submission meets the exception criteria in the IA ACCESS Handbook. For example, such exceptions include instances where a submitter does not have internet access or the submission itself cannot be submitted in an electronic format. In accordance with section 782(c) of the Tariff Act of 1930, as amended, ("the Act"), if a submitter experiences difficulty in filing a document electronically under circumstances for which an exception applies, the Department will consider the ability of the submitter and may modify the electronic filing requirement on a case-by-case basis.

Section 351.103(d)(1) currently requires each interested party to file a letter of appearance separately from any other document filed with the Department, with the exception of a petitioner filing a petition in an investigation. The Department proposes amending the regulations to specify that it is this letter of appearance that triggers the interested party's inclusion in the public service list for the segment of the proceeding. The amendment also includes a reference to the definition of "interested party" under section 351.102(b)(29). The Department is proposing this amendment to improve and clarify the explanation of how an interested party is placed on the public service list.

Sections 351.104(a), 351.104(b), 351.302(a), 351.302(c), and 351.302(d). Return of Material, Record of Proceedings, Extension of Time Limits, and Return of Untimely Filed or Unsolicited Material

Section 351.104(a) currently specifies which documents comprise the official record of an AD and CVD proceeding. The regulations state that the Secretary will not use factual information, written argument, or other material that the Secretary returns to the submitter. They also specify the circumstances under which the official record will include a copy of a returned document. Sections 351.302(a) and 351.302(d) set forth the procedures for requesting an extension of time limits and procedures for returning untimely filed submissions. Because the Department will be using an electronic filing system, rather than physically returning inadmissible electronic submissions, the Department will reject such submissions and send written notice of the rejection to the submitter. Thus, the Department proposes amending the regulations to replace the term "return" with "reject" in sections 351.104(a), 351.302(a), and 351.302(d).

Section 351.104(b) currently provides that the Secretary will maintain in the CRU a public record of each proceeding. The Department proposes amending the regulations to indicate that the public record will also be accessible online at *http://www.trade.gov/ia.*

Section 351.302(c) currently states that a request for an extension of a specific time limit must be filed in writing. The Department's experience with extension requests is that there are instances when an extension is requested by phone or by email, or the extension request is in the form of a letter, but not filed properly. The Department proposes amending the regulations to refer to section 351.303 to specify that an extension request must be in writing and filed properly with the Department through the new electronic filing system for consideration of an extension request.

Sections 351.303(a), 351.303(b), 351.303(c), 351.303(d), and 351.303(g). Filing, Document Identification, Format, Specifications and Markings, Service and Certifications

The Department proposes amending section 351.303 to require electronic filing of all documents unless a relevant exception applies. The Department also proposes to clarify the identification of documents, and to correct minor typographical errors in this section.

The Department proposes amending section 351.303(b) to add subparagraphs (1) through (4). Section 351.303(b) currently requires all documents to be addressed and submitted to the APO/Dockets Unit, Room 1870 between the hours of 8:30 a.m. and 5 p.m. on business days. The Department proposes amending this section by designating it as subparagraph (1) and specifying that manually filed submissions must be submitted between the hours of 8:30 a.m. and 5 p.m. Eastern Time on business days, but that electronically filed submissions must be filed by 5 p.m. Eastern Time on the due date. The reason for the distinction is that manually filed submissions may only be filed during business hours, but electronically filed submissions may be filed at any time, provided that they are filed in their entirety by 5 p.m. Eastern Time on the due date. The Department intends to include the term "Eastern Time" to clarify the time a submission is due when the submitter may be filing the submission from a different time zone. We also propose omitting the period after "NW" in the Department's address, which was a typographical error.

The Department proposes adding section 351.303(b)(2), which specifies that, notwithstanding sections 351.103, 351.302, 351.303, 351.304, 351.305, and 351.306 of the Department's procedures and rules, all documents must be filed electronically unless a relevant exception applies. Exceptions to the electronic filing requirements will be set forth in the IA ACCESS Handbook, which will be available at *http://www.trade.gov/ia.* The Department anticipates that the list of relevant exceptions may evolve over time, as the Department and the interested parties who use the electronic system gain experience with the electronic filing process and identify new exceptions that may be needed to accommodate previously unforeseen limitations both on the part of the Department and the users of the electronic filing system.

Furthermore, allowing exceptions to the electronic filing requirement meets the requirement in section 782(c) of the Act, which requires that a submitter notify the Department promptly of any difficulties encountered in submitting requested information in the form and manner requested, and that the submitter must suggest an alternative form in which to submit the requested information. The Department will consider the ability of the submitter, and may modify the electronic filing requirements on a case-by-case basis. The Department anticipates that the alternative suggestion that will be provided by the party would be to file the submission manually. Therefore, in the proposed regulations, the Department has not mentioned the requirement in section 782(c) of the Act that a person suggest an alternative form in which to submit the requested information. This omission does not in any way change a submitter's obligation to comply with section 782(c) of the Act. Section 351.303(b)(2) would also specify that a person making an electronic filing must comply with the procedures set forth in the IA ACCESS Handbook. These procedures may be subject to change at a future time. The Department intends to notify the public on Import Administration's website whenever it makes updates to the IA ACCESS Handbook.

The Department proposes adding section 351.303(b)(3) to specify that all submissions must be accompanied by a cover sheet as will be described in the IA ACCESS Handbook. The purpose of the cover sheet is to provide the Department with information indicating, among other things, the party filing the submission, the segment of the proceeding, and the type of submission being filed. The cover sheet will contain a barcode that will be used to identify and track the submissions. For electronic filings, the submitter will need to complete the cover sheet online at the time of filing. For manual filings, the submitter will need to complete the cover sheet, print it, and submit it as the cover to the submission. The person submitting the cover sheet is responsible for the accuracy of the information on the cover sheet.

The Department proposes adding section 351.303(b)(4) to identify and distinguish among the five document classifications that may be submitted to the Department. The reasons for this clarification are twofold. First, in the Department's experience, there has been some confusion among interested parties with regard to the identification and labeling of documents, especially with regard to documents containing double-bracketed information. Section 351.303(b)(4) is intended to standardize the identification and labeling of all documents. Second, a submitter will need to identify the document properly when completing the cover sheet and filing the document. The document identification will determine who will have access to the document. Misidentification of a document may result in the unauthorized disclosure of business proprietary information. We have moved the definition of "business proprietary version" from section 351.303(c)(2)(i), to proposed section 351.303(b)(4). We propose defining "business proprietary document or version, as applicable" rather than only "business proprietary version" to make the terminology consistent with that in proposed sections 351.303(b)(4)(i), (ii), and (iii).

The Department proposes adding sections 351.303(b)(4)(i), (ii), and (iii) to identify and define the three types of business proprietary submissions. The document described in section 351.303(b)(4)(i) is called "Business Proprietary Document—May Be Released Under APO." This business proprietary document contains only single-bracketed business proprietary information for which a party agrees to release under administrative protective order ("APO").

The document classifications described in sections 351.303(b)(4)(ii) and (iii) are business proprietary documents that use double-bracketing. The document described in section 351.303(b)(4)(ii) is called "Business Proprietary Document—May Not Be Released Under APO." This document may contain both single and double-bracketed business proprietary information, but the submitter does not agree to the release of the double-bracketed information under APO. In this document, the information inside the double brackets is included.

The third document classification described in section 351.303(b)(4)(iii) is called "Business Proprietary/APO Version—May Be Released Under APO." It will contain only single-bracketed business proprietary information. The submitter must omit the double-bracketed business proprietary information from this version because this version will be released under APO. This is why the term "APO Version" is included in the name of the document.

The Department proposes adding sections 351.303(b)(4)(iv) and (v), which identify the two types of public submissions. The first is the "Public Version," which corresponds to a business proprietary document, except it omits all business proprietary information, whether single or double-bracketed. This section also refers to the specific filing requirements for filing the

public version which is found in section 351.304(c). The second is the "Public Document," which contains only public information. There is no corresponding business proprietary document for a public document.

Section 351.303(c) deals with filing and service requirements under the one-day lag rule. In sections 351.303(c)(1), 351.303(c)(2)(ii), and 351.303(c)(2)(iii), the Department proposes deleting the requirement that a person must file multiple copies of each submission with the Department (*i.e.,* six copies of public documents, or the combination of: (A) six copies of the business proprietary version and (B) three copies of the public version of a document). The original reason for requiring multiple copies of a document was to make a copy available to each person assigned to the Import Administration team administering the proceeding. However, with implementation of electronic filing, the Import Administration team will be able to access all submissions electronically and print them from IA ACCESS. In section 351.303(c)(2)(i), the Department has deleted the sentence defining "business proprietary version" because it has been included in proposed section 351.303(b)(4).

Section 351.303(c)(1) currently states that a person must file six copies of each submission with the Department. Section 351.303(c)(2)(i) currently states a that person must file one copy of the business proprietary version of any document with the Department within the applicable time limit. The Department proposes deleting the references to copy and copies because the terms copy and copies imply paper submissions. The Department also proposes clarifying that the one-day lag rule does not apply to a petition, amendments to a petition, or any other submission filed prior to the initiation of an investigation. This amendment reflects our practice not to apply the one-day lag rule during the 20-day pre-initiation period. The reason for this practice is to ensure that a business proprietary document and public version are filed simultaneously in their final form. Under the one-day lag rule, the final business proprietary document and the public version are not due until the next business day after a business proprietary document is filed, often the next business day after an applicable deadline. When the Department has only 20 days to initiate an investigation, waiting one business day for the final version of a document further shortens an already short deadline, especially when petitioners may be required to file responses to requests for additional information. In addition, because of our obligation to provide a copy of the petition and all amendments to the petition to embassies of exporting countries named in a petition under section 351.202(f), the Department does not allow submissions under the one-day lag rule so that the embassies may obtain their copies as expeditiously as possible.

Section 351.303(c)(2)(ii) currently states that, although a person must file the final business proprietary version of a document with the Department, the person may serve only those pages containing bracketing corrections on other persons. The Department proposes amending this section to replace "business proprietary version of a document" with "business proprietary document" to make the terminology consistent with that in 351.303(b)(4)(i) and (ii). This amendment will not change the requirement that a person must file a complete, final business proprietary document on the first business day after the business proprietary document is filed. The Department also proposes specifying that the final business proprietary document must be identical in all respects to the business proprietary document filed on the previous day, except for any bracketing corrections and the omission of the warning "Bracketing of Business Proprietary Information Is Not Final For One Business Day After Date of Filing," in accordance with section 351.303(d)(2)(v). The Department believes emphasizing that the two documents must be identical with the exception of bracketing corrections and the requisite warning pertaining to bracketing is necessary because in our experience, there appears to be some confusion about whether the dates or the content of the cover letters of the two documents should remain unchanged. With this proposed amendment, the Department hopes to clarify that except as discussed above, the two documents must be identical. The Department also proposes amending this section to require persons to serve the complete final business proprietary document on other persons only if there are bracketing corrections. The Department proposes making explicit that if there are no bracketing corrections, a person need not serve a copy of the final business proprietary document. The reason service is not required in the absence of bracketing corrections is that in accordance with section 351.303(f), a person will have already served the business proprietary document filed on the due date. If there are no bracketing corrections then there is no need to serve the business proprietary document again.

Section 351.303(c)(2)(iv) currently states that if a person serves authorized applicants with a business proprietary version of a document that excludes information in double brackets pursuant to section 351.304(b)(2), the person must simultaneously file with the Department one copy of those pages in which information in double brackets has been excluded. The Department proposes amending this section by adding a reference to section 351.303(b)(4)(iii) and correctly identifying the document type as the "Business Proprietary/APO Version." The Department intends to require a person to file the complete Business Proprietary/APO Version of the document, as opposed to only those pages in which the double-bracketed information has been excluded, so that it has the complete document for the official record. The original purpose of requiring a copy of only the pages where the double bracketed information has been omitted was to conserve the amount of paper filed by the submitter. However, because the document will be filed electronically, the submitter will be able to reduce the amount of paper used while simultaneously ensuring that the Department receives the same submission that is served on the authorized applicants.

In addition to the foregoing proposed amendments to sections 351.303(c)(1) and 351.303(c)(2)(i)–(iv), the Department proposes replacing the term "business proprietary version" with "business proprietary document" in these sections, as well as in the title of section 351.303(c). These proposed amendments are intended to make the terminology in these sections consistent with that in proposed sections 351.303(b)(4)(i), (ii), and (iii).

Section 351.303(c)(3) currently requires that if factual information is submitted on computer media at the request of the Secretary, it must be accompanied by the number of copies of any computer printout specified by the Secretary. This section also requires that information on computer media must be releasable under APO, consistent with section 351.305. The Department proposes deleting the statement that the Secretary may require submission of factual information on computer media because it implies that the Secretary may make such requests only occasionally. Over time, the Department has requested with increasing frequency the submission of sales and cost databases to accompany questionnaire responses. This practice has become the norm rather than the exception. In order

to clarify how such electronic databases should be submitted in conjunction with the electronic filing requirement, the Department proposes amending this section to require that all sales files, cost files, or other electronic databases submitted to the Department be filed electronically in the format specified by the Department. If a submitter cannot file the database electronically, the Department will require the submission of the electronic database on computer media (such as a CD). Because the Department will upload the electronic databases to IA ACCESS, printouts of the databases will no longer be necessary. The Department proposes amending section 351.303(c)(3) to remind submitters that all electronic database information must be releasable under APO regardless of whether it is filed electronically or manually.

The Department proposes changing section 351.303(d) to make references to the filing terminology consistent with the other terminology used in the rest of this section. Specifically, in section 351.303(d), which deals with the format of copies, the Department proposes replacing the term "copies" with "submissions" because, as stated above, the Department will no longer require a person to file multiple copies of a submission.

Section 351.303(d)(2) currently provides the specifications and markings required for filing documents with the Department. Paragraph (d)(2) specifies that a person must submit documents on letter-size paper, single-sided, and double-spaced, and that the first page of each document must contain information in the formats described in subparagraphs (i) through (vi). The Department proposes amending paragraph (d)(2) to specify the dimensions of letter-size paper (8½ x 11 inches). Because CRU staff will need to insert all manually filed submissions into a scanner, the Department proposes requiring that manually filed documents be bound only with a paper clip, butterfly/binder clip, or rubber band. The omission of binding will ensure that the paper in the submission is not damaged, thereby facilitating the scanning process. For this reason, the Department proposes prohibiting the use of stapled, spiral, velo, or other type of solid binding in manual submissions. The Department also proposes amending paragraph (d)(2) to require the placement of the cover sheet described in paragraph (b)(3) before the first page of the document being manually filed. With regard to electronically filed documents, the Department proposes specifying that the document be formatted to print on letter-size (8½ x 11 inch) paper, single-sided and double-spaced so that the requirement is the same for both manually filed and electronically filed documents. The Department also proposes specifying that spreadsheets, unusually sized exhibits, and databases are best utilized in their original printing format and should not be reformatted for submission.

Section 351.303(d)(2)(iii) currently requires submitters to indicate on the third line of the upper right-hand corner the segment of a proceeding for which a document is being filed and, if for a review, the inclusive dates of the review, the type of review, and section number of the Act corresponding to the type of review. The Department proposes amending section 351.303(d)(2)(iii) to replace the current list of types of segments with a non-exhaustive list. The Department also proposes providing a specific date format for use in indicating the period of review, if relevant. The Department proposes eliminating the requirement that the submitter indicate the relevant section of the Act that corresponds to the type of review for which the document is submitted. The Department has observed that this marking requirement is often overlooked by submitters, and when it is included, submitters often refer only to section 751 of the Act without referring to the specific subsection. Because the Department will require a submitter to indicate the specific segment of a proceeding in which a document is being filed, the Department has determined it would be redundant to also require the submitter to specify the particular subsection of the Act corresponding to the type of review.

The Department also proposes amending section 351.303(d)(2)(v) to make it consistent with the terminology in section 351.303(b)(4). Specifically, this section currently requires that, on the fifth and subsequent lines of each submission, a submitter indicate whether any portion of the document contains business proprietary information and, if so, to list the applicable page numbers and state either "Document May Be Released Under APO" or "Document May Not Be Released Under APO." The Department proposes changing the terminology so that the term "Document" is replaced with either "Business Proprietary Document—" or "Business Proprietary/APO Version," as applicable, so that it is consistent with the terminology in section 351.303(b)(4). The Department also proposes capitalizing the first letter in the words "is" and "be" to correct typographical errors. This section also requires that the warning "Bracketing of Business Proprietary Information Is Not Final for One Business Day After Date of Filing" must not be included in the copies of the final business proprietary version filed on the next business day. The Department proposes deleting the term "the copies of" because a submitter will no longer be filing multiple copies of a submission, in accordance with proposed section 351.303(b)(2)(v). The Department also proposes replacing the term "business proprietary version" with "business proprietary document" to make the terminology consistent with that in section 351.303(b)(4).

Section 351.303(d)(2)(vi) currently requires that public versions of business proprietary documents contain the marking requirements required in paragraphs (d)(2)(i)–(v) of this section and conspicuously mark the first page "Public Version." The Department proposes amending this section to refer to both the public version and the business proprietary document in the singular. This amendment clarifies that there is only one public version of a business proprietary document. We propose also adding subparagraph 351.303(d)(2)(vii) to this section to require the same markings for a "Public Document" as for a "Public Version," with the exception being use of the word "Document" instead of "Version." These amendments bring the language in this section into conformity with the document classifications in paragraphs (b)(4).

Section 351.303(f) currently states that except as provided in sections 351.202(c), 351.207(f)(1), and paragraph (f)(3) of this section, a person filing a document with the Department simultaneously must serve a copy of the document on all other persons on the service list by personal service or first class mail. The Department proposes changing the reference to section 351.207(f)(1) to section 351.208(f)(1) to correct a typographical error.

Section 351.303(f)(1)(ii) currently states that a party may serve a public version or a business proprietary version of a document containing only the server's own business proprietary information on persons on the service list by facsimile or other electronic transmission process, with the consent of the person to be served. The Department proposes changing the reference to "business proprietary version of a document" to "business proprietary document" to make the terminology consistent with that used in proposed section 351.303(b)(4). The Department also proposes specifying that the business proprietary document may be served on persons on the APO

service list and that the public version of such a document may be served on persons on the public service list by facsimile transmission or other electronic transmission process, with the consent of the person to be served.

Section 351.303(g) currently requires that the "person's" officially responsible for the presentation of factual information in a submission to certify to the accuracy and completeness of the information. The Department proposes correcting the typographical error to change "person's" to "person" in section 351.303(g)(1).

Sections 351.304(b), 351.304(c), and 351.304(d). Identification of Business Proprietary Information, Public Version, and Returning Submissions That Do Not Conform With Section 777(b) of the Act

Section 351.304(b)(2)(i) currently states that information claimed to be exempt from disclosure under APO must be enclosed in double brackets, and must include a full explanation of the reasons for the claim. Section 351.304(b)(2)(iii) states that "the submitting person may exclude the information in double brackets from the business proprietary information version of the submission served on authorized applicants." The Department proposes amending this sentence to replace "business proprietary information version" with "Business Proprietary/APO Version" to make the terminology consistent with that in section 351.303(b)(4)(iii).

Section 351.304(c) currently provides requirements for filing the public version of a business proprietary document. Section 351.304(c)(1) specifies, among other things, that the public version must be filed on the first business day after the filing deadline for the "business proprietary version of the submission." The Department proposes amending this section to replace "business proprietary version of the submission" with "business proprietary document" to make the terminology consistent with that in sections 351.303(b)(4)(i) and (ii).

Section 351.304(c)(2) currently specifies, among other things, that if a submitting party discovers that it failed to bracket information correctly, the submitter may file a complete, corrected "business proprietary version of the submission" along with the public version. The Department proposes amending this section to replace "business proprietary version of the submission" with "business proprietary document" to make the terminology consistent with that in sections 351.303(b)(4)(i) and (ii).

Section 351.304(d)(1) currently states that the Secretary will return a submission that does not meet the requirements of section 777(b) of the Act, which governs the Department's APO rules of practice and procedure. Section 351.304(d)(1) further specifies that the submitting person may take any of four enumerated actions within two business days of the Secretary's explanation of its reasons for returning the submission. Section 351.304(d)(1)(iv) specifies that one of those enumerated actions is the submission of other material concerning the subject matter of the returned information and that, if the submitting person takes none of the enumerated actions, the Secretary will not consider the returned submission. As discussed above, because the Department will be using an electronic filing system, rather than physically return an electronic submission, the Department will instead reject the submission. Thus, the Department proposes amending the regulations to change the term "return" with "reject" in sections 351.304(d)(1) and 351.304(d)(1)(iv).

The Department is also considering providing for the implementation of electronic APO release as part of the overall transition to IA ACCESS. We do not believe it is necessary to address the actual process for such release in the Department's regulations, because the existing regulations do not include our current practice of physically releasing APO materials to APO authorized applicants. The provision for electronic release of business proprietary information under APO can be reflected in the terms of the Department's administrative protective order, and an acknowledgment of the additional security requirements that may be imposed on APO authorized applicants may be included in the APO application. We are requesting comments on the APO release process, the adequacy of providing for electronic release in the APO, and the necessity of additional security requirements in the APO application.

Comments—Deadline, Format, Number of Copies

The deadline for the submission of comments is sixty days after the publication of this notice. The Department will consider all comments received before the close of the comment period. Comments received after the end of the comment period will be considered, if possible, but their consideration cannot be assured.

Parties wishing to comment should submit comments online at *http://www.regulations.gov.* If a party is unable to submit comments online, hardcopy comments may be filed with the Department. Comments must be addressed and labeled as specified under the **ADDRESSES** heading above. Comments filed with the Department must be signed, and must consist of the original and two copies of each set of comments, including reasons for any recommendations. To help simplify the processing and distribution of comments, the Department requests that a copy of the submission on electronic media accompany the required paper copies. Such electronic copies should be on CD–ROM in either Microsoft Word format or a format that the Microsoft Word program can convert into Microsoft Word Adobe portable document format (PDF).

The Department will not accept comments accompanied by a request that a part or all of the material be treated confidentially because of its business proprietary nature or for any other reason. The Department will return such comments and materials to the persons submitting the comments and will not consider them in connection with this request for comment.

The Department will make comments received on CD–ROM available to the public on the Internet at *http://www.regulations.gov.* In addition, upon request, the Department will make one copy of any comments received in paper on CD–ROM available to the public on CD–ROMs (at cost) with specific instructions for accessing compressed data (if necessary in the Department's Central Records Unit. Any questions concerning file formatting, document conversion, access on the Web, or other electronic filing issues should be addressed to Andrew Lee Beller, Import Administration Webmaster, at (202) 482–0866, e-mail address: *webmaster-support@ita.doc.gov.*

Classification

E.O. 12866

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

Regulatory Flexibility Act

The Chief Counsel for Regulation has certified to the Chief Counsel for Advocacy of the Small Business Administration ("SBA") under the provisions of the Regulatory Flexibility Act, 5 U.S.C. 605(b), that the proposed rule would not have a significant economic impact on a substantial number of small business entities.

Under the proposed rule, parties must file electronically all submissions with

the Department, unless an exception for manual filing is applicable. If a submission is filed manually, a party need only submit one hard copy of the submission with the Department. The Department's regulations currently require parties to submit one hard copy original and five hard copies of a public document. Alternatively, under the current regulations, if a document contains business proprietary information, a party must submit one hard copy original and five hard copies of a business proprietary document and three copies of a public version.

Parties who participate in AD/CVD proceedings include U.S. manufacturers, U.S. importers, and foreign exporters and manufacturers, some of whom are affiliated with U.S. companies. Some of these entities affected by this rule may be considered small entities under the SBA standard. The Department has determined that this rule will reduce the costs to produce written copies and the Department does not anticipate that electronic filing will add any significant operating costs for small entities. Because this proposed rule will reduce costs, it will not substantially impact a significant number of small business entities participating in AD/CVD proceedings. Thus no Initial Regulatory Flexibility Act statement is required, nor has one been prepared.

Paperwork Reduction Act

This rule does not contain a collection of information for purposes of the Paperwork Reduction Act of 1980, as amended (44 U.S.C. 3501 *et seq.*).

List of Subjects in 19 CFR Part 351

Administrative practice and procedure, Antidumping, Business and industry, Cheese, Confidential business information, Countervailing duties, Freedom of information, Investigations, Reporting and recordkeeping requirements.

Dated: July 21, 2010.

Ronald K. Lorentzen,

Deputy Assistant Secretary for Import Administration.

For the reasons stated, 19 CFR Chapter III is proposed to be amended as follows:

PART 351—ANTIDUMPING AND COUNTERVAILING DUTIES

1. The authority citation for part 351 continues to read as follows:

Authority: 5 U.S.C. 301; 19 U.S.C. 1202 note; 19 U.S.C. 1303 note; 19 U.S.C. 1671 *et seq.;* and 19 U.S.C. 3538.

2. Section 351.103 is revised as follows:

§ 351.103 Central Records Unit and Administrative Protective Order and Dockets Unit.

(a) Import Administration's Central Records Unit maintains a Public File Room in Room 1117, U.S. Department of Commerce, 14th Street and Constitution Avenue, NW., Washington, DC 20230. The office hours of the Public File Room are between 8:30 a.m. and 5 p.m. Eastern Time on business days. Among other things, the Central Records Unit is responsible for maintaining an official and public record for each antidumping and countervailing duty proceeding (*see* § 351.104).

(b) Import Administration's Administrative Protective Order and Dockets Unit (APO/Dockets Unit) is located in Room 1870, U.S. Department of Commerce, 14th Street and Constitution Avenue, NW., Washington, DC 20230. The office hours of the APO/Dockets Unit are between 8:30 a.m. and 5 p.m. Eastern Time on business days. Among other things, the APO/Dockets Unit is responsible for receiving submissions from interested parties, issuing administrative protective orders (APOs), maintaining the APO service list and the public service list as provided for in paragraph (d) of this section, releasing business proprietary information under APO, and conducting APO violation investigations. The APO/Dockets Unit also is the contact point for questions and concerns regarding claims for business proprietary treatment of information and proper public versions of submissions under § 351.105 and § 351.304.

(c) *Filing of documents with the Department.* No document will be considered as having been received by the Secretary unless it is electronically filed in accordance with § 351.303(b)(2) or, where a relevant exception to electronic filing applies, it is manually submitted to the Import Administration's APO/Dockets Unit in Room 1870 and is stamped with the date, and, where necessary, the time, of receipt. Both electronically and manually filed documents must be submitted with a cover sheet, consistent with § 351.303(b)(3).

(d) *Service list.* The APO/Dockets Unit will maintain and make available a public service list for each segment of a proceeding. The service list for an application for a scope ruling is described in § 351.225(n).

(1) With the exception of a petitioner filing a petition in an investigation, all persons wishing to participate in a segment of a proceeding must file a letter of appearance. The letter of appearance must identify the name of the interested party, how that party qualifies as an interested party under § 351.102(b)(29) and section 771(9) of the Act, and the name of the firm, if any, representing the interested party in that particular segment of the proceeding. All persons who file a letter of appearance and qualify as an interested party will be included in the public service list for the segment of the proceeding in which the letter of appearance is submitted. The letter of appearance may be filed as a cover letter to an application for APO access. If the representative of the party is not requesting access to business proprietary information under APO, the letter of appearance must be filed separately from any other document filed with the Department. If the interested party is a coalition or association as defined in subparagraph (A), (E), (F) or (G) of section 771(9) of the Act, the letter of appearance must identify all of the members of the coalition or association.

(2) Each interested party that asks to be included on the public service list for a segment of a proceeding must designate a person to receive service of documents filed in that segment.

3. Section 351.104 is amended by revising paragraphs (a)(2) and (b) to read as follows:

§ 351.104 Record of proceedings.

(a) * * *

(2) *Material rejected.* (i) The Secretary, in making any determination under this part, will not use factual information, written argument, or other material that the Secretary rejects.

(ii) The official record will include a copy of a rejected document, solely for purposes of establishing and documenting the basis for rejecting the document, if the document was rejected because:

(A) The document, although otherwise timely, contains untimely filed new factual information (*see* § 351.301(b));

(B) The submitter made a nonconforming request for business proprietary treatment of factual information (*see* § 351.304);

(C) The Secretary denied a request for business proprietary treatment of factual information (*see* § 351.304);

(D) The submitter is unwilling to permit the disclosure of business proprietary information under APO (*see* § 351.304).

(iii) In no case will the official record include any document that the Secretary rejects as untimely filed, or any unsolicited questionnaire response unless the response is a voluntary response accepted under § 351.204(d) (*see* § 351.302(d)).

(b) *Public record.* The Secretary will maintain in the Central Records Unit a public record of each proceeding. The record will consist of all material contained in the official record (see paragraph (a) of this section) that the Secretary decides is public information under § 351.105(b), government memoranda or portions of memoranda that the Secretary decides may be disclosed to the general public, and public versions of all determinations, notices, and transcripts. The public record will be available to the public for inspection and copying in the Central Records Unit (*see* § 351.103). The Secretary will charge an appropriate fee for providing copies of documents. The public record will also be accessible at *http://www.trade.gov/ia.*

* * * * *

4. Section 351.302 is amended by revising paragraphs (a), (c) and (d) to read as follows:

§ 351.302 Extension of time limits; rejection of untimely filed or unsolicited material.

(a) *Introduction.* This section sets forth the procedures for requesting an extension of a time limit. In addition, this section explains that certain untimely filed or unsolicited material will be rejected together with an explanation of the reasons for the rejection of such material.

* * * * *

(c) Requests for extension of specific time limit. Before the applicable time limit specified under § 351.301 expires, a party may request an extension pursuant to paragraph (b) of this section. The request must be in writing, filed consistent with § 351.303, and state the reasons for the request. An extension granted to a party must be approved in writing.

(d) *Rejection of untimely filed or unsolicited material.* (1) Unless the Secretary extends a time limit under paragraph (b) of this section, the Secretary will not consider or retain in the official record of the proceeding:

(i) Untimely filed factual information, written argument, or other material that the Secretary rejects, except as provided under § 351.104(a)(2); or

(ii) Unsolicited questionnaire responses, except as provided under § 351.204(d)(2).

(2) The Secretary will reject such information, argument, or other material, or unsolicited questionnaire response with, to the extent practicable, written notice stating the reasons for rejection.

5. Section 351.303 is amended by revising paragraphs (a), (b), (c), (d), (f)(1), (g) introductory text, and (g)(1) to read as follows:

§ 351.303 Filing, document identification, format, translation, service, and certification of documents.

(a) *Introduction.* This section contains the procedural rules regarding filing, document identification, format, service, translation, and certification of documents and applies to all persons submitting documents to the Department for consideration in an antidumping or countervailing duty proceeding.

(b) *Filing*—(1) *In general.* Persons must address all documents to the Secretary of Commerce, Attention: Import Administration, APO/Dockets Unit, Room 1870, U.S. Department of Commerce, 14th Street and Constitution Avenue, NW., Washington, DC 20230. An electronically filed document must be received successfully in its entirety by the Department's electronic records system, IA ACCESS, by 5 p.m. Eastern Time on the due date. When applicable, a submitter must manually file a document between the hours of 8:30 a.m. and 5 p.m. Eastern Time on business days (*see* § 351.103(b)). If the applicable time limit expires on a non-business day, the Secretary will accept documents that are filed on the next business day.

(2) *Electronic filing.* Notwithstanding the relevant provisions of §§ 351.103, 351.302, 351.303, 351.304, 351.305, and 351.306 of the Department's procedures and rules, unless a relevant exception applies, a person must file all documents electronically at *http://www.trade.gov/ia.* Exceptions to the electronic filing requirements are set forth in the IA ACCESS Handbook on Electronic Filing Procedures, which is available at *http://www.trade.gov/ia.* As provided in § 351.103(c), and in accordance with section 782(c) of the Act, if a submitter is unable to comply with the electronic filing requirement under certain circumstances for which no exception applies, the submitter must notify the Department promptly of any difficulties encountered in filing the document electronically. The Department will consider the ability of the submitter and may modify the electronic filing requirements on a case-by-case basis. A person making an electronic filing must comply with the procedures set forth in the IA ACCESS Handbook on Electronic Filing Procedures.

(3) *Cover sheet.* When manually filing a document, parties must complete the cover sheet (as described in the IA ACCESS Handbook on Electronic Filing Procedures) online at *http://www.trade.gov/ia* and print the cover sheet for submission to the APO/Dockets Unit. For documents that are filed electronically, a person must complete the cover sheet for such filing online at *http://www.trade.gov/ia* at the time of the electronic filing. The person submitting the cover sheet is responsible for the accuracy of all information contained in the cover sheet.

(4) *Document identification.* Each document must be clearly identified as one of the following five document classifications and must conform with the requirements under paragraph (d)(2) of this section. Business proprietary document or version, as applicable, means a document or version of a document containing information for which a person claims business proprietary treatment under § 351.304.

(i) Business Proprietary Document—May Be Released Under APO. This business proprietary document contains single-bracketed business proprietary information that the submitter agrees to release under APO. It must contain the statement "May Be Released Under APO" in accordance with the requirements under paragraph (d)(2)(v) of this section.

(ii) Business Proprietary Document—May Not Be Released Under APO. This business proprietary document contains double-bracketed business proprietary information that the submitter does not agree to release under APO. This document must contain the statement "May Not Be Released Under APO" in accordance with the requirements under paragraph (d)(2)(v) of this section. This type of document may contain single-bracketed business proprietary information in addition to double-bracketed business proprietary information.

(iii) Business Proprietary/APO Version—May Be Released Under APO. In the event that a business proprietary document contains both single- and double-bracketed business proprietary information, the submitting person must submit a version of the document with the double-bracketed business proprietary information omitted. This version must contain the single-bracketed business proprietary information that the submitter agrees to release under APO. This version must be identified as "Business Proprietary/APO Version" and must contain the statement "May Be Released Under APO" in accordance with the requirements under paragraph (d)(2)(v) of this section.

(iv) *Public Version.* The public version excludes all business proprietary information, whether single-

or double-bracketed. Specific filing requirements for public version submissions are discussed in § 351.304(c).

(v) *Public Document.* The public document contains only public information. There is no corresponding business proprietary version for a public document.

(c) Filing of business proprietary documents and public versions under the one-day lag rule; information in double brackets.

(1) *In general.* If a submission contains information for which the submitter claims business proprietary treatment, the submitter may elect to file the submission under the one-day lag rule described in paragraph (c)(2) of this section. A petition, an amendment to a petition, and any other submission filed prior to the initiation of an investigation shall not be filed under the one-day lag rule. The business proprietary document and public version of such pre-initiation submissions must be filed simultaneously on the same day.

(2) *Application of the one-day lag rule*—(i) *Filing the business proprietary document.* A person must file a business proprietary document with the Department within the applicable time limit.

(ii) *Filing of final business proprietary document; bracketing corrections.* By the close of business one business day after the date the business proprietary document is filed under paragraph (c)(2)(i) of this section, a person must file the complete final business proprietary document with the Department. The final business proprietary document must be identical in all respects to the business proprietary document filed on the previous day except for any bracketing corrections and the omission of the warning "Bracketing of Business Proprietary Information Is Not Final for One Business Day After Date of Filing" in accordance with paragraph (d)(2)(v) of this section. A person must serve other persons with the complete final business proprietary document if there are bracketing corrections. If there are no bracketing corrections, a person need not serve a copy of the final business proprietary document.

(iii) *Filing the public version.* Simultaneously with the filing of the final business proprietary document under paragraph (c)(2)(ii) of this section, a person also must file the public version of such document (*see* § 351.304(c)) with the Department.

(iv) *Information in double brackets.* If a person serves authorized applicants with a business proprietary/APO version of a document that excludes information in double brackets pursuant to §§ 351.303(b)(4)(iii) and 351.304(b)(2), the person simultaneously must file with the Department the complete business proprietary/APO version of the document from which information in double brackets has been excluded.

(3) *Sales files, cost of production files and other electronic databases.* When a submission includes sales files, cost of production files or other electronic databases, such electronic databases must be filed electronically in accordance with paragraph (b)(2) of this section. If a submitter cannot file the database electronically, then the submitter must file such information on the computer medium specified by the Department's request for such information. The computer medium need not be accompanied by a computer printout. All electronic database information must be releasable under APO (*see* § 351.305).

(d) *Format of submissions*—(1) *In general.* Unless the Secretary alters the requirements of this section, a document filed with the Department must conform to the specification and marking requirements under paragraph (d)(2) of this section or the Secretary may reject such document in accordance with § 351.104(a).

(2) *Specifications and markings.* A person must submit manually filed documents on letter-size (8½ × 11 inch) paper, single-sided and double-spaced, bound with a paper clip, butterfly/binder clip, or rubber band. The filing of stapled, spiral, velo, or other type of solid binding is not permitted. In accordance with paragraph (b)(3) of this section, a cover sheet must be placed before the first page of the document. Electronically filed documents must be formatted to print on letter-size (8½ × 11 inch) paper, single-sided and double-spaced. Spreadsheets, unusually sized exhibits, and databases are best utilized in their original printing format and should not be reformatted for submission. A submitter must mark the first page of each document in the upper right-hand corner with the following information in the following format:

(i) On the first line, except for a petition, indicate the Department case number;

(ii) On the second line, indicate the total number of pages in the document including cover pages, appendices, and any unnumbered pages;

(iii) On the third line, indicate the specific segment of the proceeding, (*e.g.,* investigation, administrative review, scope inquiry, suspension agreement, etc.) and, if applicable, indicate the complete period of review (MM/DD/YY to MM/DD/YY);

(iv) On the fourth line, except for a petition, indicate the Department office conducting the proceeding;

(v) On the fifth and subsequent lines, indicate whether any portion of the document contains business proprietary information and, if so, list the applicable page numbers and state either: "Business Proprietary Document—May Be Released Under APO," "Business Proprietary Document—May Not Be Released Under APO," or "Business Proprietary/APO Version— May Be Released Under APO," as applicable, and consistent with § 351.303(b)(4). Indicate "Business Proprietary Treatment Requested" on the top of each page containing business proprietary information. In addition, include the warning "Bracketing of Business Proprietary Information Is Not Final for One Business Day After Date of Filing" on the top of each page containing business proprietary information in the copy of the business proprietary version filed under paragraph (c)(2)(i) of this section (one-day lag rule). Do not include this warning in the final business proprietary version filed on the next business day under paragraph (c)(2)(ii) of this section (see § 351.303(c)(2) and § 351.304(c)); and

(vi) For the public version of a business proprietary document required under § 351.304(c), complete the marking as required in paragraphs (d)(2)(i)–(v) of this section for the business proprietary document, but conspicuously mark the first page "Public Version."

(vii) For a public document, complete the marking as required in paragraphs (d)(2)(i)–(v) of this section for the business proprietary document or version, as applicable, but conspicuously mark the first page "Public Document."

* * * * *

(f) * * *

(1)(i) *In general.* Except as provided in § 351.202(c) (filing of petition), § 351.208(f)(1) (submission of proposed suspension agreement), and paragraph (f)(3) of this section, a person filing a document with the Department simultaneously must serve a copy of the document on all other persons on the service list by personal service or first class mail.

(ii) Service of public versions or a party's own business proprietary information. Notwithstanding paragraphs (f)(1)(i) and (f)(3) of this section, service of a business proprietary document containing only the server's

own business proprietary information, on persons on the APO service list, or the public version of such a document on persons on the public service list, may be made by facsimile transmission or other electronic transmission process, with the consent of the person to be served.

* * * * *

(g) *Certifications.* A person must file with each submission containing factual information the certification in paragraph (g)(1) of this section and, in addition, if the person has legal counsel or another representative, the certification in paragraph (g)(2) of this section:

(1) For the person officially responsible for presentation of the factual information:

I, (name and title), currently employed by (person), certify that (1) I have read the attached submission, and (2) the information contained in this submission is, to the best of my knowledge, complete and accurate.

* * * * *

6. Section 351.304 is amended by revising paragraphs (b), (c), (d)(1) introductory text and (d)(1)(iv) to read as follows:

§ 351.304 Establishing business proprietary treatment of information.

* * * * *

(b) *Identification of business proprietary information*—(1) *In general.* A person submitting information must identify the information for which it claims business proprietary treatment by enclosing the information within single brackets. The submitting person must provide with the information an explanation of why each item of bracketed information is entitled to business proprietary treatment. A person submitting a request for business proprietary treatment also must include an agreement to permit disclosure under an administrative protective order, unless the submitting party claims that there is a clear and compelling need to withhold the information from disclosure under an administrative protective order.

(2) Information claimed to be exempt from disclosure under administrative protective order. (i) If the submitting person claims that there is a clear and compelling need to withhold certain information from disclosure under an administrative protective order (see paragraph (a)(1)(ii) of this section), the submitting person must identify the information by enclosing the information within double brackets, and must include a full explanation of the reasons for the claim.

(ii) In an investigation, the submitting person may enclose business proprietary customer names within double brackets (see paragraph (a)(1)(iii) of this section).

(iii) The submitting person may exclude the information in double brackets from the Business Proprietary/APO Version of the submission served on authorized applicants. See § 351.303 for filing and service requirements.

(c) *Public version.* (1) A person filing a submission that contains information for which business proprietary treatment is claimed must file a public version of the submission. The public version must be filed on the first business day after the filing deadline for the business proprietary document (see § 351.303(b)). The public version must contain a summary of the bracketed information in sufficient detail to permit a reasonable understanding of the substance of the information. If the submitting person claims that summarization is not possible, the claim must be accompanied by a full explanation of the reasons supporting that claim. Generally, numerical data will be considered adequately summarized if grouped or presented in terms of indices or figures within 10 percent of the actual figure. If an individual portion of the numerical data is voluminous, at least one percent representative of that portion must be summarized. A submitter should not create a public summary of business proprietary information of another person.

(2) If a submitting party discovers that it has failed to bracket information correctly, the submitter may file a complete, corrected business proprietary document along with the public version (see § 351.303(b)). At the close of business on the day on which the public version of a submission is due under paragraph (c)(2) of this section, however, the bracketing of business proprietary information in the original business proprietary document or, if a corrected version is timely filed, the corrected business proprietary document will become final. Once bracketing has become final, the Secretary will not accept any further corrections to the bracketing of information in a submission, and the Secretary will treat non-bracketed information as public information.

(d) * * *

(1) *In general.* The Secretary will reject a submission that does not meet the requirements of section 777(b) of the Act and this section with a written explanation. The submitting person may take any of the following actions within two business days after receiving the Secretary's explanation:

* * * * *

(iv) Submit other material concerning the subject matter of the rejected information. If the submitting person does not take any of these actions, the Secretary will not consider the rejected submission.

* * * * *

[FR Doc. 2010–18389 Filed 7–27–10; 8:45 am]

BILLING CODE 3510–DS–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 882 and 890

[Docket No. FDA–2009–N–0493]

RIN 0910–ZA37

Neurological and Physical Medicine Devices; Designation of Special Controls for Certain Class II Devices and Exemption From Premarket Notification; Reopening of the Comment Period

AGENCY: Food and Drug Administration, HHS.

ACTION: Proposed rule; reopening of the comment period.

SUMMARY: The Food and Drug Administration (FDA) is reopening until September 7, 2010, the comment period for the proposed rule published in the **Federal Register** of April 5, 2010 (75 FR 17093). The document proposed to amend certain neurological and physical medicine device regulations to establish special controls for these class II devices and to exempt some of these devices from premarket notification requirements. FDA is reopening the comment period to allow further comment and to receive any new information.

DATES: Submit electronic or written comments by September 7, 2010.

ADDRESSES: You may submit comments, identified by Docket No. FDA–2009–N–0493, and/or RIN number 0910–ZA37, by any of the following methods:

Electronic Submissions

Submit electronic comments in the following way:

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

Written Submissions

Submit written submissions in the following ways:

- FAX: 301–827–6870.
- Mail/Hand delivery/Courier (for paper, disk, or CD—ROM submissions): Division of Dockets Management (HFA–305), Food and Drug Administration,

5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

Instructions: All submissions received must include the agency name and Docket No. and Regulatory Information Number (RIN) (if a RIN number has been assigned) for this rulemaking. All comments received may be posted without change to *http://www.regulations.gov*, including any personal information provided. For additional information on submitting comments, see the "Comments" heading in the **SUPPLEMENTARY INFORMATION** section of this document.

Docket: For access to the docket to read background documents or comments received, go to *http://www.regulations.gov* and insert the docket number, found in brackets in the heading of this document, into the "Search" box and follow the prompts and/or go to the Division of Dockets Management, 5630 Fishers Lane, rm.1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Robert J. DeLuca, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, rm. G214, Silver Spring, MD 20993–0002, email: *Robert.DeLuca@fda.hhs.gov*, 301–796–6630.

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of April 5, 2010 (75 FR 17093), FDA published a proposed rule to amend certain neurological device and physical medicine device regulations to establish special controls for these class II devices and to exempt some of these devices from the premarket notification requirements of the Federal Food, Drug, and Cosmetic Act. Interested persons were given until July 6, 2010, to comment on the proposed rule.

II. Request for Comments

Following publication of the April 5, 2010, proposed rule, FDA received requests to allow interested persons additional time to comment. The requests asserted that the 90-day time period was insufficient to respond fully to FDA's specific requests for comments and to allow potential respondents to thoroughly evaluate and address pertinent issues. The agency has considered the requests and is reopening the comment period until September 7, 2010. The agency believes the additional comment period allows adequate time for interested persons to submit comments without significantly delaying rulemaking on these important issues.

III. How to Submit Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) either electronic or written comments regarding this document. It is only necessary to send one set of comments. It is no longer necessary to send two copies of mailed comments. Identify comments with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m. Monday through Friday.

Dated: July 22, 2010.

David Dorsey,

Acting Deputy Commissioner for Policy, Planning and Budget.

[FR Doc. 2010–18405 Filed 7–27–10; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF JUSTICE

Bureau of Alcohol, Tobacco, Firearms, and Explosives

27 CFR Part 646

[Docket No. ATF 22P; AG Order No. 3179–2010]

RIN 1140–AA31

Implementation of the USA PATRIOT Improvement and Reauthorization Act of 2005 Regarding Trafficking in Contraband Cigarettes or Smokeless Tobacco (2006R–1P)

AGENCY: Bureau of Alcohol, Tobacco, Firearms, and Explosives (ATF), Department of Justice.

ACTION: Notice of proposed rulemaking.

SUMMARY: The Department of Justice is proposing to amend the regulations of the Bureau of Alcohol, Tobacco, Firearms, and Explosives (ATF) to implement certain provisions of the USA PATRIOT Improvement and Reauthorization Act of 2005 (enacted March 9, 2006) relating to trafficking in contraband cigarettes or smokeless tobacco. The new law amends the Contraband Cigarette Trafficking Act by: reducing the threshold amount of cigarettes necessary to trigger jurisdiction under the CCTA from a quantity in excess of 60,000 to a quantity in excess of 10,000; extending the provisions of the CCTA to cover contraband smokeless tobacco; imposing reporting requirements on persons, except tribal governments, who engage in delivery sales of more than 10,000 cigarettes or 500 single-unit consumer-sized cans or packages of smokeless tobacco in a single month; requiring that cigarettes and smokeless tobacco seized and forfeited under the CCTA be either used in law enforcement operations or destroyed; and by authorizing state and local governments, and Federal tobacco permittees to bring civil causes of action against violators of the CCTA.

DATES: Written comments must be postmarked and electronic comments must be submitted on or before October 26, 2010. Commenters should be aware that the electronic Federal Docket Management System will not accept comments after midnight Eastern Time on the last day of the comment period.

ADDRESSES: Send comments to any of the following addresses—

- James P. Ficaretta, Program Manager, Mailstop 6N–602, Enforcement Programs and Services, Bureau of Alcohol, Tobacco, Firearms, and Explosives, U.S. Department of Justice, 99 New York Avenue, NE., Washington, DC 20226; *Attn: ATF 22P.* Written comments must appear in a minimum 12-point size of type (.17 inches), include your mailing address, be signed, and may be of any length.
- 202–648–9741 (facsimile).
- *http://www.regulations.gov.* Federal eRulemaking portal; follow the instructions for submitting comments.

You may also view an electronic version of this proposed rule at the *http://www.regulations.gov* site.

Comments may also be submitted electronically to ATF to *http://www.regulations.gov* by using the electronic comment form provided on that site. You may also view an electronic version of this proposed rule at the *http://www.regulations.gov site.* Comments submitted electronically must contain your name and mailing address. They must also reference this document docket number, as noted above, and be legible when printed on 8½″ x 11″ paper. ATF will treat comments submitted electronically as originals and it will not acknowledge receipt of comments submitted electronically. Interested parties will not be able to submit comments electronically to ATF via *http://www.regulations.gov* after the comment period closes.

See the Public Participation section at the end of the **SUPPLEMENTARY INFORMATION** section for instructions and requirements for submitting written comments, and for information on how to request a public hearing.

FOR FURTHER INFORMATION CONTACT: James P. Ficaretta; Enforcement Programs and Services; Bureau of Alcohol, Tobacco, Firearms, and Explosives; U.S. Department of Justice;

99 New York Avenue, NE., Washington, DC 20226, telephone (202) 648–7094.

SUPPLEMENTARY INFORMATION:

I. Background

In 1978, the Contraband Cigarette Trafficking Act (CCTA), 18 U.S.C. Chapter 114, was enacted to deter the interstate smuggling of cigarettes where the taxation on tobacco products varies between the States. The Bureau of Alcohol, Tobacco, Firearms, and Explosives (ATF) was given primary jurisdiction to enforce and administer the CCTA. Contraband cigarettes were originally defined as any quantity of more than 60,000 cigarettes that bear no evidence of the payment of applicable state tax.

The legislative history of the CCTA and ATF's investigative efforts over the years have established that organized crime has been involved in the diversion of legal tobacco products into the illegal market. Moreover, several investigations by ATF and its law enforcement partners have established links to international terrorist groups, including Hezbollah and al Qaeda. Since the enactment of the CCTA, cigarette smuggling has grown in complexity. Not only are cigarettes smuggled between low-tax and high-tax States, they are smuggled through international borders. The counterfeiting of legitimate brands is also very prevalent. The trafficking of contraband cigarettes is a worldwide problem. Billions of dollars of tax revenue are lost by all levels of government throughout the world due to the smuggling of cigarettes. Much of the illicit profit gained by organized crime and terrorist groups is used in furtherance of their criminal enterprises.

The trafficking in counterfeit and contraband tobacco products also poses a serious health risk to our society. There are no standards of production in counterfeit product. This allows for such things as biological or chemical contamination of the product. Furthermore, contraband cigarettes are more likely to be sold to underage persons than legitimate product. Finally, the sale of counterfeit and contraband products poses a serious financial threat to legitimate manufacturers, wholesalers, and retailers.

II. USA PATRIOT Improvement and Reauthorization Act of 2005—Proposed Rule

Public Law 109–177 (120 Stat. 192), the USA PATRIOT Improvement and Reauthorization Act of 2005 ("the Act"), was enacted on March 9, 2006. Section 121 of the Act made several amendments to the CCTA, 18 U.S.C. 2341 *et seq.* The provisions of section 121 and the proposed implementing regulations (if applicable), are discussed in the following paragraphs.

Section 121(a)—Threshold Quantity for Treatment as Contraband Cigarettes

Prior to amendment, section 2342 of the CCTA made it unlawful for any person knowingly to ship, transport, receive, possess, sell, distribute, or purchase contraband cigarettes. Contraband cigarettes were defined as any quantity in excess of 60,000 cigarettes that bear no evidence of the payment of applicable state tax. Section 121(a) of the Act amended the CCTA by reducing the number of cigarettes that trigger application of the CCTA from a quantity in excess of 60,000 to a quantity in excess of 10,000 and which bear no evidence of the payment of applicable state or local tax, if the States or local governments require such indicia of tax payment.

Proposed amendments to the regulations to reflect the statutorily imposed reduction to the CCTA threshold are contained in 27 CFR 646.141, 646.143, 646.146, and 646.147. The Department is also proposing to amend § 646.143 by adding a definition for the term "cigarette." The proposed definition reflects the meaning of the term set forth in the CCTA as amended, i.e., to update the existing regulatory language to conform to the statutory change.

Section 121(b)—Contraband Smokeless Tobacco

Section 121(b) amended the CCTA by extending its provisions to include contraband smokeless tobacco and by defining the terms "smokeless tobacco" and "contraband smokeless tobacco." The term "smokeless tobacco" means any finely cut, ground, powdered, or leaf tobacco that is intended to be placed in the oral or nasal cavity or otherwise consumed without being combusted. The term "contraband smokeless tobacco" means a quantity in excess of 500 single-unit consumer-sized cans or packages of smokeless tobacco, or their equivalent, that are in the possession of any person other than—

1. A person holding a permit issued pursuant to chapter 52 of the Internal Revenue Code of 1986 as manufacturer of tobacco products or as an export warehouse proprietor, a person operating a customs bonded warehouse pursuant to section 311 or 555 of the Tariff Act of 1930 (19 U.S.C. 1311, 1555), or an agent of such person;

2. A common carrier transporting such smokeless tobacco under a proper bill of lading or freight bill which states the quantity, source, and designation of such smokeless tobacco;

3. A person who is licensed or otherwise authorized by the State where such smokeless tobacco is found to engage in the business of selling or distributing tobacco products, and has complied with the accounting, tax, and payment requirements relating to such license or authorization with respect to such smokeless tobacco; or

4. An officer, employee, or agent of the United States or a State, or any department, agency, or instrumentality of the United States or a State (including any political subdivision of a State), having possession of such smokeless tobacco in connection with the performance of official duties.

Proposed regulations that implement the provisions of section 121(b) are in 27 CFR 646.143, 646.146, 646.147, and 646.154.

Section 121(c)—Recordkeeping, Reporting, and Inspection

Section 121(c) of the Act amended the CCTA by:

- Authorizing the Attorney General to prescribe regulations concerning additional recordkeeping requirements that he considers appropriate for purposes of enforcement of the CCTA on persons who ship, sell, or distribute more than 10,000 cigarettes or 500 single-unit consumer-sized cans or packages of smokeless tobacco in a single transaction.
- Requiring persons, except for tribal governments, who engage in a delivery sale, and who ship, sell, or distribute more than 10,000 cigarettes or 500 single-unit consumer-sized cans or packages of smokeless tobacco within a single month, to submit to the Attorney General a report that sets forth the following:

1. The person's beginning and ending inventory of cigarettes and cans or packages of smokeless tobacco (in total) for such month.

2. The total quantity of cigarettes and cans or packages of smokeless tobacco that the person received within such month from each other person (itemized by name and address).

3. The total quantity of cigarettes and cans or packages of smokeless tobacco that the person distributed within such month to each person (itemized by name and address) other than a retail purchaser.

- Adding the term "delivery sale," which means any sale of cigarettes or smokeless tobacco in interstate commerce to a consumer if—

(a) The consumer submits the order for such sale by means of a telephone or other method of voice transmission, the mails, or the Internet or other online service, or by any other means where the consumer is not in the same physical location as the seller when the purchase or offer of sale is made; or

(b) The cigarettes or smokeless tobacco are delivered by use of the mails, common carrier, private delivery service, or any other means where the consumer is not in the same physical location as the seller when the consumer obtains physical possession of the cigarettes or smokeless tobacco.

Proposed regulations that reflect the new CCTA requirements regarding contraband smokeless tobacco are in 27 CFR 646.143 and 646.146. The regulatory language is identical to the statutory language.

• Specifying that any report required to be submitted under the CCTA to the Attorney General must also be submitted to the Secretary of the Treasury and to the attorneys general and the tax administrators of the States from where the shipments, deliveries, or distributions both originated and concluded.

Proposed regulations that reflect the new CCTA requirements regarding contraband smokeless tobacco are in 27 CFR 646.146. The regulatory language is identical to the statutory language.

Section 121(d)—Disposal or Use of Forfeited Cigarettes and Smokeless Tobacco

Pursuant to section 121(d) of the Act, any contraband cigarettes or contraband smokeless tobacco involved in any violation of the CCTA will be subject to seizure and forfeiture and will be either (1) destroyed and not resold, or (2) used for undercover investigative operations for the detection and prosecution of crimes, and then destroyed and not resold.

Proposed regulations that implement this new CCTA provision are in 27 CFR 646.155. The regulatory language is identical to the statutory language.

Section 121(e)—Effect on State and Local Law

Section 121(e) of the Act amended the CCTA to make it clear that the CCTA is not intended to affect the concurrent jurisdiction of a state or local government to enact and enforce its own cigarette tax laws, to provide for the confiscation of cigarettes or smokeless tobacco and other property seized for violation of such laws, and to provide for penalties for the violation of such laws. This section also amended the CCTA to make it clear that the CCTA is not intended to inhibit or otherwise affect any coordinated law enforcement effort by a number of state or local governments, through interstate compact or otherwise, to provide for the administration of state or local cigarette tax laws, to provide for the confiscation of cigarettes or smokeless tobacco and other property seized in violation of such laws, and to establish cooperative programs for the administration of such laws. This statutory change does not necessitate any amendments to these regulations.

Section 121(f)—Enforcement

Section 121(f) of the Act creates a new civil cause of action allowing state and local governments and federal tobacco permittees under the Internal Revenue Code to prevent or restrain CCTA violations in Federal district court. In addition, these entities could also seek civil penalties and monetary damages, and injunctive or equitable relief. This statutory change does not necessitate any amendments to these regulations.

Section 121(g)—Conforming and Clerical Amendments

Section 121(g) made several conforming and clerical amendments to the CCTA (*e.g.,* a change in the title of chapter 114 and a change in the section headings of sections 2343 and 2345) that do not necessitate any regulatory changes. This statutory change does not necessitate any amendments to these regulations.

III. Miscellaneous Amendment of the Regulations

In general, the regulations at 27 CFR 646.150 provide that each distributor of cigarettes must retain the records required by §§ 646.146 and 646.147 for three years following the close of the year in which the records are made. The distributor must keep the required records on his business premises. ATF is considering extending the record retention requirement to five years. The amendment would harmonize the regulations with the applicable statute of limitations for CCTA violations, which is five years. ATF is soliciting comments on this issue.

How This Document Complies With the Federal Administrative Requirements for Rulemaking

A. Executive Order 12866

This proposed rule has been drafted and reviewed in accordance with Executive Order 12866, "Regulatory Planning and Review" section 1(b), The Principles of Regulation. The Department of Justice has determined that this proposed rule is a "significant regulatory action" under Executive Order 12866, section 3(f), Regulatory Planning and Review, and accordingly this proposed rule has been reviewed by the Office of Management and Budget. However, this proposed rule will not have an annual effect on the economy of $100 million, and will not adversely affect in a material way the economy, a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or state, local, or tribal governments or communities. Accordingly, this proposed rule is not an "economically significant" rulemaking as defined by Executive Order 12866. The proposed information requirements are contained in records that are kept in the normal course of business. Likewise, the reporting requirements contained in this proposed rule merely augment existing federal law as set forth in the Jenkins Act, 15 U.S.C. 375.

B. Executive Order 13132

This proposed 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. Therefore, in accordance with section 6 of Executive Order 13132, the Attorney General has determined that this proposed regulation does not have sufficient federalism implications to warrant the preparation of a federalism summary impact statement.

C. Executive Order 12988

This proposed rule meets the applicable standards set forth in sections 3(a) and 3(b)(2) of Executive Order 12988.

D. Regulatory Flexibility Act

The Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*) requires an agency to conduct a regulatory flexibility analysis of any rule subject to notice and comment rulemaking requirements unless the head of 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. The Attorney General has reviewed this proposed regulation and, by approving it, certifies that this proposed rule will not have a significant economic impact on a substantial number of small entities. The proposed requirements apply only to entities that sell the threshold quantities of cigarettes or smokeless tobacco in a single

transaction. In addition, the proposed information requirements are contained in the records that are kept in the normal course of business and the proposed reporting requirements merely augment existing federal law as set forth in the Jenkins Act, 15 U.S.C. 375.

ATF estimates that this proposed rule will have an impact on no more than 3,000 businesses with the majority of those being small businesses. ATF further estimates that the annual economic impact will be less than $700,000 per year. ATF estimates for this proposed rule are as follows:

Mailing Costs (stamp and envelope): $.50 × 3,000 businesses × 12 months = $180,000.

Labor Costs: One hour of labor ($13.50/hr) for filling out ATF F 5200.XX, filing and mailing × 3,000 × 12 = $486,000.

E. Small Business Regulatory Enforcement Fairness Act of 1996

This proposed rule is not a major rule as defined by section 251 of the Small Business Regulatory Enforcement Act of 1996 (5 U.S.C. 804). This proposed rule will not result in an annual effect on the economy of $100 million or more; a major increase in costs or prices; or significant adverse effects on competition, employment, investment, innovation, or on the ability of United States-based companies to compete with foreign-based companies in domestic and export markets.

F. Unfunded Mandates Reform Act of 1995

This proposed rule will not result in the expenditure by state, local, and tribal governments, in the aggregate, or by the private sector of $100 million or more in any one year, and it will not significantly or uniquely affect small governments. Therefore, no actions were deemed necessary under the provisions of the Unfunded Mandates Reform Act of 1995.

G. Paperwork Reduction Act

The collections of information contained in this notice of proposed rulemaking have been submitted to the Office of Management and Budget for review in accordance with the Paperwork Reduction Act of 1995 (44 U.S.C. 3507(d)). Comments on the collections of information should be sent to the Office of Management and Budget, Attention: Desk Officer for the Bureau of Alcohol, Tobacco, Firearms, and Explosives, Office of Information and Regulatory Affairs, Washington, DC 20503, with copies to the Chief, Document Services Branch, Bureau of Alcohol, Tobacco, Firearms, and Explosives, at the address previously specified. Comments are specifically requested concerning:

- Whether the proposed collections of information are necessary for the proper performance of the functions of the Bureau of Alcohol, Tobacco, Firearms, and Explosives, including whether the information will have practical utility;
- The accuracy of the estimated burden associated with the proposed collections of information (see below);
- How the quality, utility, and clarity of the information to be collected may be enhanced; and
- How the burden of complying with the proposed collections of information may be minimized, including through the application of automated collection techniques or other forms of information technology.

The collections of information in this proposed regulation are in 27 CFR 646.146, 646.147, and 646.150. This information is required to implement the provisions of the USA PATRIOT Improvement and Reauthorization Act of 2005 regarding trafficking in contraband cigarettes or smokeless tobacco. The likely respondents are businesses.

Estimated total annual reporting and/or recordkeeping burden: 36,000 hours.

Estimated average burden hours per respondent and/or recordkeeper: 12 hours.

Estimated number of respondents and/or recordkeepers: 3,000.

Estimated annual frequency of responses: 12.

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a valid control number assigned by the Office of Management and Budget.

Public Participation

A. Comments Sought

ATF is requesting comments on the proposed regulations from all interested persons. ATF is also specifically requesting comments on the clarity of this proposed rule and how it may be made easier to understand. All comments must reference this document docket number (ATF 22P), be legible, and include your name and mailing address. ATF will treat all comments as originals and it will not acknowledge receipt of comments.

Comments received on or before the closing date will be carefully considered. Comments received after that date will be given the same consideration if it is practical to do so, but assurance of consideration cannot be given except as to comments received on or before the closing date.

B. Confidentiality

Comments, whether submitted electronically or in paper, will be made available for public viewing at ATF, and on the Internet as part of the President's eRulemaking initiative, and are subject to the Freedom of Information Act. Commenters who do not want their name or other personal identifying information posted on the Internet should submit their comment by mail or facsimile, along with a separate cover sheet that contains their personal identifying information. Both the cover sheet and comment must reference this docket number. Information contained in the cover sheet will not be posted on the Internet. Any personal identifying information that appears within the comment will be posted on the Internet and will not be redacted by ATF.

Any material that the commenter considers to be inappropriate for disclosure to the public should not be included in the comment. Any person submitting a comment shall specifically designate that portion (if any) of his comments that contains material that is confidential under law (*e.g.,* trade secrets, processes, etc.). Any portion of a comment that is confidential under law shall be set forth on pages separate from the balance of the comment and shall be prominently marked "confidential" at the top of each page. Confidential information will be included in the rulemaking record but will not be disclosed to the public. Any comments containing material that is not confidential under law may be disclosed to the public. In any event, the name of the person submitting a comment is not exempt from disclosure.

C. Submitting Comments

Comments may be submitted in any of three ways:

- *Mail:* Send written comments to ATF at the address listed in the **ADDRESSES** section of this document. Written comments must appear in a minimum 12-point size of type (.17 inches), include your mailing address, be signed, and may be of any length.
- *Facsimile:* You may submit comments by facsimile transmission to 202–648–9741. Faxed comments must:

(1) Be legible;

(2) Be on 8½″ x 11″ paper;

(3) Contain a legible, written signature; and

(4) Be no more than five pages long. ATF will not accept faxed comments that exceed five pages.

- *Federal eRulemaking Portal:* To submit comments to ATF via the Federal eRulemaking portal, visit *http://www.regulations.gov* and follow

the instructions for submitting comments.

D. Request for Hearing

Any interested person who desires an opportunity to comment orally at a public hearing should submit his or her request, in writing, to the Director of ATF within the 90-day comment period. The Director, however, reserves the right to determine, in light of all circumstances, whether a public hearing is necessary.

Disclosure

Copies of this proposed rule and the comments received will be available for public inspection by appointment during normal business hours at: ATF Reading Room, Room 1E–063, 99 New York Avenue, NE., Washington, DC 20226; *telephone:* (202) 648–7080.

Drafting Information

The author of this document is James P. Ficaretta; Enforcement Programs and Services; Bureau of Alcohol, Tobacco, Firearms, and Explosives.

List of Subjects in 27 CFR Part 646

Administrative practice and procedure, Authority delegations, Cigars and cigarettes, Claims, Excise taxes, Packaging and containers, Penalties, Reporting and recordkeeping requirements, Seizures and forfeitures, Smokeless tobacco, Surety bonds, Tobacco.

Authority and Issuance

Accordingly, for the reasons discussed in the preamble, 27 CFR Part 646 is proposed to be amended as follows:

PART 646—CONTRABAND CIGARETTES AND SMOKELESS TOBACCO

1. The authority citation for 27 CFR part 646 continues to read as follows:

Authority: 18 U.S.C. 2341–2346.

2. Section 646.141 is revised to read as follows:

§ 646.141 Scope of part.

The regulations in this subpart relate to the distribution of cigarettes in excess of 10,000 and smokeless tobacco in excess of 500 single-unit consumer-sized cans or packages in a single transaction.

3. Section 646.143 is amended by revising the definitions for "Business premises," "Contraband cigarettes," "Disposition," "Distributor," and "Exempted person" and by adding definitions for the terms "Cigarette," "Contraband smokeless tobacco," "Delivery sale," "Interstate commerce," and "Smokeless tobacco" to read as follows:

§ 646.143 Meaning of terms.

* * * * *

Business premises. When used with respect to a distributor, the property on which the cigarettes or smokeless tobacco are kept or stored. The business premises include the property where the records of a distributor are kept.

Cigarette. (a) Any roll of tobacco wrapped in paper or in any substance not containing tobacco; and

(b) Any roll of tobacco wrapped in any substance containing tobacco which, because of its appearance, the type of tobacco used in the filler, or its packaging and labeling, is likely to be offered to, or purchased by, consumers as a cigarette described in paragraph (a) of this definition.

* * * * *

Contraband cigarettes. Any quantity of cigarettes in excess of 10,000, if—

(a) The cigarettes bear no evidence of the payment of applicable state or local cigarette taxes in the State or locality where such cigarettes are found;

(b) The State or local government in which the cigarettes are found requires a stamp, impression, or other indication to be placed on packages or other containers of cigarettes to evidence payment of cigarette taxes; and

(c) The cigarettes are in the possession of any person other than an exempted person.

Contraband smokeless tobacco. Any quantity of smokeless tobacco in excess of 500 single-unit consumer-sized cans or packages, or their equivalent, that are in the possession of any person other than an exempted person.

Delivery sale. Any sale of cigarettes or smokeless tobacco in interstate commerce to a consumer if—

(a) The consumer submits the order for such sale by means of a telephone or other method of voice transmission, the mails, or the Internet or other online service, or by any other means where the consumer is not in the same physical location as the seller when the purchase or offer of sale is made; or

(b) The cigarettes or smokeless tobacco are delivered by use of the mails, common carrier, private delivery service, or any other means where the consumer is not in the same physical location as the seller when the consumer obtains physical possession of the cigarettes or smokeless tobacco.

Disposition. The movement of cigarettes or smokeless tobacco from a person's business premises, wherever situated, by shipment or other means of distribution.

* * * * *

Distributor. Any person who distributes more than 10,000 cigarettes, or smokeless tobacco in excess of 500 single-unit consumer-sized cans or packages, in a single transaction.

Exempted person. (a) With respect to cigarettes in excess of 10,000, any person who is—

(1) Holding a permit issued pursuant to chapter 52 of the Internal Revenue Code of 1954 as a manufacturer of tobacco products or as an export warehouse proprietor;

(2) Operating a customs bonded warehouse pursuant to section 311 or 555 of the Tariff Act of 1930 (19 U.S.C. 1311 or 1555);

(3) An agent of a tobacco products manufacturer, an export warehouse proprietor, or an operator of a customs bonded warehouse;

(4) A common or contract carrier transporting the cigarettes involved under a proper bill of lading or freight bill which states the quantity, source, and destination of the cigarettes;

(5) Licensed or otherwise authorized by the State, in which he possesses cigarettes, to account for and pay cigarette taxes imposed by that State; and who has complied with the accounting and payment requirements relating to his license or authorization with respect to the cigarettes involved; or

(6) An officer, employee, or agent of the United States, of an individual State, or of a political subdivision of a State and having possession of cigarettes in connection with the performance of official duties.

(7) Operating within a foreign-trade zone established under 19 U.S.C., section 81b, when the cigarettes involved have been entered into the zone under zone-restricted status or, in respect to foreign cigarettes, have been admitted into the zone but have not been entered in the United States.

(b) With respect to smokeless tobacco in excess of 500 single-unit consumer-sized cans or packages, any person who is—

(1) Holding a permit issued pursuant to chapter 52 of the Internal Revenue Code of 1986 as manufacturer of tobacco products or as an export warehouse proprietor, a person operating a customs bonded warehouse pursuant to section 311 or 555 of the Tariff Act of 1930 (19 U.S.C. 1311, 1555), or an agent of such person;

(2) A common or contract carrier transporting such smokeless tobacco under a proper bill of lading or freight

bill which states the quantity, source, and designation of such smokeless tobacco;

(3) Licensed or otherwise authorized by the State where such smokeless tobacco is found to engage in the business of selling or distributing tobacco products; and who has complied with the accounting, tax, and payment requirements relating to such license or authorization with respect to such smokeless tobacco; or

(4) An officer, employee, or agent of the United States, of an individual State, or of a political subdivision of a State and having possession of such smokeless tobacco in connection with the performance of official duties.

Interstate commerce. Commerce between a State and any place outside the State, or commerce between points in the same State but through any place outside the State.

* * * * *

Smokeless tobacco. Any finely cut, ground, powdered, or leaf tobacco that is intended to be placed in the oral or nasal cavity or otherwise consumed without being combusted.

* * * * *

4. The centered heading preceding section 646.146 is revised to read as "Records and Reports."

5. Sections 646.146 and 646.147 are revised to read as follows:

§ 646.146 General requirements.

(a) Each distributor of cigarettes or smokeless tobacco shall keep copies of invoices, bills of lading, or other suitable commercial records equivalent thereto relating to each disposition of more than 10,000 cigarettes or smokeless tobacco in excess of 500 single-unit consumer-sized cans or packages. Dividing a single agreement for the disposition of more than 10,000 cigarettes or smokeless tobacco in excess of 500 single-unit consumer-sized cans or packages into the delivery of smaller components of 10,000 cigarettes or less or smokeless tobacco of not more than 500 single-unit consumer-sized cans or packages does not exempt the distributor from the recordkeeping requirements of this part. The distributor shall include the information prescribed in § 646.147 in his commercial records of disposition.

(b)(1) Except for a tribal government, each distributor who engages in a delivery sale, and who ships, sells, or distributes cigarettes in excess of 10,000, or smokeless tobacco in excess of 500 single-unit consumer-sized cans or packages, or their equivalent, within a single month, shall prepare and submit to the Director ATF Form 5200.XX, in accordance with the instructions on the form. Form 5200.XX shall include the following information:

(i) The distributor's beginning and ending inventory of cigarettes and cans or packages of smokeless tobacco (in total) for such month.

(ii) The total quantity of cigarettes and cans or packages of smokeless tobacco that the distributor received within such month from each other distributor (itemized by name and address).

(iii) The total quantity of cigarettes and cans or packages of smokeless tobacco that was distributed within such month to each person (itemized by name and address) other than a retail purchaser.

(2) A copy of completed ATF Form 5200.XX shall also be submitted by each distributor described in paragraph (b)(1) of this section to the Secretary of the Treasury and to the attorneys general and the tax administrators of the States from where the shipments, deliveries, or distributions both originated and concluded.

§ 646.147 Required information.

(a) *Distributors who are exempted persons.* Each distributor who is an exempted person as defined in § 646.143 shall show the following information in his commercial records.

(1) For each disposition of more than 10,000 cigarettes or smokeless tobacco in excess of 500 single-unit consumer-sized cans or packages to an exempted person; or for each disposition of more than 10,000 cigarettes or smokeless tobacco in excess of 500 single-unit consumer-sized cans or packages to a person who is not an exempted person and which is delivered by the distributor to the recipient's place of business, the distributor shall show on dated records—

(i) The full name of the purchaser (or the recipient if there is no purchaser);

(ii) The street address (including city and state) to which the cigarettes or smokeless tobacco are destined; and

(iii) The quantity of cigarettes or smokeless tobacco disposed of.

(2) For each disposition of more than 10,000 cigarettes or smokeless tobacco in excess of 500 single-unit consumer-sized cans or packages, other than the dispositions specified in paragraph (a)(1) of this section, the distributor shall show on dated records—

(i) The full name of the purchaser (if any);

(ii) The name, address (including city and state), and signature of the person receiving the cigarettes or smokeless tobacco;

(iii) The street address (including city and state) to which the cigarettes or smokeless tobacco are destined;

(iv) The quantity of cigarettes or smokeless tobacco disposed of;

(v) The driver's license number of the individual receiving the cigarettes or smokeless tobacco;

(vi) The license number of the vehicle in which the cigarettes or smokeless tobacco are removed from the distributor's business premises;

(vii) A declaration by the individual receiving the cigarettes or smokeless tobacco of the specific purpose of receipt (such as personal use, resale, delivery to another person, etc.); and

(viii) A declaration by the person receiving the cigarettes or smokeless tobacco of the name and address of his principal when he is acting as an agent.

(b) *Distributors who are not exempted persons.* Each distributor who is not an exempted person as defined in § 646.143 shall show on dated commercial records the information specified in paragraphs (a)(2)(i) through (viii) of this section for each disposition of more than 10,000 cigarettes or smokeless tobacco in excess of 500 single-unit consumer-sized cans or packages.

6. Section 646.150 is amended by revising paragraph (b)(2) to read as follows:

§ 646.150 Retention of records.

* * * * *

(b) * * *

(2) The tobacco products manufacturer will keep the required record for each disposition of more than 10,000 cigarettes or smokeless tobacco in excess of 500 single-unit consumer-sized cans or packages from the agent's premises for the full retention period specified in paragraph (a) of this section; and

* * * * *

§ 646.154 [Amended]

7. Section 646.154(a) is amended by adding "or contraband smokeless tobacco" after "contraband cigarettes".

8. Section 646.155 is revised to read as follows:

§ 646.155 Forfeitures.

(a) Any contraband cigarettes or contraband smokeless tobacco involved in any violation of the provisions of 18 U.S.C. chapter 114 shall be subject to seizure and forfeiture. The provisions of 18 U.S.C. chapter 46 relating to civil forfeitures shall extend to any seizure or civil forfeiture under this section. Any cigarettes or smokeless tobacco so seized and forfeited shall be either—

(1) Destroyed and not resold; or

(2) Used for undercover investigative operations for the detection and prosecution of crimes, and then destroyed and not resold.

(b) Any vessel, vehicle, or aircraft used to transport, carry, convey, or conceal or possess any contraband cigarettes or contraband smokeless tobacco with respect to which there has been committed any violation of any provision of 18 U.S.C. chapter 114 or the regulations in this subpart shall be subject to seizure and forfeiture pursuant to 49 U.S.C. 80302–80303. The provisions of 18 U.S.C. chapter 46 relating to civil forfeitures shall extend to any seizure or civil forfeiture under this section.

Dated: July 22, 2010.

Eric H. Holder, Jr.,

Attorney General.

[FR Doc. 2010–18552 Filed 7–27–10; 8:45 am]

BILLING CODE 4410–FY–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[EPA–R01–OAR–2010–0459; A–1–FRL–9182–6]

Approval and Promulgation of Air Quality Implementation Plans; Rhode Island; Determination of Attainment of the 1997 Ozone Standard for the Providence, RI Area

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: The EPA is proposing to determine that the Providence (All of Rhode Island) moderate 1997 8-hour ozone nonattainment area continues to attain the 1997 8-hour National Ambient Air Quality Standard (NAAQS) for ozone. This determination is based upon complete, quality-assured, certified ambient air monitoring data that show the area has monitored attainment of the 1997 8-hour ozone NAAQS for the 2007–2009 monitoring period. Preliminary data available through June 15, 2010 also are consistent with continued attainment. In addition, in accordance with the Clean Air Act, EPA is proposing to determine, that this area has attained the 1997 ozone NAAQS as of June 15, 2010, its applicable attainment date.

DATES: Written comments must be received on or before August 27, 2010.

ADDRESSES: Submit your comments, identified by Docket ID Number EPA–R01–OAR–2010–0459 by one of the following methods:

1. *http://www.regulations.gov:* Follow the on-line instructions for submitting comments.

2. *E-mail: arnold.anne@epa.gov*

3. *Fax:* (617) 918–0047.

4. *Mail:* "Docket Identification Number EPA–R01–OAR–2010–0459," Anne Arnold, U.S. Environmental Protection Agency, EPA New England Regional Office, 5 Post Office Square, Suite 100 (mail code: OEP05–2), Boston, MA 02109–3912.

5. *Hand Delivery or Courier.* Deliver your comments to: Anne Arnold, Manager, Air Quality Planning Unit, Office of Ecosystem Protection, U.S. Environmental Protection Agency, EPA New England Regional Office, 5 Post Office Square, Suite 100, Boston, MA 02109–3912. Such deliveries are only accepted during the Regional Office's normal hours of operation. The Regional Office's official hours of business are Monday through Friday, 8:30 a.m. to 4:30 p.m., excluding legal holidays.

Instructions: Direct your comments to Docket ID No. EPA–R01–OAR–2010–0459. EPA's policy is that all comments received will be included in the public docket without change and may be made available online at *http://www.regulations.gov,* including any personal information provided, unless the comment includes information claimed to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Do not submit through *http://www.regulations.gov*, or e-mail, information that you consider to be CBI or otherwise protected. The *http://www.regulations.gov* Web site is an "anonymous access" system, which means EPA will not know your identity or contact information unless you provide it in the body of your comment. If you send an e-mail comment directly to EPA without going through *http://www.regulations.gov* your e-mail address will be automatically captured and included as part of the comment that is placed in the public docket and made available on the Internet. If you submit an electronic comment, EPA recommends that you include your name and other contact information in the body of your comment and with any disk or CD–ROM you submit. If EPA cannot read your comment due to technical difficulties and cannot contact you for clarification, EPA may not be able to consider your comment. Electronic files should avoid the use of special characters, any form of encryption, and be free of any defects or viruses.

Docket: All documents in the electronic docket are listed in the *http://www.regulations.gov* index. Although listed in the index, some information is not publicly available, *i.e.,* CBI or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the Internet and will be publicly available only in hard copy form. Publicly available docket materials are available either electronically in *http://www.regulations.gov* or in hard copy at Office of Ecosystem Protection, U.S. Environmental Protection Agency, EPA New England Regional Office, 5 Post Office Square, Suite 100, Boston, MA. EPA requests that if at all possible, you contact the person listed in the **FOR FURTHER INFORMATION CONTACT** section to schedule your inspection. The Regional Office's official hours of business are Monday through Friday, 8:30 a.m. to 4:30 p.m., excluding legal holidays.

FOR FURTHER INFORMATION CONTACT: Richard P. Burkhart, Air Quality Planning Unit, U.S. Environmental Protection Agency, EPA New England Regional Office, 5 Post Office Square, Suite 100, Boston, MA 02109–3912, telephone number (617) 918–1664, fax number (617) 918–0664, e-mail *Burkhart.Richard@epa.gov*.

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

Organization of this document. The following outline is provided to aid in locating information in this preamble.

I. What actions is EPA taking?
II. What is the effect of these actions?
III. What is the background for these actions?
IV. What is EPA's analysis of the relevant air quality data?
V. Proposed Actions
VI. Statutory and Executive Order Reviews

I. What actions is EPA taking?

EPA is proposing to determine that the Providence (All of Rhode Island) moderate 8-hour ozone nonattainment area continues to attain the 1997 8-hour NAAQS for ozone. This determination is based upon complete, quality-assured and certified ambient air monitoring data that show the area has monitored attainment of the 1997 ozone NAAQS for the 2007–2009 monitoring period. Preliminary data available through June 15, 2010 are also consistent with continued attainment. In addition, under section 181(b)(2)(A) of the Clean Air Act (CAA), EPA is proposing to determine that this area has attained the 1997 ozone NAAQS by its applicable attainment date (June 15, 2010).

II. What is the effect of these actions?

Under section 181(b)(2)(A) of the CAA and the provisions of EPA's ozone implementation rule (see 40 CFR Section 51.902(a)), EPA is proposing to determine that this area has attained the

1997 ozone NAAQS by its applicable attainment date of June 15, 2010. The effect of a final determination of attainment by the area's attainment date would be to discharge EPA's obligation under section 181(b)(2)(A), and to establish that, in accordance with that section, the area would not be reclassified for failure to attain by its applicable attainment date. This proposed action, if finalized, would not constitute a redesignation to attainment under the Clean Air Act (CAA) section 107(d)(3), because we would not yet have an approved maintenance plan for the area as required under section 175A of the CAA, nor a determination that the area has met the other requirements for redesignation. The classification and designation status of the area would remain moderate nonattainment for the 1997 8-hour ozone NAAQS until such time as EPA determines that the area meets the CAA requirements for redesignation to attainment.

III. What is the background for these actions?

On April 30, 2004 (69 FR 23857), EPA designated as nonattainment any area that was violating the 1997 8-hour ozone NAAQS based on the three most recent years (2001–2003) of air quality data. The Providence (All of Rhode Island) area was designated as a moderate ozone nonattainment area. Subsequently, on June 3, 2010, EPA approved a clean data determination for the Rhode Island area, based on 2006–2008 ozone data (see 75 FR 31288). That action suspended the requirements for the area to submit an attainment demonstration, a reasonable further progress plan, section 172(c)(9) contingency measures, and any other planning State Implementation Plans (SIPs) related to attainment of the 1997 8-hour ozone NAAQS for so long as the area continues to attain the 1997 ozone NAAQS. 40 CFR 51.918. Complete, certified ozone air quality data for 2007 through 2009, as well as preliminary data available through June 15, 2010, show that the Rhode Island area continues to meet the 1997 8-hour ozone standard.

IV. What is EPA's analysis of the relevant air quality data?

The EPA has reviewed the ambient air monitoring data for ozone, consistent with the requirements contained in 40 CFR part 50 and recorded in the Air Quality Data System (AQS) database, for Providence (All of Rhode Island) area, from 2007 through 2009. On the basis of its review, EPA proposes to conclude that the area attained the 1997 8-hour ozone standard at the end of the 2009 ozone season, based on three years of complete, quality-assured and state-certified 2007–2009 ozone data. Preliminary data available through June 15, 2010 are also consistent with continued attainment.

Under EPA regulations at 40 CFR part 50, the 1997 8-hour ozone standard is attained at a site when the 3-year average of the annual fourth-highest daily maximum 8-hour average ozone concentrations at an ozone monitor is less than or equal to 0.08 parts per million (ppm) (*i.e.,* 0.084 ppm, based on the rounding convention in 40 CFR part 50, appendix I). This 3-year average is referred to as the design value. When the design value is less than or equal to 0.084 ppm at each monitoring site within the area, then the area is meeting the NAAQS. Also, the data completeness requirement is met when the average percent of days with valid ambient monitoring data is greater than 90%, and no single year has less than 75% data completeness as determined in Appendix I of 40 CFR Part 50.

Table 1 shows the fourth-highest daily maximum 8-hour average ozone concentrations for the Rhode Island nonattainment area monitors for the years 2007–2009, and the ozone design values for these same monitors based on 2007–2009.

TABLE 1—2007–2009 FOURTH-HIGH 8-HOUR AVERAGE OZONE CONCENTRATIONS AND 2007–2009 DESIGN VALUES (PARTS PER MILLION) IN THE RHODE ISLAND AREA

Site ID	Site location	4th High 2007	4th High 2008	4th High 2009	Design value (07–09)
440030002	West Greenwich	0.089	0.074	0.069	0.077
440071010	East Providence	0.088	0.077	0.066	0.078
440090007	Narragansett	0.083	0.081	0.068	0.076

EPA's review of these data indicates that the Rhode Island ozone nonattainment area has met the 1997 8-hour ozone NAAQS, based on 2007–2009 data. EPA believes these data, coupled with preliminary data available through June 15, 2010, indicate that the Rhode Island area has also attained the standard as of its applicable attainment date of June 15, 2010. Thus, in accordance with CAA section 181(b)(2), EPA is also proposing to determine that the Rhode Island area has attained the standard by its applicable attainment date.

EPA is soliciting public comment on the issues discussed in this notice or on other relevant matters pertaining to this rulemaking action. These comments will be considered before EPA takes final action. Interested parties may participate in the Federal rulemaking procedure by submitting written comments to the EPA New England Regional Office listed in the **ADDRESSES** section of this **Federal Register**.

V. Proposed Actions

EPA is proposing to determine that the Providence (All of Rhode Island) 1997 8-hour ozone moderate nonattainment area continues to attain the 1997 8-hour ozone standard, based on complete, quality-assured data from 2007 through 2009. As provided in 40 CFR 51.918, if EPA finalizes this determination, the requirements for Rhode Island to submit planning SIPs related to attainment of the 1997 8-hour ozone NAAQS for this area remain suspended, for so long as the area continues to attain the standard.[1] In addition, under section 181(b)(2)(A) of the Clean Air Act and the provisions of EPA's ozone implementation rule (see 40 CFR 51.902(a)), EPA is proposing to determine that this area has attained the 1997 ozone NAAQS by its applicable attainment date of June 15, 2010.

VI. Statutory and Executive Order Reviews

Theses actions propose to make determinations of attainment based on air quality, and would, if finalized, result in the continued suspension of certain Federal requirements, and would not impose additional requirements beyond those imposed by state law. For that reason, these proposed actions:

[1] Rhode Island submitted an attainment demonstration, reasonable further progress plan and contingency measures for this area on April 30, 2008. EPA has not taken action on these submittals.

• Are 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);

• Do not impose an information collection burden under the provisions of the Paperwork Reduction Act (44 U.S.C. 3501 *et seq.*);

• Are 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.*);

• Do 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);

• Do not have Federalism implications as specified in Executive Order 13132 (64 FR 43255, August 10, 1999);

• Are not economically significant regulatory actions based on health or safety risks subject to Executive Order 13045 (62 FR 19885, April 23, 1997);

• Are not significant regulatory actions subject to Executive Order 13211 (66 FR 28355, May 22, 2001);

• Are not subject to the 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

• Do not provide EPA with the discretionary authority to address, as appropriate, disproportionate human health or environmental effects, using practicable and legally permissible methods, under Executive Order 12898 (59 FR 7629, February 16, 1994).

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

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.

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

Dated: July 15, 2010.

H. Curtis Spalding,

Regional Administrator, EPA New England.

[FR Doc. 2010–18553 Filed 7–27–10; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA–HQ–OPP–2010-0423; FRL–8835–7]

Mevinphos; Proposed Data Call-in Order for Pesticide Tolerance

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed order.

SUMMARY: This document proposes to require the submission of various data required to support the continuation of the tolerances for the pesticide mevinphos. Pesticide tolerances are established under the Federal Food, Drug, and Cosmetic Act (FFDCA).

DATES: Comments must be received on or before September 27, 2010.

ADDRESSES: Submit your comments, identified by docket identification (ID) number EPA–HQ–OPP–2010–0423, 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–2010–0423. 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: K. Avivah Jakob, Pesticide Re-evaluation Division, Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave, NW., Washington, DC 20460–0001; telephone number: (703) 305–1328; e-mail address: *jakob.kathryn@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.

II. FFDCA Data Call-In Authority

In this document, EPA proposes to issue an order requiring the submission of various data to support the continuation of the mevinphos tolerances at 40 CFR 180.157. Under section 408(f) of the Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C. 346a(f), EPA is authorized to require, by order, submission of data "reasonably required to support the continuation of a tolerance" when such data cannot be obtained under the Data Call-In authority of section 3(c)(2)(B) of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), 7 U.S.C. 136a(c)(2)(B), or section 4 of the Toxic Substances Control Act (TSCA), 15 U.S.C. 2603. A section 408(f) Data Call-In order may only be issued following notice and a comment period of not less than 60 days.

A section 408(f) Data Call-In order must contain the following elements:

1. A requirement that one or more persons submit to EPA a notice identifying the person(s) who commit to submit the data required in the order.

2. A description of the required data and the required reports connected to such data.

3. An explanation of why the required data could not be obtained under section 3(c)(2)(B) of FIFRA or section 4 of TSCA.

4. The required submission date for the notice identifying one or more interested persons who commit to submit the required data and the required submission dates for all the data and reports required in the order. (21 U.S.C. 346a(f)(1)(C)).

EPA may by order modify or revoke the affected tolerances if any one of the following submissions is not made in a timely manner:

- A notice identifying one or more interested persons who commit to submit the data.
- The data itself.
- The reports required under a section 408(f) order are not submitted by the date specified in the order. (21 U.S.C. 346a(f)(2)).

III. Regulatory Background for Mevinphos

Mevinphos is a contact/systemic insecticide-acaricide. It is not currently registered under FIFRA and may not be sold, distributed, or used in the United States. Mevinphos' FIFRA registration was canceled in 1994. However, 15 FFDCA tolerances remain for residues of mevinphos on the following commodities: Broccoli, cabbage, cauliflower, celery, cucumbers, grapes, lettuce, melons, peas, peppers, spinach, strawberries, summer squash, tomatoes, and watermelon (40 CFR 180.157). Since there are currently no domestic registrations for mevinphos, these tolerances are referred to as "import tolerances."

Mevinphos is a member of a family of pesticides known as the organophosphates. EPA has concluded mevinphos and other organophosphate pesticides share a common mechanism of toxicity. As with other organophosphates, the principal toxic effects induced by mevinphos are related to its cholinesterase-inhibiting activity. It produces the associated clinical signs such as tremors, unsteady gait, decreased activity, salivation, disturbed balance in rats and rabbits, and decreased cholinesterase activity (plasma, brain) in rats and rabbits following acute, subchronic, and chronic oral exposure.

In September 2000, EPA issued an Interim Tolerance Reassessment Eligibility Decision (ITRED) for mevinphos in connection with its obligation under the Food Quality Protection Act of 1996 (FQPA), to evaluate whether all tolerances in existence at the time of the passage of FQPA met the revised safety standard that the FQPA adopted for FFDCA section 408. In the ITRED, EPA concluded that the risks of mevinphos when evaluated in isolation from other organophosphates met the revised safety standard in FFDCA section 408. This conclusion was labeled "interim," however, because EPA had not yet completed a cumulative risk assessment for the organophosphates. In July 2006, EPA completed its cumulative risk assessment for the organophosphate pesticides finding that these tolerances met the revised safety standard.

The ITRED called attention to several data gaps for mevinphos including:

1. A developmental neurotoxicity (DNT) study in rats (with expanded protocol to extend the postnatal treatment period and to measure cholinesterase inhibition in offspring) as was required for all organophosphate pesticides.

2. Various studies evaluating mevinphos residue levels on treated crops. EPA noted that it would be taking steps to require the submission of this data. Subsequently, the manufacturer of mevinphos submitted residue data for grapes and frozen storage stability data for broccoli, cucumbers, lettuce, tomatoes, and strawberries. However, the registrant has not submitted a DNT study or residue data for the remaining imported commodities.

Under section 3(g) of FIFRA and implementing regulations, EPA has

established a review program for pesticides registered under FIFRA. The goal of that program is a periodic review of pesticide registrations every 15 years to ensure that the registrations satisfy FIFRA standards and are based on "current scientific and other knowledge regarding the pesticide." (40 CFR 155.40(a)). EPA is in the preliminary stages of the registration review process for organophosphate pesticides. Although mevinphos is not registered under FIFRA, EPA will be re-examining mevinphos with the other registered organophosphates because of the organophosphates shared mechanism of toxicity.

In re-examining mevinphos, EPA has identified several studies noted in the ITRED as data gaps for which data have not been submitted and one new regulatory data requirement for which a study is needed. These data are necessary to support the continuation of mevinphos tolerances and are listed below.

IV. Data Requirements

A. Required Data and Reports

Pursuant to FFDCA section 408(f), EPA has determined that additional data are reasonably required to support the continuation of the tolerances for mevinphos which are codified at 40 CFR 180.157. Accordingly, EPA proposes to issue a final order requiring the submission of the following data:

1. Comparative Cholinesterase Assay (Test Guideline 870.6300). A protocol and a final report are required.

Rationale. As an organophosphate pesticide (OP), inhibition of acetylcholinesterase (AChE) is the critical effect for use in human health risk assessment. Many OPs were subject to a Data-Call-In for the developmental neurotoxicity study (DNT). This DCI also included the requirement for AChE inhibition data to evaluate comparative sensitivity in juvenile and adult rats. These data are most often collected in a study called the comparative cholinesterase assay (CCA). Since that time, CCA studies for more than 20 OPs have been submitted to OPP. Although for some OPs no difference in sensitivity has been observed in juvenile and adult animals, for many of the OPs, juveniles have been shown to be more sensitive. At this time, OPP has determined that a CCA is required for mevinphos to evaluate the potential for increased sensitivity in juvenile animals compared with that of adult animals. Given that the AChE data provided in the CCAs have provided more sensitive results than DNT studies for the OPs, a DNT study for mevinphos is not required at this time.

2. Immunotoxicity Study (Test Guideline 870.7800). A final report and protocol are required.

Rationale. This is a new data requirement under 40 CFR part 158 as a part of the data requirements for registration of a pesticide (food and non-food uses).

The Immunotoxicity Test Guideline (Harmonized Guideline 870.7800) prescribes functional immunotoxicity testing and is designed to evaluate the potential of a repeated chemical exposure to produce adverse effects (i.e., suppression) on the immune system. Immunosuppression is a deficit in the ability of the immune system to respond to a challenge of bacterial or viral infections such as tuberculosis (TB), severe acquired respiratory syndrome (SARS), or neoplasia.

3. Directions for Use (Test Guideline 860.1200)

Rationale. The Agency needs use directions, which appear on the Mexico label(s).

4. Crop Field Trials (Test Guideline 860.1500) – (broccoli, cabbage, cauliflower, celery, grapes, lettuce, peas, peppers, spinach, strawberries, summer squash, and tomatoes.)

Rationale. Field trials are required for each commodity/commodity group according to guidelines that take into account where the crop is grown and how much of the crop is grown. Field trials are required for each type of formulation because the formulation can have significant effect on the magnitude of the pesticide residue left on the crop. Residue trials also need to represent the maximum application rate on the label and have a geographic distribution representative of the commodity/commodity group. On June 1, 2000 (65 FR 35069) (FRL–6559–3), EPA published in the **Federal Register**, a Notice which provided detailed guidance on applying current U.S. data requirements for the establishment or continuance of tolerances for pesticide residues in or on imported foods. A copy of that Notice is available in the docket of this proposed order. That Notice contains instructions for determining number and location of field trials.

5. Processing Study (tomatoes) (Test Guideline 860.1520)

Rationale. Processing studies are required to determine whether residues in raw commodities may be expected to degrade or concentrate during food processing. If residues concentrate in a processed commodity, a food or feed additive tolerance must be established. If residues do not concentrate in a processed commodity, the tolerance for the raw agricultural commodity applies to all processed food or feed derived from it.

B. Persons who Commit to Submit the Required Data

After this 60–day comment period closes, the Agency will respond to comments, if appropriate, and may issue a final order requiring the submission of various data for mevinphos in the **Federal Register**. If EPA issues such an order, persons who are interested in the continuation of the mevinphos tolerances must notify the Agency by completing and submitting the required "§408(f) Order Response" form (available in the docket) within 90 days after publication of the final order in the **Federal Register**.

The "§408(f) Order Response Form" requires the identification of persons who will submit the required data and lists the options available to support the required data:

i. Develop new data.

ii. Submit an Existing Study — submit existing data not submitted previously to the Agency by anyone,

iii. Upgrade a Study – submit or cite data to upgrade a study classified by EPA as partially acceptable and upgradable,

iv. Cite an Existing Study – cite an existing study that EPA classified as acceptable or an existing study that has been submitted but not reviewed by the Agency.

C. Required Dates for Submission of Data/Reports

The table below lists the time allocated for both the completion and submission of each study. The required submission date is calculated from the date of publication in the **Federal Register** of the final order.

Guideline Requirement Number	Study Title	Timeframe for protocol submission	Timeframe for data submission
860.1200	Directions for use	Not required	12 months

Guideline Requirement Number	Study Title	Timeframe for protocol submission	Timeframe for data submission
860.1500	Crop Field Trials (broccoli, cabbage, cauliflower, celery, grapes, lettuce, peas, peppers, spinach, strawberries, summer squash, and tomatoes)	Not Required	24 months
860.1520	Processing studies (tomatoes)	Not Required	24 months
870.6300	Comparative Cholinesterase Assay	6 months	12 months
870.7800	Immunotoxicity Study	6 months	12 months

D. Failure to Submit

If the Agency does not receive a §408(f) Response Form identifying a person who agrees to submit the required data within 90 days after publication of the final order, EPA will proceed to revoke the mevinphos tolerances at 40 CFR 180.157. Such revocation order is subject to the objection and hearing procedure in FFDCA section 408(g)(2) but the only material issue in such a procedure is whether a submission required by the order was made in a timely fashion.

Additional events that may be the basis for modification or revocation of mevinphos tolerances include, but are not limited to the following:

1. No person submits on the required schedule an acceptable proposal or final protocol when such is required to be submitted to the Agency for review.
2. No person submits on the required schedule an adequate progress report on a study as required by the order.
3. No person submits on the required schedule acceptable data as required by the final order.
4. No person submits supportable certifications as to the conditions of submitted data, where required by order and where no other cited or submitted study meets the data requirements the study was intended to fulfill.

V. Statutory and Executive Order Reviews

As required by statute, this proposal to require submission of data in support of tolerances is in the form of an order and not a rule. (21 U.S.C. 346a(f)(1)(C)). Under the Administrative Procedures Act, orders are expressly excluded from the definition of a rule. (5 U.S.C. 551(4)). Accordingly, the regulatory assessment requirements imposed on rulemaking do not, therefore, apply to this action.

List of Subjects in 40 CFR Part 180

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

Dated: July 22, 2010.

Richard P. Keigwin, Jr.,

Director, Pesticide Re-evaluation Division, Office of Pesticide Programs.

[FR Doc. 2010–18541 Filed 7–27–10; 8:45 am]

BILLING CODE 6560–50–S

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA–HQ–OPP–2010–0490; FRL–8834–1]

Aluminum tris(O-ethylphosphonate), Butylate, Chlorethoxyfos, Clethodim, et al.; Proposed Tolerance Actions

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: In accordance with current Agency practice to describe more clearly the measurement and scope or coverage of the tolerances, EPA is proposing minor revisions to tolerance expressions for a number of pesticide active ingredients, including the insecticides chlorethoxyfos, clofentezine, cyromazine, etofenprox, fenbutatin-oxide, fosthiazate, propetamphos, and tebufenozide; the fungicides aluminum tris(*O*-ethylphosphonate) and fenarimol; the herbicides butylate, clethodim, clomazone, fenoxaprop-ethyl, flumetsulam, flumiclorac pentyl, fluridone, fomesafen, glufosinate ammonium, lactofen, propyzamide, quinclorac, and pyridate; and the fungicide/bactericide oxytetracycline. Also, EPA is proposing to revoke the tolerances for aluminum tris(*O*-ethylphosphonate) on pineapple fodder and forage because they are not considered to be significant livestock feed items, and revise specific tolerance nomenclatures for aluminum tris(*O*-ethylphosphonate), clethodim, flumetsulam, and fluridone. In addition, EPA will be removing several expired tolerances for aluminum tris(*O*-ethylphosphonate), etofenprox, propyzamide, and tebufenozide.

DATES: Comments must be received on or before September 27, 2010.

ADDRESSES: Submit your comments, identified by docket identification (ID) number EPA–HQ–OPP–2010–0490, by one of the following methods:

- *Federal eRulemaking Portal*: *http://www.regulations.gov*. Follow the o*N*-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–2010–0490. EPA's policy is that all comments received will be included in the docket without change and may be made available o*N*-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:

Joseph Nevola, Pesticide Re-evaluation Division (7508P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave, NW., Washington, DC 20460–0001; telephone number: (703) 308-8037; e-mail address: *nevola.joseph@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. To determine whether you or your business may be affected by this action, you should carefully examine the applicability provisions in Unit II.A. 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.

C. What Can I do if I Wish the Agency to Maintain a Tolerance that the Agency Proposes to Revoke?

This proposed rule provides a comment period of 60 days for any person to state an interest in retaining a tolerance proposed for revocation. If EPA receives a comment within the 60–day period to that effect, EPA will not proceed to revoke the tolerance immediately. However, EPA will take steps to ensure the submission of any needed supporting data and will issue an order in the **Federal Register** under the Federal Food, Drug, and Cosmetic Act (FFDCA) section 408(f), if needed. The order would specify data needed and the timeframes for its submission, and would require that within 90 days some person or persons notify EPA that they will submit the data. If the data are not submitted as required in the order, EPA will take appropriate action under FFDCA.

EPA issues a final rule after considering comments that are submitted in response to this proposed rule. In addition to submitting comments in response to this proposal, you may also submit an objection at the time of the final rule. If you fail to file an objection to the final rule within the time period specified, you will have waived the right to raise any issues resolved in the final rule. After the specified time, issues resolved in the final rule cannot be raised again in any subsequent proceedings.

II. Background

A. What Action is the Agency Taking?

In accordance with current Agency practice to describe more clearly the measurement and scope or coverage of tolerances, including applicable metabolites and degradates, EPA is proposing minor revisions to tolerance expressions for a number of pesticide active ingredients, including the insecticides chlorethoxyfos, clofentezine, cyromazine, etofenprox, fenbutatin-oxide, fosthiazate, propetamphos, and tebufenozide; the fungicides aluminum tris(*O*-ethylphosphonate) and fenarimol; the herbicides butylate, clethodim, clomazone, fenoxaprop-ethyl, flumetsulam, flumiclorac pentyl, fluridone, fomesafen, glufosinate ammonium, lactofen, propyzamide, quinclorac, and pyridate; and the fungicide/bactericide oxytetracycline. Also, EPA is proposing to revoke the tolerances for aluminum tris(*O*-

ethylphosphonate) on pineapple fodder and forage because they are not considered to be significant livestock feed items, and therefore are no longer needed, and revise specific tolerance nomenclatures for aluminum tris(*O*-ethylphosphonate), clethodim, flumetsulam, and fluridone. Additional minor modifications are being made for reasons described in the discussion below pertaining to specific pesticides. It is EPA's general practice to propose revocation of those tolerances/tolerance exemptions for residues of pesticide active ingredients on crop uses for which there are no active registrations under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), unless any person submits comments on the proposal that indicate a need for the tolerance to cover residues in or on imported commodities or legally treated domestic commodities. In addition, EPA will be removing several expired tolerances for aluminum tris(*O*-ethylphosphonate), etofenprox, propyzamide, and tebufenozide.

Certain tolerances pertaining to the pesticides subject to this proposal have expired due to previous EPA regulation setting expiration dates. When the Agency finalizes the changes proposed in this document, EPA will also remove the expired tolerances from the Code of Federal Regulations. The amended regulatory text below reflects removal of the tolerances. The Agency is not accepting comments regarding the expired tolerances.

1. *Aluminum tris(O-ethylphosphonate)*. In order to describe more clearly the measurement and scope or coverage of the tolerances, EPA is proposing to revise the introductory text containing the tolerance expression in 40 CFR 180.415(a) to read as follows:

Tolerances are established for residues of the fungicide aluminum tris(*O*-ethylphosphonate), including its metabolites and degradates, in or on the commodities in the table in this paragraph. Compliance with the tolerance levels specified in this paragraph is to be determined by measuring only aluminum tris(*O*-ethylphosphonate), in or on the commodity.

Because pineapple, fodder and pineapple, forage are no longer considered by the Agency to be significant livestock feed items as delineated in "Table 1. – Raw Agricultural and Processed Commodities and Feedstuffs Derived from Crops," which is found under OCSPP Harmonized Test Guidelines for Residue Chemistry in 860.1000 dated August 1996 (available at *http://www.epa.gov/ocspp/pubs/frs/publications/Test_Guidelines/series860.htm*), EPA determined that these tolerances in 40 CFR 180.415(a) are no longer needed, and therefore should be revoked. Consequently, EPA is proposing to revoke the tolerances in 40 CFR 180.415(a) on pineapple, fodder and pineapple, forage.

In addition, EPA is proposing to revise commodity terminology to conform to current Agency practice in 40 CFR 180.415(a) as follows: "fruit, pome" to "fruit, pome, group 11."

In order to describe more clearly the measurement and scope or coverage of the tolerances, EPA is proposing to revise the introductory text containing the tolerance expression in 40 CFR 180.415(c) to read as follows:

Tolerances with regional registration are established for residues of the fungicide aluminum tris(*O*-ethylphosphonate), including its metabolites and degradates, in or on the commodities in the table in this paragraph. Compliance with the tolerance levels specified in this paragraph is to be determined by measuring only aluminum tris(*O*-ethylphosphonate), in or on the commodity.

2. *Butylate*. In order to describe more clearly the measurement and scope or coverage of the tolerances, EPA is proposing to revise the introductory text containing the tolerance expression in 40 CFR 180.232(a) to read as follows:

Tolerances are established for residues of the herbicide butylate, including its metabolites and degradates, in or on the commodities in the table in this paragraph. Compliance with the tolerance levels specified in this paragraph is to be determined by measuring only butylate, *S*-ethyl bis(2-methylpropyl)carbamothioate, in or on the commodity.

3. *Chlorethoxyfos*. In order to describe more clearly the measurement and scope or coverage of the tolerances, EPA is proposing to revise the section heading in 40 CFR 180.486 from phosphorothioic acid, *O,O*-diethyl *O*-(1,2,2,2-tetrachloroethyl) ester to chlorethoxyfos, redesignate the existing paragraph from 40 CFR 180.486 to 180.486(a), and revise the introductory text containing the tolerance expression in newly designated 40 CFR 180.486(a) to read as follows:

Tolerances are established for residues of the insecticide chlorethoxyfos, including its metabolites and degradates, in or on the commodities in the table in this paragraph. Compliance with the tolerance levels specified in this paragraph is to be determined by measuring only chlorethoxyfos, *O,O*-diethyl *O*-(1,2,2,2-tetra chloroethyl) phosphorothioate, in or on the commodity.

In accordance with current Agency practice, EPA is proposing to revise 40 CFR 180.486 by adding separate paragraphs (b), (c), and (d), and reserving those paragraphs for tolerance exemptions for section 18 emergency exemptions, tolerances with regional registrations, and tolerances with indirect or inadvertent residues, respectively.

4. *Clethodim*. In order to harmonize with Codex and describe more clearly the measurement and scope or coverage of the tolerances, EPA is proposing that all the existing animal and plant tolerances for clethodim in 40 CFR 180.458(a)(1), 180.458(a)(2), and 180.458(a)(3) be expressed under the same tolerance expression in one paragraph, as 40 CFR 180.458(a), to read as follows:

Tolerances are established for residues of the herbicide clethodim, including its metabolites and degradates, in or on the commodities in the table in this paragraph. Compliance with the tolerance levels specified in this paragraph is to be determined by measuring only the sum of clethodim, 2-[(1E)-1-[[[(2E)-3-chloro-2-propenyl]oxy]imino]propyl]-5-[2-(ethylthio) propyl]-3-hydroxy-2-cyclohexen-1-one, and its metabolites containing the 5-(2-ethylthiopropyl)cyclohexene-3-one and 5-(2-ethylthiopropyl)-5-hydroxycyclohexene-3-one moieties and their sulphoxides and sulphones, calculated as the stoichiometric equivalent of clethodim, in or on the commodity.

Also, EPA is proposing to revise commodity terminology to conform to current Agency practice in newly designated 40 CFR 180.458(a) from "flax seed" to "flax, seed" and "vegetable, legume group 6, except soybean" to "vegetable, legume, group 6, except soybean."

5. *Clofentezine*. In order to describe more clearly the measurement and scope or coverage of the tolerances, EPA is proposing to revise the introductory text containing the tolerance expression in 40 CFR 180.446(a)(1) to read as follows:

Tolerances are established for residues of the insecticide clofentezine, including its metabolites and degradates, in or on the commodities in the table in this paragraph. Compliance with the tolerance levels specified in this paragraph is to be determined by measuring only clofentezine, 3,6-bis(2-chlorophenyl)-1,2,4,5-tetrazine, in or on the commodity.

In order to describe more clearly the measurement and scope or coverage of the tolerances, EPA is proposing to revise the introductory text containing the tolerance expression in 40 CFR 180.446(a)(2) to read as follows:

Tolerances are established for residues of the insecticide clofentezine, including its metabolites and degradates, in or on the commodities in the table in this paragraph. Compliance with the tolerance levels specified in this paragraph is to be

determined by measuring only the sum of clofentezine, 3,6-bis(2-chlorophenyl)-1,2,4,5-tetrazine, and its metabolite, 3-(2-chloro-4-hydroxyphenyl)-6-(2-chlorophenyl)-1,2,4,5-tetrazine, calculated as the stoichiometric equivalent of clofentezine, in or on the commodity.

6. *Clomazone*. In order to describe more clearly the measurement and scope or coverage of the tolerances, EPA is proposing to revise the introductory text containing the tolerance expression in 40 CFR 180.425(a) to read as follows:

Tolerances are established for residues of the herbicide clomazone, including its metabolites and degradates, in or on the commodities in the table in this paragraph. Compliance with the tolerance levels specified in this paragraph is to be determined by measuring only clomazone, 2-(2-chlorophenyl)methyl-4,4-dimethyl-3-isoxa zolidinone, in or on the commodity.

7. *Cyromazine*. In order to describe more clearly the measurement and scope or coverage of the tolerances, EPA is proposing to revise the introductory text containing the tolerance expression in 40 CFR 180.414(a)(1) to read as follows:

Tolerances are established for residues of the insecticide cyromazine, including its metabolites and degradates, in or on the commodities in the table in this paragraph. Compliance with the tolerance levels specified in this paragraph is to be determined by measuring only cyromazine, *N*-cyclopropyl-1,3,5-triazine-2,4,6-triamine, in or on the commodity.

Also, in order to describe more clearly the measurement and scope or coverage of the tolerances, EPA is proposing to revise the introductory text containing the tolerance expression in 40 CFR 180.414(a)(2) and remove existing subparagraphs (a)(2)(i), (a)(2)(ii), (a)(2)(iii), (a)(2)(iv), and (a)(2)(v). The revised paragraph (a)(2) reads as follows:

A tolerance of 5.0 parts per million is established for residues of the insecticide cyromazine, including its metabolites and degradates, in or on poultry feed when used as a feed additive only in feed for chicken layer hens and chicken breeder hens at the rate of not more than 0.01 pound of cyromazine per ton of poultry feed for control of flies in manure of treated chicken layer hens and chicken breeder hens, provided the feeding of cyromazine-treated feed must stop at least 3 days (72 hours) before slaughter. If the feed is formulated by any person other than the end user, the formulator must inform the end user, in writing, of the 3–day (72 hours) pre-slaughter interval. Compliance with the tolerance level specified in this paragraph is to be determined by measuring only cyromazine, *N*-cyclopropyl-1,3,5-triazine-2,4,6-triamine, in or on the commodity.

In addition, in order to describe more clearly the measurement and scope or coverage of the tolerances, EPA is proposing to revise the introductory text containing the tolerance expression in 40 CFR 180.414(d) to read as follows:

Tolerances are established for the indirect or inadvertent residues of the insecticide cyromazine, including its metabolites and degradates, in or on the commodities in the table in this paragraph when present therein as a result of the application of cyromazine to growing crops listed in paragraph (a)(1) of this section. Compliance with the tolerance levels specified in this paragraph is to be determined by measuring only cyromazine, *N*-cyclopropyl-1,3,5-triazine-2,4,6-triamine, in or on the commodity.

8. *Etofenprox*. In order to describe more clearly the measurement and scope or coverage of the tolerances, EPA is proposing to revise the introductory text containing the tolerance expression in 40 CFR 180.620(a) to read as follows:

A tolerance is established for residues of the insecticide etofenprox, including its metabolites and degradates, in or on the commodity in the table in this paragraph. Compliance with the tolerance level specified in this paragraph is to be determined by measuring only etofenprox, 2-(4-ethoxyphenyl)-2-methylpropyl 3-phenoxybenzyl ether, in or on the commodity.

9. *Fenarimol*. In order to describe more clearly the measurement and scope or coverage of the tolerances, EPA is proposing to revise the introductory text containing the tolerance expression in 40 CFR 180.421(a) to read as follows:

Tolerances are established for residues of the fungicide fenarimol, including its metabolites and degradates, in or on the commodities in the table in this paragraph. Compliance with the tolerance levels specified in this paragraph is to be determined by measuring only fenarimol, alpha-(2-chlorophenyl)-alpha-(4-chloro phenyl)-5-pyrimidinemethanol, in or on the commodity.

10. *Fenbutatin-oxide*. In order to describe more clearly the measurement and scope or coverage of the tolerances, EPA is proposing to revise the section heading in 40 CFR 180.362 from hexakis (2-methyl-2-phenylpropyl)distannoxane to fenbutatin-oxide and revise the introductory text containing the tolerance expression in 40 CFR 180.362(a)(1) to read as follows:

Tolerances are established for residues of the miticide/acaricide fenbutatin-oxide, including its metabolites and degradates, in or on the plant commodities in the table in this paragraph. Compliance with the tolerance levels specified in this paragraph is to be determined by measuring only fenbutatin-oxide, hexakis (2-methyl-2-phenyl propyl)distannoxane, in or on the commodity.

In order to describe more clearly the measurement and scope or coverage of the tolerances, EPA is proposing to revise the introductory text containing the tolerance expression in 40 CFR 180.362(a)(2) to read as follows:

Tolerances are established for residues of the miticide/acaricide fenbutatin-oxide, including its metabolites and degradates, in or on the animal commodities in the table in this paragraph. Compliance with the tolerance levels specified in this paragraph is to be determined by measuring only the sum of fenbutatin-oxide, hexakis (2-methyl-2-phenylpropyl)distannoxane, and its organotin metabolites, dihydroxybis(2-methyl-2-phenylpropyl)stannane and 2-methyl-2-phenylpropylstannoic acid, calculated as the stoichiometric equivalent of fenbutatin-oxide, in or on the commodity.

In the May 2002 Tolerance Reassessment Decision (TRED) for fenbutatin-oxide, EPA determined that in order to better harmonize with Codex Alimentarius, the tolerance expression for plant commodities should include the parent compound only for compliance. Currently, there is one regional tolerance in 40 CFR 180.362(c) for residues of the parent compound and its organotin metabolites calculated as the parent compound in or on raspberry. Therefore, in order to better harmonize with Codex and describe more clearly the measurement and scope or coverage of the tolerances, EPA is proposing to revise the introductory text containing the tolerance expression in 40 CFR 180.362(c) to read as follows:

A tolerance with regional registration is established for residues of the miticide/acaricide fenbutatin-oxide, including its metabolites and degradates, in or on the plant commodity in the table in this paragraph. Compliance with the tolerance level specified in this paragraph is to be determined by measuring only fenbutatin-oxide, hexakis (2-methyl-2-phenylpropyl)distannoxane, in or on the commodity.

11. *Fenoxaprop-ethyl*. In order to describe more clearly the measurement and scope or coverage of the tolerances, EPA is proposing to revise the introductory text containing the tolerance expression in 40 CFR 180.430(a) to read as follows:

Tolerances are established for residues of the herbicide fenoxaprop-ethyl, including its metabolites and degradates, in or on the commodities in the table in this paragraph. Compliance with the tolerance levels specified in this paragraph is to be determined by measuring only the sum of fenoxaprop-ethyl, (±)-ethyl 2-[4-[(6-chloro-2-benzoxazolyl)oxy]phenoxy]propanoate, and its metabolites, 2-[4-[(6-chloro-2-benzoxazolyl)oxy]phenoxy]propanoic acid and 6-chloro-2,3-dihydrobenzoxazol-2-one, calculated as the stoichiometric equivalent of fenoxaprop-ethyl, in or on the commodity.

Also, in order to describe more clearly the measurement and scope or coverage

of the tolerances, EPA is proposing to revise the introductory text containing the tolerance expression in 40 CFR 180.430(b) to read as follows:

Time-limited tolerances are established for residues of the herbicide fenoxaprop-ethyl, including its metabolites and degradates, in or on the commodities in the table in this paragraph in connection with use of fenoxaprop-ethyl under section 18 emergency exemptions granted by EPA. Compliance with the tolerance levels specified in this paragraph is to be determined by measuring only the sum of fenoxaprop-ethyl, (±)-ethyl 2-[4-[(6-chloro-2-benzoxazolyl)oxy]phenoxy]propanoate, and its metabolites, 2-[4-[(6-chloro-2-benzoxazolyl)oxy]phenoxy]propanoic acid and 6-chloro-2,3-dihydrobenzoxazol-2-one, calculated as the stoichiometric equivalent of fenoxaprop-ethyl, in or on the commodity. The tolerances expire and are revoked on the dates specified in the table in this paragraph.

12. *Flumetsulam*. In order to describe more clearly the measurement and scope or coverage of the tolerances, EPA is proposing to redesignate the existing paragraph from 40 CFR 180.468 to 180.468(a) and revise the introductory text containing the tolerance expression in newly designated 40 CFR 180.468(a) to read as follows:

Tolerances are established for residues of the herbicide flumetsulam, including its metabolites and degradates, in or on the commodities in the table in this paragraph. Compliance with the tolerance levels specified in this paragraph is to be determined by measuring only flumetsulam, *N*-(2,6-difluorophenyl)-5-methyl-(1,2,4)-triazolo-(1,5a)-pyrimidine-2-sulfonamide, in or on the commodity.

In accordance with current Agency practice, EPA is proposing to amend 40 CFR 180.468 by adding separate paragraphs (b), (c), and (d), and reserving those paragraphs for tolerance exemptions for section 18 emergency exemptions, tolerances with regional registrations, and tolerances with indirect or inadvertent residues, respectively.

In addition, EPA is proposing to revise commodity terminology to conform to current Agency practice in newly designated 40 CFR 180.468(a) as follows: "bean, dry" to "bean, dry, seed;" and "soybean" to "soybean, seed."

13. *Flumiclorac pentyl*. In order to describe more clearly the measurement and scope or coverage of the tolerances, EPA is proposing to revise the introductory text containing the tolerance expression in 40 CFR 180.477(a) to read as follows:

Tolerances are established for residues of the herbicide flumiclorac pentyl, including its metabolites and degradates, in or on the commodities in the table in this paragraph. Compliance with the tolerance levels specified in this paragraph is to be determined by measuring only flumiclorac pentyl, pentyl(2-chloro-4-fluoro-5-(1,3,4,5,6,7-hexahydro-1,3-dioxo-2*H*-isoindol-2-yl)phenoxy)acetate, in or on the commodity.

14. *Fluridone*. In order to describe more clearly the measurement and scope or coverage of the tolerances, EPA is proposing to redesignate the existing paragraph from 40 CFR 180.420(a) to 180.420(a)(1), add a table for existing commodities, and revise the introductory text containing the tolerance expression in newly designated 40 CFR 180.420(a)(1) to read as follows:

Tolerances are established for residues of the herbicide fluridone, including its metabolites and degradates, in or on the commodities in the table in this paragraph. Compliance with the tolerance levels specified in this paragraph is to be determined by measuring only the sum of fluridone, 1-methyl-3-phenyl-5-(3-(trifluoro methyl)phenyl)-4(1*H*)-pyridinone, and its bound residues, calculated as the stoichiometric equivalent of fluridone, in or on the commodity.

Also, in order to describe more clearly the measurement and scope or coverage of the tolerances, EPA is proposing to redesignate the existing paragraph from 40 CFR 180.420(b) to 180.420(a)(2) and revise the introductory text containing the tolerance expression in newly designated 40 CFR 180.420(a)(2) to read as follows:

Tolerances are established for residues of the herbicide fluridone, including its metabolites and degradates, in or on the commodities in the table in this paragraph. Compliance with the tolerance levels specified in this paragraph is to be determined by measuring only fluridone, 1-methyl-3-phenyl-5-(3-(trifluoromethyl) phenyl)-4(1*H*)-pyridinone, in or on the commodity.

In addition, in order to describe more clearly the measurement and scope or coverage of the tolerances, EPA is proposing to redesignate the existing paragraph from 40 CFR 180.420(c) to 180.420(d) and revise the introductory text containing the tolerance expression in newly designated 40 CFR 180.420(d) to read as follows:

Tolerances are established for indirect or inadvertent residues of the herbicide fluridone, including its metabolites and degradates, in or on the irrigated crop commodities and crop groupings in the table in this paragraph, resulting from use of irrigation water containing residues of 0.15 ppm following applications of fluridone on or around aquatic sites. Where tolerances are established at higher levels from other uses of fluridone on the following crops, the higher tolerance also applies to residues in the irrigated commodity. Compliance with the tolerance levels specified in this paragraph is to be determined by measuring only fluridone, 1-methyl-3-phenyl-5-(3-(trifluoromethyl)phenyl)-4(1*H*)-pyridinone, in or on the commodity.

In accordance with current Agency practice, EPA is proposing to amend 40 CFR 180.420 by adding separate paragraphs (b) and (c), and reserving those paragraphs for tolerance exemptions for section 18 emergency exemptions and tolerances with regional registrations, respectively.

In addition, EPA is proposing to revise commodity terminology to conform to current Agency practice in the table to newly designated 40 CFR 180.420(d) as follows: "citrus" to "fruit, citrus, group 10;" "cucurbits" to "vegetable, cucurbit, group 9;" "fruit, pome" to "fruit, pome, group 11; "fruit, small" to "berry, group 13;" "cranberry;" "grape;" and "strawberry;" "fruit, stone" to "fruit, stone, group 12; "grain, crop" to "grain, cereal, group 15" and "grain, cereal, forage, fodder and straw, group 16;" "legume, forage" to "animal feed, nongrass, group 18;" nut" to "nut, tree, group 14;" "vegetable, fruiting" to "vegetable, fruiting, group 8;" "vegetable, leafy" to "vegetable, leafy, except brassica, group 4" and "vegetable, brassica, leafy, group 5;" "vegetable, root crop" to "vegetable, root and tuber, group 1" and "vegetable, leaves of root and tuber, group 2;" "vegetable, seed and pod" to "vegetable, legume, group 6" and "okra."

15. *Fomesafen*. In order to describe more clearly the measurement and scope or coverage of the tolerances, EPA is proposing to revise the introductory text containing the tolerance expression in 40 CFR 180.433(a) to read as follows:

Tolerances are established for residues of the herbicide fomesafen, including its metabolites and degradates, in or on the commodities in the table in this paragraph from the application of its sodium salt. Compliance with the tolerance levels specified in this paragraph is to be determined by measuring only fomesafen, 5-(2-chloro-4-(trifluoromethyl)phenoxy)-*N*-(methylsulfonyl)-2-nitrobenzamide, in or on the commodity.

16. *Fosthiazate*. In order to describe more clearly the measurement and scope or coverage of the tolerances, EPA is proposing to revise the introductory text containing the tolerance expression in 40 CFR 180.596(a) to read as follows:

A tolerance is established for residues of the insecticide fosthiazate, including its metabolites and degradates, in or on the commodity in the table in this paragraph. Compliance with the tolerance level specified in this paragraph is to be determined by measuring only the sum of fosthiazate, *O*-ethyl *S*-(1-methylpropyl)(2-

oxo-3-thiazolidinyl)phosphonothioate, and its metabolite, *O*-ethyl *S*-(1-methylpropyl)(2-(methylsulfonyl)ethyl)phosphorami dothioate, calculated as the stoichiometric equivalent of fosthiazate, in or on the commodity.

17. *Glufosinate ammonium*. In order to describe more clearly the measurement and scope or coverage of the tolerances, EPA is proposing to revise the introductory text containing the tolerance expression in 40 CFR 180.473(a) to read as follows:

Tolerances are established for residues of the herbicide glufosinate ammonium, including its metabolites and degradates, in or on the commodities in the table in this paragraph. Compliance with the tolerance levels specified in this paragraph is to be determined by measuring only the sum of glufosinate ammonium, 2-amino-4-(hydroxy methylphosphinyl)butanoic acid monoammonium salt, and its metabolites, 2-acetamido-4-methylphosphinicobutanoic acid and 3-methylphosphinicopropionic acid, calculated as the stoichiometric equivalent of 2-amino-4-(hydroxymethylphos phinyl)butanoic acid, in or on the commodity.

Also, in order to describe more clearly the measurement and scope or coverage of the tolerances, EPA is proposing to revise the introductory text containing the tolerance expression in 40 CFR 180.473(d) to read as follows:

Tolerances are established for indirect or inadvertent residues of the herbicide glufosinate ammonium, including its metabolites and degradates, in or on the commodities in the table in this paragraph when present therein as a result of the application of glufosinate ammonium to crops listed in the table in paragraph (a) of this section. Compliance with the tolerance levels specified in this paragraph is to be determined by measuring only the sum of glufosinate ammonium, 2-amino-4-(hydroxy methylphosphinyl)butanoic acid monoammonium salt, and its metabolite, 3-methylphosphinicopropionic acid, calculated as the stoichiometric equivalent of 2-amino-4-(hydroxymethylphosphinyl)butanoic acid, in or on the commodity.

18. *Lactofen*. In order to describe more clearly the measurement and scope or coverage of the tolerances, EPA is proposing to revise the introductory text containing the tolerance expression in 40 CFR 180.432(a) to read as follows:

Tolerances are established for residues of the herbicide lactofen, including its metabolites and degradates, in or on the commodities in the table in this paragraph. Compliance with the tolerance levels specified in this paragraph is to be determined by measuring only lactofen, 2-ethoxy-1-methyl-2-oxoethyl 5-[2-chloro-4-(trifluoromethyl)phenoxy]-2-nitrobenzoate, in or on the commodity.

Also, in order to describe more clearly the measurement and scope or coverage of the tolerances, EPA is proposing to revise the introductory text containing the tolerance expression in 40 CFR 180.432(c) to read as follows:

Tolerances with regional registration are established for residues of the herbicide lactofen, including its metabolites and degradates, in or on the commodities in the table in this paragraph. Compliance with the tolerance levels specified in this paragraph is to be determined by measuring only lactofen, 2-ethoxy-1-methyl-2-oxoethyl 5-[2-chloro-4-(trifluoromethyl)phenoxy]-2-nitrobenzoate, in or on the commodity.

19. *Oxytetracycline*. In order to describe more clearly the measurement and scope or coverage of the tolerances, EPA is proposing to designate the existing paragraph in 40 CFR 180.337 as § 180.337(a) and revise the introductory text containing the tolerance expression in newly designated 40 CFR 180.337(a) to read as follows:

Tolerances are established for residues of the fungicide/bactericide oxytetracycline, including its metabolites and degradates, in or on the commodities in the table in this paragraph. Compliance with the tolerance levels specified in this paragraph is to be determined by measuring only oxytetracycline, (4S,4aR,5S,5aR,6S,12aS)-4-(dimethylamino)-1,4,4a,5,5a,6,11,12a-octahydro-3,5,6,10,12,12a-hexahydroxy-6-methyl-1,11-dioxo-2-naphthacene carboxamide, in or on the commodity.

In accordance with current Agency practice, EPA is proposing to revise 40 CFR 180.337 by adding separate paragraphs (b), (c), and (d), and reserving those paragraphs for section 18 emergency exemptions, tolerances with regional registrations, and tolerances with indirect or inadvertent residues, respectively.

20. *Propetamphos*. In order to describe more clearly the measurement and scope or coverage of the tolerances, EPA is proposing in 40 CFR 180.541 to remove paragraphs (a)(1), (a)(2), and (a)(3) and revise paragraph (a), including the introductory text containing the tolerance expression, to read as follows:

A tolerance of 0.1 part per million is established for residues of the insecticide propetamphos, including its metabolites and degradates, in or on food or feed commodities when present therein as a result of the treatment of food- or feed-handling establishments with propetamphos. Direct application shall be limited solely to spot and/or crack and crevice treatment in food- or feed-handling establishments where food or feed and food or feed products are held, processed, prepared, served, or sold. Spray and dust concentrations shall be limited to a maximum of 1 percent active ingredient. For crack and crevice treatment, equipment capable of delivering a dust or a pin-stream of spray directly into cracks and crevices shall be used. For spot treatment, a coarse, low-pressure spray shall be used to avoid contamination of food, feed, or food-contact/feed-contact surfaces. Compliance with the tolerance level specified in this paragraph is to be determined by measuring only propetamphos, 1-methylethyl-(2E)-3-((ethyl amino)methoxyphosphinothioyl)oxy)-2-butenoate, in or on the commodity.

21. *Propyzamide*. In order to describe more clearly the measurement and scope or coverage of the tolerances, EPA is proposing to revise the introductory text containing the tolerance expression in 40 CFR 180.317(a) to read as follows:

Tolerances are established for residues of the herbicide propyzamide, including its metabolites and degradates, in or on the commodities in the table in this paragraph. Compliance with the tolerance levels specified in this paragraph is to be determined by measuring only those propyzamide residues convertible to methyl 3,5-dichlorobenzoate, expressed as the stoichiometric equivalent of propyzamide, 3,5-dichloro-*N*-(1,1-dimethyl-2-propynyl) benzamide, in or on the commodity.

Also, in order to describe more clearly the measurement and scope or coverage of the tolerances, EPA is proposing to revise the introductory text containing the tolerance expression in 40 CFR 180.317(c) to read as follows:

Tolerances with regional registration are established for residues of the herbicide propyzamide, including its metabolites and degradates, in or on the commodities in the table in this paragraph. Compliance with the tolerance levels specified in this paragraph is to be determined by measuring only those propyzamide residues convertible to methyl 3,5-dichlorobenzoate, expressed as the stoichiometric equivalent of propyzamide, 3,5-dichloro-*N*-(1,1-dimethyl-2-propynyl)ben zamide, in or on the commodity.

In addition, in order to describe more clearly the measurement and scope or coverage of the tolerances, EPA is proposing to revise the introductory text containing the tolerance expression in 40 CFR 180.317(d) to read as follows:

Tolerances are established for indirect or inadvertent residues of the herbicide propyzamide, including its metabolites and degradates, in or on the commodities in the table in this paragraph. Compliance with the tolerance levels specified in this paragraph is to be determined by measuring only those propyzamide residues convertible to methyl 3,5-dichlorobenzoate, expressed as the stoichiometric equivalent of propyzamide, 3,5-dichloro-*N*-(1,1-dimethyl-2-propynyl)benzamide, in or on the commodity.

22. *Pyridate*. In order to describe more clearly the measurement and scope or coverage of the tolerances, EPA is proposing to revise the introductory text containing the tolerance expression in 40 CFR 180.462(a) to read as follows:

Tolerances are established for residues of the herbicide pyridate, including its

metabolites and degradates, in or on the commodities in the table in this paragraph. Compliance with the tolerance levels specified in this paragraph is to be determined by measuring only the sum of pyridate, *O*-(6-chloro-3-phenyl-4-pyrid azinyl)-*S*-octyl-carbonothioate, and its metabolites, 6-chloro-3-phenyl-pyridazine-4-ol and conjugates of 6-chloro-3-phenyl-pyrid azine-4-ol, calculated as the stoichiometric equivalent of pyridate, in or on the commodity.

23. *Quinclorac*. In order to describe more clearly the measurement and scope or coverage of the tolerances, EPA is proposing to revise the introductory text containing the tolerance expression in 40 CFR 180.463(a) to read as follows:

Tolerances are established for residues of the herbicide quinclorac, including its metabolites and degradates, in or on the commodities in the table in this paragraph. Compliance with the tolerance levels specified in this paragraph is to be determined by measuring only quinclorac, 3,7-dichloro-8-quinolinecarboxylic acid, in or on the commodity.

Also, in order to describe more clearly the measurement and scope or coverage of the tolerances, EPA is proposing to revise the introductory text containing the tolerance expression in 40 CFR 180.463(b) to read as follows:

Time-limited tolerances are established for residues of the herbicide quinclorac, including its metabolites and degradates, in or on the commodity in the table in this paragraph. Compliance with the tolerance level specified in this paragraph is to be determined by measuring only quinclorac, 3,7-dichloro-8-quinolinecarboxylic acid, in or on the commodity. The tolerance expires and is revoked on the date specified in the table in this paragraph.

24. *Tebufenozide*. In order to describe more clearly the measurement and scope or coverage of the tolerances, EPA is proposing to revise the introductory text containing the tolerance expression in 40 CFR 180.482(a)(1) to read as follows:

Tolerances are established for residues of the insecticide tebufenozide, including its metabolites and degradates, in or on the commodity in the table in this paragraph. Compliance with the tolerance level specified in this paragraph is to be determined by measuring only tebufenozide, 3,5-dimethylbenzoic acid 1-(1,1-dimethyl ethyl)-2-(4-ethylbenzoyl)hydrazide, in or on the commodity.

In order to describe more clearly the measurement and scope or coverage of the tolerances, EPA is proposing to revise the introductory text containing the tolerance expression in 40 CFR 180.482(a)(2) to read as follows:

Tolerances are established for residues of the insecticide tebufenozide, including its metabolites and degradates, in or on the commodity in the table in this paragraph. Compliance with the tolerance level specified in this paragraph is to be determined by measuring only the sum of tebufenozide, 3,5-dimethylbenzoic acid 1-(1,1-dimethylethyl)-2-(4-ethylbenzoyl)hydra zide, and its metabolites, 3,5-dimethyl benzoic acid 1-(1,1-dimethylethyl)-2-((4-car boxymethyl)benzoyl)hydrazide, 3-hydroxy methyl-5-methylbenzoic acid 1-(1,1-dimethyl ethyl)-2-(4-ethylbenzoyl)hydrazide, stearic acid conjugate of 3-hydroxymethyl-5-methyl benzoic acid 1-(1,1-dimethylethyl)-2-(4-ethyl benzoyl)hydrazide, and 3-hydroxymethyl-5-methylbenzoic acid 1-(1,1-dimethylethyl)-2-(4-(1-hydroxyethyl)benzoyl)hydrazide, calculated as the stoichiometric equivalent of tebufenozide, in or on the commodity.

In order to describe more clearly the measurement and scope or coverage of the tolerances, EPA is proposing to revise the introductory text containing the tolerance expression in 40 CFR 180.482(d) to read as follows:

Tolerances are established for indirect or inadvertent residues of the insecticide tebufenozide, including its metabolites and degradates, in or on the commodities in the table in this paragraph when present therein as a result of the application of tebufenozide to growing crops listed in paragraph (a)(1) of this section. Compliance with the tolerance levels specified in this paragraph is to be determined by measuring only the sum of tebufenozide, 3,5-dimethylbenzoic acid 1-(1,1-dimethylethyl)-2-(4-ethylbenzoyl)hydra zide, and its metabolite, 3,5-dimethylbenzoic acid 1-(1,1-dimethylethyl)-2-(4-(1-hydroxy ethyl)benzoyl)hydrazide calculated as the stoichiometric equivalent of tebufenozide, in or on the commodity.

B. What is the Agency's Authority for Taking this Action?

A "tolerance" represents the maximum level for residues of pesticide chemicals legally allowed in or on raw agricultural commodities and processed foods. Section 408 of FFDCA, 21 U.S.C. 346a, as amended by FQPA of 1996, Public Law 104–170, authorizes the establishment of tolerances, exemptions from tolerance requirements, modifications in tolerances, and revocation of tolerances for residues of pesticide chemicals in or on raw agricultural commodities and processed foods. Without a tolerance or exemption, food containing pesticide residues is considered to be unsafe and therefore "adulterated" under section 402(a) of FFDCA, 21 U.S.C. 342(a). Such food may not be distributed in interstate commerce (21 U.S.C. 331(a)). For a food-use pesticide to be sold and distributed, the pesticide must not only have appropriate tolerances under the FFDCA, but also must be registered under FIFRA (7 U.S.C. 136 *et seq.*). Food-use pesticides not registered in the United States must have tolerances in order for commodities treated with those pesticides to be imported into the United States.

EPA's general practice is to propose revocation of tolerances/tolerance exemptions for residues of pesticide active ingredients on crops for which FIFRA registrations no longer exist and on which the pesticide may therefore no longer be used in the United States. EPA has historically been concerned that retention of tolerances that are not necessary to cover residues in or on legally treated foods may encourage misuse of pesticides within the United States. Nonetheless, EPA will establish and maintain tolerances even when corresponding domestic uses are canceled if the tolerances, which EPA refers to as "import tolerances," are necessary to allow importation into the United States of food containing such pesticide residues. However, where there are no imported commodities that require these import tolerances, the Agency believes it is appropriate to revoke tolerances for unregistered pesticides in order to prevent potential misuse.

Furthermore, as a general matter, the Agency believes that retention of import tolerances not needed to cover any imported food may result in unnecessary restriction on trade of pesticides and foods. Under section 408 of FFDCA, a tolerance/tolerance exemption may only be established or maintained if EPA determines that the tolerance is safe based on a number of factors, including an assessment of the aggregate exposure to the pesticide and an assessment of the cumulative effects of such pesticide and other substances that have a common mechanism of toxicity. In doing so, EPA must consider potential contributions to such exposure from all tolerances. If the cumulative risk is such that the tolerances in aggregate are not safe, then every one of these tolerances is potentially vulnerable to revocation. Furthermore, if unneeded tolerances are included in the aggregate and cumulative risk assessments, the estimated exposure to the pesticide would be inflated. Consequently, it may be more difficult for others to obtain needed tolerances or to register needed new uses. To avoid potential trade restrictions, the Agency is proposing to revoke tolerances/tolerance exemptions for residues on crops for which FIFRA registrations no longer exist, unless someone expresses a need for such tolerances/tolerance exemptions. Through this proposed rule, the Agency is inviting individuals who need these import tolerances to identify themselves and the tolerances

that are needed to cover imported commodities.

Parties interested in retention of the tolerances/tolerance exemptions should be aware that additional data may be needed to support retention. These parties should be aware that, under FFDCA section 408(f), if the Agency determines that additional information is reasonably required to support the continuation of a tolerance, EPA may require that parties interested in maintaining the tolerances provide the necessary information. If the requisite information is not submitted, EPA may issue an order revoking the tolerance/tolerance exemption at issue.

C. When Do These Actions Become Effective?

EPA is proposing that revision of specific tolerance expressions proposed herein, revocation of the tolerances for aluminum tris(*O*-ethylphosphonate) on pineapple fodder and forage, and revision of specific commodity terminologies (tolerance nomenclatures) for aluminum tris(*O*-ethylphosphonate), clethodim, flumetsulam, and fluridone become effective on the date of publication of the final rule in the **Federal Register**. If you have comments, please submit comments as described under **SUPPLEMENTARY INFORMATION.**

Any commodities listed in this proposal treated with the pesticides subject to this proposal, and in the channels of trade following the tolerance revocations, shall be subject to FFDCA section 408(l)(5), as established by FQPA. Under this unit, any residues of these pesticides in or on such food shall not render the food adulterated so long as it is shown to the satisfaction of the Food and Drug Administration that:

1. The residue is present as the result of an application or use of the pesticide at a time and in a manner that was lawful under FIFRA, and

2. The residue does not exceed the level that was authorized at the time of the application or use to be present on the food under a tolerance or exemption from tolerance. Evidence to show that food was lawfully treated may include records that verify the dates when the pesticide was applied to such food.

III. International Residue Limits

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

The Codex has not established a MRL for aluminum tris (*O*-ethylphosphonate), butylate, chlorethoxyfos, clomazone, fenoxaprop-ethyl, flumetsulam, flumiclorac pentyl, fluridone, fomesafen, fosthiazate, lactofen, oxytetracycline (pesticide use), propetamphos, propyzamide, pyridate, and quinclorac, or MRL on rice grain for etofenprox.

The Codex has established MRLs for clethodim in or on various commodities including beans (dry) at 2 milligrams per kilogram (mg/kg), beans, except broad bean and soybean at 0.5 mg/kg, cotton seed at 0.5 mg/kg, eggs at 0.05 mg/kg, field pea (dry) at 2 mg/kg, onion, bulb at 0.5 mg/kg, peanut at 5 mg/kg, sugar beet at 0.1 mg/kg, and sunflower seed at 0.5 mg/kg. These MRLs are different than the tolerances established for clethodim in the United States because of differences in use patterns and/or good agricultural practices. However, the changes in the U.S. tolerance expression which are proposed herein would harmonize U.S. tolerances with Codex MRLs for edible offal (mammalian), meat (from mammals other than marine mammals), milks, potato, poultry meat, poultry edible offal, soybean (dry), and tomato.

The Codex has established MRLs for clofentezine in or on various commodities including edible offal (mammalian) at 0.05 mg/kg, grapes at 2 mg/kg, milks at 0.05 mg/kg, stone fruits at 0.5 mg/kg, and tree nuts at 0.5 mg/kg. These MRLs are different than the tolerances established for clofentezine in the United States because of differences in residue definition for animal commodities and use patterns and/or good agricultural practices for plant commodities.

The Codex has established MRLs for cyromazine in or on various commodities with a residue definition of the parent compound only for compliance, including edible offal (mammalian) at 0.3 mg/kg, eggs at 0.3 mg/kg, fruiting vegetables other than cucurbits at 1 mg/kg, meat (from mammals other than marine mammals) at 0.3 mg/kg, milks at 0.01 mg/kg, mushrooms at 7 mg/kg, onion, bulb at 0.1 mg/kg, peppers, chili (dry) at 10 mg/kg, poultry meat at 0.1 mg/kg, and poultry, edible offal at 0.2 mg/kg. These MRLs are different than the tolerances established for cyromazine in the United States because of differences in use patterns and/or good agricultural practices.

The Codex has established MRLs for fenarimol in or on various commodities with a residue definition of the parent compound only for compliance, including banana at 0.2 mg/kg, cattle kidney at 0.02 mg/kg, cattle meat at 0.02 mg/kg, grape at 0.3 mg/kg, and pome fruits at 0.3 mg/kg. These MRLs are different than the tolerances established for fenarimol in the United States because of differences in use patterns and/or good agricultural practices.

The Codex has established MRLs for fenbutatin-oxide in or on various commodities with a residue definition of the parent compound only for compliance, including cherries at 10 mg/kg, citrus fruits at 5 mg/kg, citrus pulp, dry at 25 mg/kg, and cucumber at 0.5 mg/kg. These MRLs are different than the tolerances established for fenbutatin-oxide in the United States because of differences in use patterns and/or good agricultural practices.

The Codex has established MRLs for glufosinate ammonium in or on various commodities including banana at 0.2 mg/kg, berries and other small fruits at 0.1 mg/kg, edible offal (mammalian) at 0.1 mg/kg, eggs at 0.05 mg/kg, milks at 0.02 mg/kg, potato at 0.5 mg/kg, poultry meat at 0.05 mg/kg, poultry, edible offal at 0.1 mg/kg, rape seed at 5 mg/kg, and sugar beet at 0.05 mg/kg. These MRLs are different than the tolerances established for glufosinate ammonium in the United States because of differences in the residue definitions.

The Codex has established MRLs for tebufenozide in or on various commodities with a residue definition of the parent compound only for compliance, including almond hulls at 30 mg/kg, citrus fruits at 2 mg/kg, cranberry at 0.5 mg/kg, edible offal (mammalian) at 0.02 mg/kg, grapes at 2 mg/kg, leafy vegetables at 10 mg/kg, meat (from mammals other than marine mammals) at 0.05 mg/kg, milks at 0.01 mg/kg, mints at 20 mg/kg, pome fruits at 1 mg/kg, and walnuts at 0.05 mg/kg. These MRLs are different than the tolerances established for tebufenozide in the United States because of differences in residue definition for animal commodities and use patterns and/or good agricultural practices for plant commodities.

IV. Statutory and Executive Order Reviews

In this proposed rule, EPA is proposing to revise tolerance expressions to describe more clearly the measurement and scope or coverage of the tolerances, and revoke the tolerances for aluminum tris(*O*-ethylphosphonate) on pineapple fodder and forage. The Office of Management and Budget (OMB) has exempted these types of actions (e.g., tolerance actions for which extraordinary circumstances do not exist) from review under Executive Order 12866, entitled *Regulatory Planning and Review* (58 FR 51735, October 4, 1993). Because this proposed rule has been exempted from review under Executive Order 12866 due to its lack of significance, this proposed rule is not subject to Executive Order 13211, entitled *Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use* (66 FR 28355, May 22, 2001). This proposed rule does not contain any information collections subject to OMB approval under the Paperwork Reduction Act (PRA), 44 U.S.C. 3501 *et seq.*, or impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act of 1995 (UMRA) (Public Law 104–4). Nor does it require any special considerations as required by Executive Order 12898, entitled *Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations* (59 FR 7629, February 16, 1994); or OMB review or any other Agency action under Executive Order 13045, entitled *Protection of Children from Environmental Health Risks and Safety Risks* (62 FR 19885, April 23, 1997). This action does not involve any technical standards that would require Agency consideration of voluntary consensus standards pursuant to section 12(d) of the National Technology Transfer and Advancement Act of 1995 (NTTAA), Public Law 104–113, section 12(d) (15 U.S.C. 272 note). Pursuant to the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq.*), the Agency previously assessed whether establishment of tolerances, exemptions from tolerances, raising of tolerance levels, expansion of exemptions, or revocations might significantly impact a substantial number of small entities and concluded that, as a general matter, these actions do not impose a significant economic impact on a substantial number of small entities. These analyses for tolerance establishments and modifications, and for tolerance revocations were published on May 4, 1981 (46 FR 24950) and on December 17, 1997 (62 FR 66020) (FRL–5753–1), respectively, and were provided to the Chief Counsel for Advocacy of the Small Business Administration. Taking into account this analysis, and available information concerning the pesticides listed in this proposed rule, the Agency hereby certifies that this proposed rule will not have a significant negative economic impact on a substantial number of small entities. In a memorandum dated May 25, 2001, EPA determined that eight conditions must all be satisfied in order for an import tolerance or tolerance exemption revocation to adversely affect a significant number of small entity importers, and that there is a negligible joint probability of all eight conditions holding simultaneously with respect to any particular revocation. (This Agency document is available in the docket of this proposed rule). Furthermore, for the pesticide named in this proposed rule, the Agency knows of no extraordinary circumstances that exist as to the present proposal that would change the EPA's previous analysis. Any comments about the Agency's determination should be submitted to the EPA along with comments on the proposal, and will be addressed prior to issuing a final rule. In addition, the Agency has determined that this action will not have a substantial direct effect on 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, entitled *Federalism* (64 FR 43255, August 10, 1999). 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." This proposed rule directly regulates growers, food processors, food handlers, and food retailers, not States. This action does not alter the relationships or distribution of power and responsibilities established by Congress in the preemption provisions of section 408(n)(4) of FFDCA. For these same reasons, the Agency has determined that this proposed rule does not have any "tribal implications" as described in Executive Order 13175, entitled *Consultation and Coordination with Indian Tribal Governments* (65 FR 67249, November 9, 2000). Executive Order 13175, 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." "Policies that have tribal implications" is defined in the Executive order to include regulations that have "substantial direct effects on one or more Indian tribes, on the relationship between the Federal Government and the Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes." This proposed rule 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, as specified in Executive Order 13175. Thus, Executive Order 13175 does not apply to this proposed rule.

List of Subjects in 40 CFR Part 180

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

Dated: July 15, 2010.

Steven Bradbury,

Director, Office of Pesticide Programs.

Therefore, it is proposed that 40 CFR chapter I be amended as follows:

PART 180—[AMENDED]

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

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

2. In § 180.232 revise the introductory text in paragraph (a) to read as follows.

§ 180.232 Butylate; tolerances for residues.

(a) * * * Tolerances are established for residues of the herbicide butylate, including its metabolites and degradates, in or on the commodities in the table in this paragraph. Compliance with the tolerance levels specified in this paragraph is to be determined by measuring only butylate, *S*-ethyl bis(2-methylpropyl)carbamothioate, in or on the commodity.

* * * * *

3. Section 180.317 is amended as follows:

i. Revise the introductory text in paragraph (a);

ii. Revise paragraph (b);

iii. Revise the introductory text in paragraph (c);

iv. Revise the introductory text in paragraph (d).

The revised text reads as follows:

§ 180.317 Propyzamide; tolerances for residues.

(a) * * * Tolerances are established for residues of the herbicide propyzamide, including its metabolites and degradates, in or on the commodities in the table in this paragraph. Compliance with the tolerance levels specified in this paragraph is to be determined by measuring only those propyzamide residues convertible to methyl 3,5-dichlorobenzoate, expressed as the stoichiometric equivalent of propyzamide, 3,5-dichloro-*N*-(1,1-dimethyl-2-propynyl)benzamide, in or on the commodity.

* * * * *

(b) *Section 18 emergency exemptions*. [Reserved]

(c) * * * Tolerances with regional registration are established for residues of the herbicide propyzamide, including its metabolites and degradates, in or on the commodities in the table in this paragraph. Compliance with the tolerance levels specified in this paragraph is to be determined by measuring only those propyzamide residues convertible to methyl 3,5-dichlorobenzoate, expressed as the stoichiometric equivalent of propyzamide, 3,5-dichloro-*N*-(1,1-dimethyl-2-propynyl)benzamide, in or on the commodity.

* * * * *

(d) * * * Tolerances are established for indirect or inadvertent residues of the herbicide propyzamide, including its metabolites and degradates, in or on the commodities in the table in this paragraph. Compliance with the tolerance levels specified in this paragraph is to be determined by measuring only those propyzamide residues convertible to methyl 3,5-dichlorobenzoate, expressed as the stoichiometric equivalent of propyzamide, 3,5-dichloro-*N*-(1,1-dimethyl-2-propynyl)benzamide, in or on the commodity.

* * * * *

4. Revise § 180.337 to read as follows:

§ 180.337 Oxytetracycline; tolerances for residues.

(a) *General*. Tolerances are established for residues of the fungicide/bactericide oxytetracycline, including its metabolites and degradates, in or on the commodities in the table in this paragraph. Compliance with the tolerance levels specified in this paragraph is to be determined by measuring only oxytetracycline, (4S,4aR,5S,5aR,6S,12aS)-4-(dimethyl amino)-1,4,4a,5,5a,6,11,12a-octahydro-3,5,6,10,12,12a-hexahydroxy-6-methyl-1,11-dioxo-2-naphthacenecarboxamide, in or on the commodity.

Commodity	Parts per million
Apple	0.35
Peach	0.35
Pear	0.35

(b) *Section 18 emergency exemptions*. [Reserved]

(c) *Tolerances with regional registrations*. [Reserved]

(d) *Indirect or inadvertent residues*. [Reserved]

5. Section 180.362 is amended as follows:

i. Revise the section heading;

ii. Revise the introductory text in paragraph (a)(1);

iii. Revise the introductory text in paragraph (a)(2);

iv. Revise the introductory text in paragraph (c).

The revised text read as follows:

§ 180.362 Fenbutatin-oxide; tolerances for residues.

(a) * * * (1) Tolerances are established for residues of the miticide/acaricide fenbutatin-oxide, including its metabolites and degradates, in or on the plant commodities in the table in this paragraph. Compliance with the tolerance levels specified in this paragraph is to be determined by measuring only fenbutatin-oxide, hexakis (2-methyl-2-phenylpropyl)distannoxane, in or on the commodity.

* * * * *

(2) Tolerances are established for residues of the miticide/acaricide fenbutatin-oxide, including its metabolites and degradates, in or on the animal commodities in the table in this paragraph. Compliance with the tolerance levels specified in this paragraph is to be determined by measuring only the sum of fenbutatin-oxide, hexakis (2-methyl-2-phenylpropyl)distannoxane, and its organotin metabolites, dihydroxybis(2-methyl-2-phenylpropyl)stannane and 2-methyl-2-phenylpropylstannoic acid, calculated as the stoichiometric equivalent of fenbutatin-oxide, in or on the commodity.

* * * * *

(c) * * * A tolerance with regional registration is established for residues of the miticide/acaricide fenbutatin-oxide, including its metabolites and degradates, in or on the plant commodity in the table in this paragraph. Compliance with the tolerance level specified in this paragraph is to be determined by measuring only fenbutatin-oxide, hexakis (2-methyl-2-phenylpropyl)distannoxane, in or on the commodity.

* * * * *

6. Section 180.414 is amended as follows:

i. Revise the introductory text in paragraph (a)(1);

ii. Revise paragraph (a)(2);

iii. Revise the introductory text in paragraph (d).

The revised reads as follows:

§ 180.414 Cyromazine; tolerances for residues.

(a) * * * (1) Tolerances are established for residues of the insecticide cyromazine, including its metabolites and degradates, in or on the commodities in the table in this paragraph. Compliance with the tolerance levels specified in this paragraph is to be determined by measuring only cyromazine, *N*-cyclopropyl-1,3,5-triazine-2,4,6-triamine, in or on the commodity.

* * * * *

(2) A tolerance of 5.0 parts per million is established for residues of the insecticide cyromazine, including its metabolites and degradates, in or on poultry feed when used as a feed additive only in feed for chicken layer hens and chicken breeder hens at the rate of not more than 0.01 pound of cyromazine per ton of poultry feed for control of flies in manure of treated chicken layer hens and chicken breeder hens, provided the feeding of cyromazine-treated feed must stop at least 3 days (72 hours) before slaughter. If the feed is formulated by any person other than the end user, the formulator must inform the end user, in writing, of the 3–day (72 hours) pre-slaughter interval. Compliance with the tolerance level specified in this paragraph is to be determined by measuring only cyromazine, *N*-cyclopropyl-1,3,5-triazine-2,4,6-triamine, in or on the commodity.

* * * * *

(d) * * * Tolerances are established for the indirect or inadvertent residues of the insecticide cyromazine, including its metabolites and degradates, in or on the commodities in the table in this paragraph when present therein as a result of the application of cyromazine to growing crops listed in paragraph (a)(1) of this section. Compliance with the tolerance levels specified in this

paragraph is to be determined by measuring only cyromazine, *N*-cyclopropyl-1,3,5-triazine-2,4,6-triamine, in or on the commodity.

* * * * *

7. Section 180.415 is amended as follows:

i. Revise paragraph (a);

ii. Revise the introductory text in paragraph (c).

The revised text reads as follows:

§ 180.415 Aluminum tris (*O*-ethylphosphonate); tolerances for residues.

(a) *General*. Tolerances are established for residues of the fungicide aluminum tris(*O*-ethylphosphonate), including its metabolites and degradates, in or on the commodities in the table in this paragraph. Compliance with the tolerance levels specified in this paragraph is to be determined by measuring only aluminum tris(*O*-ethylphosphonate), in or on the commodity.

Commodity	Parts per million
Avocado	25
Banana	3.0
Bushberry subgroup 13B	40
Caneberry subgroup 13A	0.1
Cranberry	0.5
Fruit, citrus, group 10	5.0
Fruit, pome, group 11	10
Ginseng	0.1
Hop, dried cones	45
Juneberry	40
Lingonberry	40
Nut, macadamia	0.20
Onion, bulb	0.5
Onion, green	10.0
Pea, succulent	0.3
Pineapple	0.1
Salal	40
Strawberry	75
Tomato	3
Turnip, greens	40
Turnip, roots	15
Vegetable, brassica, leafy, group 5	60
Vegetable, cucurbit, group 9	15
Vegetable, leafy, except brassica, group 4	100

* * * * *

(c) * * * Tolerances with regional registration are established for residues of the fungicide aluminum tris(*O*-ethylphosphonate), including its metabolites and degradates, in or on the commodities in the table in this paragraph. Compliance with the tolerance levels specified in this paragraph is to be determined by measuring only aluminum tris(*O*-ethylphosphonate), in or on the commodity.

* * * * *

8. Revise § 180.420 to read as follows:

§ 180.420 Fluridone; tolerances for residues.

(a) *General*. (1) Tolerances are established for residues of the herbicide fluridone, including its metabolites and degradates, in or on the commodities in the table in this paragraph. Compliance with the tolerance levels specified in this paragraph is to be determined by measuring only the sum of fluridone, 1-methyl-3-phenyl-5-(3-(trifluoromethyl)phenyl)-4(1*H*)-pyridinone, and its bound residues, calculated as the stoichiometric equivalent of fluridone, in or on the commodity.

Commodity	Parts per million
Crayfish	0.5
Fish	0.5

(2) Tolerances are established for residues of the herbicide fluridone, including its metabolites and degradates, in or on the commodities in the table in this paragraph. Compliance with the tolerance levels specified in this paragraph is to be determined by measuring only fluridone, 1-methyl-3-phenyl-5-(3-(trifluoromethyl)phenyl)-4(1*H*)-pyridinone, in or on the commodity.

Commodity	Parts per million
Cattle, fat	0.05
Cattle, kidney	0.1
Cattle, liver	0.1
Cattle, meat	0.05
Cattle, meat byproducts	0.05
Egg	0.05
Goat, fat	0.05
Goat, kidney	0.1
Goat, liver	0.1
Goat, meat	0.05
Goat, meat byproducts	0.05
Hog, fat	0.05
Hog, kidney	0.1
Hog, liver	0.1
Hog, meat	0.05
Hog, meat byproducts	0.05
Horse, fat	0.05
Horse, kidney	0.1
Horse, liver	0.1
Horse, meat	0.05
Horse, meat byproducts	0.05
Milk	0.05
Poultry, fat	0.05
Poultry, kidney	0.01
Poultry, liver	0.01
Poultry, meat	0.05
Poultry, meat byproducts	0.05
Sheep, fat	0.05
Sheep, kidney	0.1
Sheep, liver	0.1
Sheep, meat	0.05
Sheep, meat byproducts	0.05

(b) *Section 18 emergency exemptions*. [Reserved]

(c) *Tolerances with regional registrations*. [Reserved]

(d) *Indirect or inadvertent residues*. Tolerances are established for indirect or inadvertent residues of the herbicide fluridone, including its metabolites and degradates, in or on the irrigated crop commodities and crop groupings in the table in this paragraph, resulting from use of irrigation water containing residues of 0.15 ppm following applications of fluridone on or around aquatic sites. Where tolerances are established at higher levels from other uses of fluridone on the following crops, the higher tolerance also applies to residues in the irrigated commodity. Compliance with the tolerance levels specified in this paragraph is to be determined by measuring only fluridone, 1-methyl-3-phenyl-5-(3-(trifluoromethyl)phenyl)-4(1*H*)-pyridinone, in or on the commodity.

Commodity	Parts per million
Animal feed, nongrass, group 18	0.15
Avocado	0.1
Berry, group 13	0.1
Cotton, undelinted seed	0.1
Cranberry	0.1
Fruit, citrus, group 10	0.1
Fruit, pome, group 11	0.1
Fruit, stone, group 12	0.1
Grain, cereal, forage, fodder and straw, group 16	0.1
Grain, cereal, group 15	0.1
Grape	0.1
Grass, forage	0.15
Hop, dried cones	0.1
Nut, tree, group 14	0.1
Okra	0.1
Strawberry	0.1
Vegetable, brassica, leafy, group 5	0.1
Vegetable, cucurbit, group 9	0.1
Vegetable, fruiting, group 8	0.1
Vegetable, leafy, except brassica, group 4	0.1
Vegetable, leaves of root and tuber, group 2	0.1
Vegetable, legume, group 6	0.1
Vegetable, root and tuber, group 1	0.1

9. In § 180.421 revise the introductory text in paragraph (a) to read as follows:

§ 180.421 Fenarimol; tolerances for residues.

(a) * * * Tolerances are established for residues of the fungicide fenarimol, including its metabolites and degradates, in or on the commodities in the table in this paragraph. Compliance with the tolerance levels specified in this paragraph is to be determined by measuring only fenarimol, alpha-(2-chlorophenyl)-alpha-(4-chlorophenyl)-5-

pyrimidinemethanol, in or on the commodity.

* * * * *

10. In § 180.425 revise the introductory text in paragraph (a) to read as follows.

§ 180.425 Clomazone; tolerances for residues.

(a) * * * Tolerances are established for residues of the herbicide clomazone, including its metabolites and degradates, in or on the commodities in the table in this paragraph. Compliance with the tolerance levels specified in this paragraph is to be determined by measuring only clomazone, 2-(2-chloro phenyl)methyl-4,4-dimethyl-3-isoxa zolidinone, in or on the commodity.

* * * * *

11. Section 180.430 is amended as follows:

i. Revise the introductory text in paragraph (a);

ii. Revise the introductory text in paragraph (b).

The revised text reads as follows:

§ 180.430 Fenoxaprop-ethyl; tolerances for residues.

(a) * * * Tolerances are established for residues of the herbicide fenoxaprop-ethyl, including its metabolites and degradates, in or on the commodities in the table in this paragraph. Compliance with the tolerance levels specified in this paragraph is to be determined by measuring only the sum of fenoxaprop-ethyl, (±)-ethyl 2-[4-[(6-chloro-2-benzoxa zolyl)oxy]phenoxy]propanoate, and its metabolites, 2-[4-[(6-chloro-2-benzoxa zolyl)oxy]phenoxy]propanoic acid and 6-chloro-2,3-dihydrobenzoxazol-2-one, calculated as the stoichiometric equivalent of fenoxaprop-ethyl, in or on the commodity.

* * * * *

(b) * * * Time-limited tolerances are established for residues of the herbicide fenoxaprop-ethyl, including its metabolites and degradates, in or on the commodities in the table in this paragraph in connection with use of fenoxaprop-ethyl under section 18 emergency exemptions granted by EPA. Compliance with the tolerance levels specified in this paragraph is to be determined by measuring only the sum of fenoxaprop-ethyl, (±)-ethyl 2-[4-[(6-chloro-2-benzoxazolyl)oxy]phenoxy] propanoate, and its metabolites, 2-[4-[(6-chloro-2-benzoxazolyl)oxy]phenoxy] propanoic acid and 6-chloro-2,3-di hydrobenzoxazol-2-one, calculated as the stoichiometric equivalent of fenoxaprop-ethyl, in or on the commodity. The tolerances expire and are revoked on the dates specified in the table in this paragraph.

* * * * *

12. Section 180.432 is amended as follows:

i. Revise the introductory text in paragraph (a);

ii. Revise the introductory text in paragraph (c).

The revised text reads as follows:

§ 180.432 Lactofen; tolerances for residues.

(a) * * * Tolerances are established for residues of the herbicide lactofen, including its metabolites and degradates, in or on the commodities in the table in this paragraph. Compliance with the tolerance levels specified in this paragraph is to be determined by measuring only lactofen, 2-ethoxy-1-methyl-2-oxoethyl 5-[2-chloro-4-(trifluoromethyl)phenoxy]-2-nitro benzoate, in or on the commodity.

* * * * *

(c) * * * Tolerances with regional registration are established for residues of the herbicide lactofen, including its metabolites and degradates, in or on the commodities in the table in this paragraph. Compliance with the tolerance levels specified in this paragraph is to be determined by measuring only lactofen, 2-ethoxy-1-methyl-2-oxoethyl 5-[2-chloro-4-(trifluoromethyl)phenoxy]-2-nitro benzoate, in or on the commodity.

* * * * *

13. In § 180.433 revise the introductory text in paragraph (a) to read as follows.

§ 180.433 Fomesafen; tolerances for residues.

(a) * * * Tolerances are established for residues of the herbicide fomesafen, including its metabolites and degradates, in or on the commodities in the table in this paragraph from the application of its sodium salt. Compliance with the tolerance levels specified in this paragraph is to be determined by measuring only fomesafen, 5-(2-chloro-4-(trifluoro methyl)phenoxy)-*N*-(methylsulfonyl)-2-nitrobenzamide, in or on the commodity.

* * * * *

14. Section 180.446 is amended as follows:

i. Revise the introductory text in paragraph (a)(1);

ii. Revise the introductory text in paragraph (a)(2).

The revised text reads as follows:

§ 180.446 Clofentezine; tolerances for residues.

(a) * * * (1) Tolerances are established for residues of the insecticide clofentezine, including its metabolites and degradates, in or on the commodities in the table in this paragraph. Compliance with the tolerance levels specified in this paragraph is to be determined by measuring only clofentezine, 3,6-bis(2-chlorophenyl)-1,2,4,5-tetrazine, in or on the commodity.

* * * * *

(2) Tolerances are established for residues of the insecticide clofentezine, including its metabolites and degradates, in or on the commodities in the table in this paragraph. Compliance with the tolerance levels specified in this paragraph is to be determined by measuring only the sum of clofentezine, 3,6-bis(2-chlorophenyl)-1,2,4,5-tetra zine, and its metabolite, 3-(2-chloro-4-hydroxyphenyl)-6-(2-chlorophenyl)-1,2,4,5-tetrazine, calculated as the stoichiometric equivalent of clofentezine, in or on the commodity.

* * * * *

15. Revise § 180.458 to read as follows:

§ 180.458 Clethodim; tolerances for residues.

(a) *General*. Tolerances are established for residues of the herbicide clethodim, including its metabolites and degradates, in or on the commodities in the table in this paragraph. Compliance with the tolerance levels specified in this paragraph is to be determined by measuring only the sum of clethodim, 2-[(1E)-1-[[[(2E)-3-chloro-2-propenyl] oxy]imino]propyl]-5-[2-(ethylthio) propyl]-3-hydroxy-2-cyclohexen-1-one, and its metabolites containing the 5-(2-ethylthiopropyl)cyclohexene-3-one and 5-(2-ethylthiopropyl)-5-hydroxycyclo hexene-3-one moieties and their sulphoxides and sulphones, calculated as the stoichiometric equivalent of clethodim, in or on the commodity.

Commodity	Parts per million
Alfalfa, forage	6.0
Alfalfa, hay	10
Artichoke, globe	1.2
Asparagus	1.7
Bean, dry, seed	2.5
Beet, sugar, molasses	1.0
Beet, sugar, roots	0.20
Beet, sugar, tops	1.0
Brassica, head and stem, subgroup 5A	3.0
Brassica, leafy greens, subgroup 5B	3.0
Bushberry subgroup 13-07B	0.20
Caneberry subgroup 13-07A	0.30

Commodity	Parts per million
Canola, meal	1.0
Canola, seed	0.50
Cattle, fat	0.2
Cattle, meat	0.2
Cattle, meat byproducts	0.2
Clover, forage	10.0
Clover, hay	20.0
Corn, field, forage	0.2
Corn, field, grain	0.2
Corn, field, stover	0.2
Cotton, meal	2.0
Cotton, undelinted seed	1.0
Cranberry	0.50
Egg	0.2
Flax, meal	1.0
Flax, seed	0.6
Goat, fat	0.2
Goat, meat	0.2
Goat, meat byproducts	0.2
Herb subgroup 19A	12.0
Hog, fat	0.2
Hog, meat	0.2
Hog, meat byproducts	0.2
Hop, dried cones	0.5
Horse, fat	0.2
Horse, meat	0.2
Horse, meat byproducts	0.2
Leaf petioles subgroup 4B	0.60
Leafy greens subgroup 4A	2.0
Melon subgroup 9A	2.0
Milk	0.05
Mustard, seed	0.50
Onion, bulb	0.20
Onion, green	2.0
Peach	0.20
Peanut	3.0
Peanut, hay	3.0
Peanut, meal	5.0
Peppermint, tops	5.0
Potato	0.5
Potato, granules/flakes	2.0
Poultry, fat	0.2
Poultry, meat	0.2
Poultry, meat byproducts	0.2
Radish, tops	0.70
Safflower, meal	10.0
Safflower, seed	5.0
Sesame, seed	0.35
Sheep, fat	0.2
Sheep, meat	0.2
Sheep, meat byproducts	0.2
Soybean	10.0
Soybean, soapstock	15.0
Spearmint, tops	5.0
Squash/cucumber subgroup 9B	0.50
Strawberry	3.0
Sunflower, meal	10.0
Sunflower, seed	5.0
Turnip, greens	3.0
Vegetable, fruiting, group 8	1.0
Vegetable, legume, group 6, except soybean	3.5
Vegetable, root, except sugar beet, subgroup 1B	1.0
Vegetable, tuberous and corm, subgroup 1C	1.0

(b) *Section 18 emergency exemptions.* [Reserved]

(c) *Tolerances with regional registrations.* [Reserved]

(d) *Indirect or inadvertent residues.* [Reserved]

16. In § 180.462 revise the introductory text in paragraph (a) to read as follows:

§ 180.462 Pyridate; tolerances for residues.

(a) * * * Tolerances are established for residues of the herbicide pyridate, including including its metabolites and degradates, in or on the commodities in the table in this paragraph. Compliance with the tolerance levels specified in this paragraph is to be determined by measuring only the sum of pyridate, *O*-(6-chloro-3-phenyl-4-pyridazinyl)-*S*-octyl-carbonothioate, and its metabolites, 6-chloro-3-phenyl-pyridazine-4-ol and conjugates of 6-chloro-3-phenyl-pyridazine-4-ol, calculated as the stoichiometric equivalent of pyridate, in or on the commodity.

* * * * *

17. Section 180.463 is amended as follows:

i. Revise the introductory text in paragraph (a);

ii. Revise the introductory text in paragraph (b).

The revised text reads as follows:

§ 180.463 Quinclorac; tolerances for residues.

(a) * * * Tolerances are established for residues of the herbicide quinclorac, including its metabolites and degradates, in or on the commodities in the table in this paragraph. Compliance with the tolerance levels specified in this paragraph is to be determined by measuring only quinclorac, 3,7-dichloro-8-quinolinecarboxylic acid, in or on the commodity.

* * * * *

(b) * * * Time-limited tolerances are established for residues of the herbicide quinclorac, including its metabolites and degradates, in or on the commodity in the table in this paragraph. Compliance with the tolerance level specified in this paragraph is to be determined by measuring only quinclorac, 3,7-dichloro-8-quinolinecarboxylic acid, in or on the commodity. The tolerance expires and is revoked on the date specified in the table in this paragraph.

* * * * *

18. Revise § 180.468 to read as follows:

§ 180.468 Flumetsulam; tolerances for residues.

(a) *General.* Tolerances are established for residues of the herbicide flumetsulam, including its metabolites and degradates, in or on the commodities in the table in this paragraph. Compliance with the tolerance levels specified in this paragraph is to be determined by measuring only flumetsulam, *N*-(2,6-difluorophenyl)-5-methyl-(1,2,4)-tria zolo-(1,5a)-pyrimidine-2-sulfonamide, in or on the commodity.

Commodity	Parts per million
Bean, dry, seed	0.05
Corn, field, forage	0.05
Corn, field, grain	0.05
Corn, field, stover	0.05
Soybean, seed	0.05

(b) *Section 18 emergency exemptions.* [Reserved]

(c) *Tolerances with regional registrations.* [Reserved]

(d) *Indirect or inadvertent residues.* [Reserved]

19. Section 180.473 is amended as follows:

i. Revise the introductory text in paragraph (a);

ii. Revise the introductory text in paragraph (d).

The revised text reads as follows:

§ 180.473 Glufosinate; tolerances for residues.

(a) * * * Tolerances are established for residues of the herbicide glufosinate ammonium, including its metabolites and degradates, in or on the commodities in the table in this paragraph. Compliance with the tolerance levels specified in this paragraph is to be determined by measuring only the sum of glufosinate ammonium, 2-amino-4-(hydroxy methylphosphinyl)butanoic acid monoammonium salt, and its metabolites, 2-acetamido-4-methyl phosphinicobutanoic acid and 3-methyl phosphinicopropionic acid, calculated as the stoichiometric equivalent of 2-amino-4-(hydroxymethylphos phinyl)butanoic acid, in or on the commodity.

* * * * *

(d) * * * Tolerances are established for indirect or inadvertent residues of the herbicide glufosinate ammonium, including its metabolites and degradates, in or on the commodities in the table in this paragraph when present therein as a result of the application of glufosinate ammonium to crops listed in paragraph (a) of this section. Compliance with the tolerance levels specified in this paragraph is to be determined by measuring only the sum of glufosinate ammonium, 2-amino-4-(hydroxymethylphosphinyl)butanoic acid monoammonium salt, and its metabolite, 3-methylphosphinico

propionic acid, calculated as the stoichiometric equivalent of 2-amino-4-(hydroxymethylphosphinyl)butanoic acid, in or on the commodity.

* * * * *

20. In §180.477 revise the introductory text in paragraph (a) to read as follows:

§ 180.477 Flumiclorac pentyl; tolerances for residues.

(a) * * * Tolerances are established for residues of the herbicide flumiclorac pentyl, including its metabolites and degradates, in or on the commodities in the table in this paragraph. Compliance with the tolerance levels specified in this paragraph is to be determined by measuring only flumiclorac pentyl, pentyl(2-chloro-4-fluoro-5-(1,3,4,5,6,7-hexahydro-1,3-dioxo-2*H*-isoindol-2-yl) phenoxy)acetate, in or on the commodity.

* * * * *

21. Section 180.482 is amended as follows:

i. Revise the introductory text in paragraph (a)(1);

ii. Revise the introductory text in paragraph (a)(2);

iii. Revise paragraph (b);

iv. Revise the introductory text in paragraph (d).

The revised text reads as follows:

§ 180.482 Tebufenozide; tolerances for residues.

(a) * * * (1) Tolerances are established for residues of the insecticide tebufenozide, including its metabolites and degradates, in or on the commodities in the table in this paragraph. Compliance with the tolerance levels specified in this paragraph is to be determined by measuring only tebufenozide, 3,5-dimethylbenzoic acid 1-(1,1-dimethyl ethyl)-2-(4-ethylbenzoyl)hydrazide, in or on the commodity.

* * * * *

(2) Tolerances are established for residues of the insecticide tebufenozide, including its metabolites and degradates, in or on the commodities in the table in this paragraph. Compliance with the tolerance levels specified in this paragraph is to be determined by measuring only the sum of tebufenozide, 3,5-dimethylbenzoic acid 1-(1,1-dimethylethyl)-2-(4-ethyl benzoyl)hydrazide, and its metabolites, 3,5-dimethylbenzoic acid 1-(1,1-dimethylethyl)-2-((4-carboxymethyl)benzoyl)hydrazide, 3-hydroxymethyl-5-methylbenzoic acid 1-(1,1-dimethyl ethyl)-2-(4-ethylbenzoyl)hydrazide, stearic acid conjugate of 3-hydroxy methyl-5-methylbenzoic acid 1-(1,1-dimethylethyl)-2-(4-ethylbenzoyl)hydrazide, and 3-hydroxymethyl-5-methyl benzoic acid 1-(1,1-dimethylethyl)-2-(4-(1-hydroxyethyl)benzoyl)hydrazide, calculated as the stoichiometric equivalent of tebufenozide, in or on the commodity.

* * * * *

(b) *Section 18 emergency exemptions.* [Reserved]

* * * * *

(d) * * * Tolerances are established for indirect or inadvertent residues of the insecticide tebufenozide, including its metabolites and degradates, in or on the commodities in the table in this paragraph when present therein as a result of the application of tebufenozide to growing crops listed in paragraph (a)(1) of this section. Compliance with the tolerance levels specified in this paragraph is to be determined by measuring only the sum of tebufenozide, 3,5-dimethylbenzoic acid 1-(1,1-dimethylethyl)-2-(4-ethyl benzoyl)hydrazide, and its metabolite, 3,5-dimethylbenzoic acid 1-(1,1-dimethylethyl)-2-(4-(1-hydroxy ethyl)benzoyl)hydrazide calculated as the stoichiometric equivalent of tebufenozide, in or on the commodity.

* * * * *

22. Revise § 180.486 to read as follows:

§ 180.486 Chlorethoxyfos; tolerances for residues.

(a) *General.* Tolerances are established for residues of the insecticide chlorethoxyfos, including its metabolites and degradates, in or on the commodities in the table in this paragraph. Compliance with the tolerance levels specified in this paragraph is to be determined by measuring only chlorethoxyfos, *O,O*-diethyl *O*-(1,2,2,2-tetrachloroethyl) phosphorothioate, in or on the commodity.

Commodity	Parts per million
Corn, field, forage	0.01
Corn, field, grain	0.01
Corn, field, stover	0.01
Corn, pop, grain	0.01
Corn, pop, stover	0.01
Corn, sweet, forage	0.01
Corn, sweet, kernel plus cob with husks removed	0.01
Corn, sweet, stover	0.01

(b) *Section 18 emergency exemptions.* [Reserved]

(c) *Tolerances with regional registrations.* [Reserved]

(d) *Indirect or inadvertent residues.* [Reserved]

23. In § 180.541 revise paragraph (a) to read as follows:

§ 180.541 Propetamphos; tolerances for residues.

(a) *General.* A tolerance of 0.1 part per million is established for residues of the insecticide propetamphos, including its metabolites and degradates, in or on food or feed commodities when present therein as a result of the treatment of food- or feed-handling establishments with propetamphos. Direct application shall be limited solely to spot and/or crack and crevice treatment in food- or feed-handling establishments where food or feed and food or feed products are held, processed, prepared, served, or sold. Spray and dust concentrations shall be limited to a maximum of 1 percent active ingredient. For crack and crevice treatment, equipment capable of delivering a dust or a pin-stream of spray directly into cracks and crevices shall be used. For spot treatment, a coarse, low-pressure spray shall be used to avoid contamination of food, feed, or food-contact/feed-contact surfaces. Compliance with the tolerance level specified in this paragraph is to be determined by measuring only propetamphos, 1-methylethyl-(2E)-3-((ethylamino)methoxyphosphinothioyl) oxy)-2-butenoate, in or on the commodity.

* * * * *

24. In § 180.596 revise the introductory text in paragraph (a) to read as follows:

§ 180.596 Fosthiazate; tolerances for residues.

(a) * * * A tolerance is established for residues of the insecticide fosthiazate, including its metabolites and degradates, in or on the commodity in the table in this paragraph. Compliance with the tolerance level specified in this paragraph is to be determined by measuring only the sum of fosthiazate, *O*-ethyl *S*-(1-methyl propyl)(2-oxo-3-thiazolidinyl)phos phonothioate, and its metabolite, *O*-ethyl *S*-(1-methylpropyl)(2-(methyl sulfonyl)ethyl)phosphoramidothioate, calculated as the stoichiometric equivalent of fosthiazate, in or on the commodity.

* * * * *

25. Revise § 180.620 to read as follows:

§ 180.620 Etofenprox; tolerances for residues.

(a) *General.* A tolerance is established for residues of the insecticide etofenprox, including its metabolites and degradates, in or on the commodity in the table in this paragraph. Compliance with the tolerance level specified in this paragraph is to be determined by measuring only

etofenprox, 2-(4-ethoxyphenyl)-2-methylpropyl 3-phenoxybenzyl ether, in or on the commodity.

Commodity	Parts per million
Rice, grain	0.01

(b) *Section 18 emergency exemptions.* [Reserved]

(c) *Tolerances with regional registrations.* [Reserved]

(d) *Indirect or inadvertent residues.* [Reserved]

[FR Doc. 2010–18373 Filed 7–27–10; 8:45 am]

BILLING CODE 6560–50–S

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 721

[EPA–HQ–OPPT–2009–0686; FRL–8828–3]

RIN 2070–AB27

Proposed Significant New Use Rule for Multi-walled Carbon Nanotubes; Reopening of Comment Period

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule; reopening of comment period.

SUMMARY: EPA issued a proposed rule in the **Federal Register** of February 3, 2010, concerning a proposed significant new use rule (SNUR) for the chemical substance identified generically as multi-walled carbon nanotubes (P–08–199). In order to address public comments, EPA is adding information to the docket and reopening the comment period. This document reopens the comment period for 30 days.

DATES: Comments, identified by docket identification (ID) number EPA–HQ–OPPT–2009–0686, must be received on or before August 27, 2010.

ADDRESSES: Follow the detailed instructions as provided under **ADDRESSES** in the **Federal Register** document of February 3, 2010.

FOR FURTHER INFORMATION CONTACT: *For technical information contact*: Jim Alwood, Chemical Control Division (7405M), Office of Pollution Prevention and Toxics, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001; telephone number: (202) 564–8974; e-mail address: *alwood.jim@epa.gov*.

For general information contact: The TSCA-Hotline, ABVI-Goodwill, 422 South Clinton Ave., Rochester, NY 14620; telephone number: (202) 554–1404; e-mail address: *TSCA-Hotline@epa.gov*.

SUPPLEMENTARY INFORMATION: This document reopens the public comment period established in the **Federal Register** of February 3, 2010 (75 FR 5546) (FRL–8796–7). In that document, EPA proposed a SNUR for the chemical substance identified generically as multi-walled carbon nanotubes as identified in Premanufacture Notice (PMN) P–08–199. EPA received several comments in response to the proposed SNUR. EPA will address those comments when it issues the final SNUR. One commenter noted that neither the proposed rule nor the docket contained specific carbon nanotube data or data supporting the nature of the dermal concern for carbon nanotubes. That commenter stated it was not possible to assess the Agency's evaluation and determination under § 721.170(b)(3)(ii) based on the current record. Another commenter noted that EPA's subsequent reviews and concerns for carbon nanotubes have expanded and that the proposed SNUR should reflect those updated data. EPA has added additional explanation and references of its health and environmental concerns for carbon nanotubes to the public docket for consideration. EPA is hereby reopening the comment period for 30 days to allow for any public comments in response to this additional data.

To submit comments, or access the docket, please follow the detailed instructions as provided under **ADDRESSES** in the February 3, 2010 **Federal Register** document. If you have questions, consult the technical person listed under **FOR FURTHER INFORMATION CONTACT**.

List of Subjects in 40 CFR Part 721

Environmental protection, Chemicals, Hazardous substances, Reporting, and recordkeeping requirements.

Dated: July 15, 2010.

Wendy C. Hamnett,

Director, Office of Pollution Prevention and Toxics.

[FR Doc. 2010–18543; Filed 7–27–10; 8:45 am]

BILLING CODE 6560–50–S

FEDERAL COMMUNICATIONS COMMISSION

47 CFR Part 76

[MB Docket No. 10–148; FCC 10–130]

Implementation of Section 203 of the Satellite Television Extension and Localism Act of 2010 (STELA); Amendments to Section 340 of the Communications Act

AGENCY: Federal Communications Commission.

ACTION: Proposed rule.

SUMMARY: In this document, the Commission proposes changes to its satellite television "significantly viewed" rules to implement Section 203 of the Satellite Television Extension and Localism Act of 2010 (STELA). Section 203 of the STELA amends Section 340 of the Communications Act, which gives satellite carriers the authority to offer out-of-market but "significantly viewed" broadcast television network stations as part of their local service to subscribers. The STELA requires the Commission to issue final rules in this proceeding on or before November 24, 2010.

DATES: Comments are due on or before August 17, 2010; reply comments are due on or before August 27, 2010.

ADDRESSES: You may submit comments, identified by MB Docket No. 10–148, by any of the following methods:

- *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the instructions for submitting comments.
- *Federal Communications Commission's Electronic Comment Filing System (ECFS) Web Site: http://fjallfoss.fcc.gov/ecfs/.* Follow the instructions for submitting comments.
- *Mail:* All filings must be addressed to the Commission's Secretary, Office of the Secretary, Federal Communications Commission, 445 12th Street, SW., Washington, DC 20554.
- *People with Disabilities:* Contact the FCC to request reasonable accommodations (accessible format documents, sign language interpreters, CART, etc.) by e-mail: *FCC504@fcc.gov* or phone: 202–418–0530; or TTY: 202–418–0432.

For detailed instructions for submitting comments and additional information on the rulemaking process, see the section V. "PROCEDURAL MATTERS" heading of the **SUPPLEMENTARY INFORMATION** section of this document.

FOR FURTHER INFORMATION CONTACT: For additional information on this proceeding, Evan Baranoff, *Evan.Baranoff@fcc.gov,* of the Media Bureau, Policy Division, (202) 418–7142.

SUPPLEMENTARY INFORMATION: This is a summary of the Commission's *Notice of Proposed Rulemaking* (NPRM), FCC 10–130, adopted on July 22, 2010, and released on July 23, 2010. The full text of this document is available electronically via ECFS at *http://fjallfoss.fcc.gov/ecfs/*or may be downloaded at *http://hraunfoss.fcc.gov/edocs-public/attachmatch/FCC–10–130.pdf.* (Documents will be available electronically in ASCII, Word 97, and/or Adobe Acrobat.) This document is also available for public inspection and copying during regular business hours in the FCC Reference Center, Federal Communications Commission, 445 12th Street, SW., CY–A257, Washington, DC 20554. The complete text may be purchased from the Commission's copy contractor, 445 12th Street, SW., Room CY–B402, Washington, DC 20554. Alternative formats are available for people with disabilities (Braille, large print, electronic files, audio format), by sending an e-mail to *fcc504@fcc.gov* or calling the Commission's Consumer and Governmental Affairs Bureau at (202) 418–0530 (voice), (202) 418–0432 (TTY).

Summary of the Notice of Proposed Rulemaking

I. Introduction

1. In this Notice of Proposed Rulemaking (NPRM), we propose changes to our satellite television "significantly viewed" rules to implement Section 203 of the Satellite Television Extension and Localism Act of 2010 (STELA).[1] Section 203 of the STELA amends Section 340 of the Communications Act of 1934 ("Communications Act" or "Act"), which gives satellite carriers the authority to offer out-of-market but "significantly viewed" broadcast television network stations as part of their local service to subscribers.[2] The STELA requires the Commission to issue final rules in this proceeding on or before Wednesday, November 24, 2010.[3]

2. Significantly viewed ("SV") stations are television broadcast stations that the Commission has determined have sufficient over-the-air (*i.e.,* non-cable or non-satellite) viewing[4] to be considered local for certain purposes and so are not constrained by the boundary of that station's local market or Designated Market Area ("DMA"). The individual TV station, or cable operator or satellite carrier that seeks to carry the station, may petition the Commission to obtain "significantly viewed" status for the station,[5] and placement on the SV List.[6] The designation of "significantly viewed" status allows a station assigned to one market to be treated as a "local" station with respect to a particular cable or satellite community[7] in another market, and, thus, enables its cable or satellite carriage into said community in that other market.[8] Whereas cable operators have had carriage rights for SV stations since 1972,[9] satellite carriers have had such authority only since 2004[10] and may only retransmit SV network stations to "eligible" satellite subscribers.[11] These satellite subscriber eligibility restrictions are intended to prevent satellite carriers from favoring an SV network station over the in-market (local) station affiliated with the same network.[12]

3. Section 203 of the STELA eliminates two statutory limitations on subscriber eligibility to receive SV network stations from satellite carriers.[13] To implement the STELA, we propose the following changes to our satellite subscriber eligibility rules:

- We propose to eliminate the requirement that satellite carriers offer "equivalent bandwidth" to the local and SV network station pair, and to require instead carriage of the local network affiliate in high definition (HD) as a precondition to satellite carriage of the HD programming of an SV station affiliated with the same network.
- We propose to eliminate the requirement that a subscriber receive the specific local network station (as part of the satellite carrier's "local-into-local" service) in order for that subscriber to also receive an SV station affiliated with the same network and to

[1] The Satellite Television Extension and Localism Act of 2010 (STELA) sec. 203, Pub. L. 111–175, 124 Stat. 1218, 1245 (2010) (sec. 203 codified as amended at 47 U.S.C. 340, other STELA amendments codified in scattered sections of 17 and 47 U.S.C.). The STELA was enacted on May 27, 2010 (S. 3333, 111th Cong.). This proceeding to implement STELA sec. 203 (titled "Significantly Viewed Stations"), 124 Stat. at 1245, and the related statutory copyright license provisions in STELA sec. 103 (titled "Modifications to Statutory License for Satellite Carriers in Local Markets"), 124 Stat. at 1227–28, is one of a number of Commission proceedings that are required to implement the STELA.

[2] 47 U.S.C. 340. We note that the nature of SV carriage under Section 340 is permissive (and not mandatory), meaning the statute applies when a satellite carrier chooses to carry an SV station and has obtained retransmission consent from such SV station. *Id.* at 340(d).

[3] The STELA requires the Commission to take all actions necessary to promulgate a rule to implement the amendments within 270 days after the date of the enactment. STELA sec. 203(b). The STELA establishes February 27, 2010 as its effective date or "date of enactment," even though the law was enacted by Presidential signature on May 27, 2010. STELA sec. 307. Congress backdated the STELA's effective date to protect the satellite carriers that continued to provide distant signals (which, at that time, included significantly viewed signals) during a two-day gap in coverage of the distant signal statutory copyright license, which expired on February 28 and was not extended until March 2, 2010. Congress passed four short-term extensions of the distant signal statutory copyright license (December 19, 2009, March 2, March 25 and April 15, 2010) before finally passing STELA to reauthorize the license for five years.

[4] To qualify for significantly viewed status (*i.e.,* for placement on the significantly viewed list or "SV List"), an SV station can be either a "network" station or an "independent" station, with network stations requiring a higher share of viewing hours. 47 CFR 76.5(i)(1) and (2). The Commission's rules define network station as one of the "three major national television networks" (*i.e.,* ABC, CBS or NBC). 47 CFR 76.5(j) and (k). Parties may demonstrate that stations are significantly viewed either on a community basis or on a county-wide basis. 47 CFR 76.54(b), (d).

[5] *See* 47 CFR 76.5, 76.7, 76.54. A TV station, cable operator or satellite carrier that wishes to have a station designated significantly viewed must file a petition pursuant to the pleading requirements in 47 CFR 76.7(a)(1) and use the method described in 47 CFR 76.54 to demonstrate that the station is significantly viewed as defined in 47 CFR 76.5(i). *SHVERA Significantly Viewed Report and Order,* FCC 05–187, 70 FR 76504, December 27, 2005.

[6] The significantly viewed list or "SV List" identifies the list of stations the Commission has determined to be significantly viewed in specified counties and communities. The list applies to both cable and satellite providers. The Commission updates this list as necessary upon the appropriate demonstrations by stations or cable or satellite providers. The current SV List is available on the Media Bureau's Web site at *http://www.fcc.gov/mb/.*

[7] We note that the SV station can only be carried in the cable or satellite community in which it is significantly viewed. *See* 47 CFR 76.5(dd) (defining cable "community unit") and 76.5(gg) (defining a "satellite community").

[8] For copyright purposes, significantly viewed status means that cable and satellite providers may carry the distant but SV station with the reduced copyright payment obligations applicable to local (in-market) stations. *See* 17 U.S.C. 111(a), (c), (d), and (f), as amended by STELA sec. 104 (relating to cable statutory copyright license) and 122(a)(2), as amended by STELA sec. 103 (relating to satellite statutory copyright license).

[9] *See Cable Television Report and Order,* FCC 72–108, 37 FR 3252, February 3, 1972 (adopting the concept of "significantly viewed" signals to differentiate between otherwise out-of-market television stations "that have sufficient audience to be considered local and those that do not").

[10] Section 202 of the Satellite Home Viewer Extension and Reauthorization Act of 2004 (SHVERA) created Section 340 of the Communications Act, which authorized satellite carriage of Commission-determined SV stations. *See* SHVERA sec. 202, Pub. L. 108–447, 118 Stat 2809, 3393 (2004) (codified in 47 U.S.C. 340). *See also SHVERA Significantly Viewed Report and Order.*

[11] *See* 47 U.S.C. 340(b) and 47 CFR 76.54(g) and (h).

[12] 47 U.S.C. 340(b)(1) and (2). *See, e.g., SHVERA Significantly Viewed Report and Order.* The Copyright Act's definitions of "network station" and "non-network station" will apply for purposes of determining subscriber eligibility to receive an SV network station. *See* 47 U.S.C. 339(d) and 47 U.S.C 122(j)(4), as amended, applying the definitions of such terms in 47 U.S.C 119(d)(2) and (9). Unlike the definition in the Commission's rules, which specifically include only ABC, CBS and NBC, the Copyright Act definition of "network station" may include other stations. *See SHVERA Significantly Viewed Report and Order.*

[13] 47 U.S.C. 340(b)(1) and (2).

require instead that the subscriber receive local-into-local satellite service.

II. Background

4. In May 2010, Congress passed and the President signed the STELA, which amends the 1988 copyright laws [14] and the Communications Act of 1934 [15] to "modernize, improve and simplify the compulsory copyright licenses governing the retransmission of distant and local television signals by cable and satellite television operators." [16] Congress intended for the STELA to increase competition and service to satellite and cable consumers and update the law to reflect the completion of the digital television (DTV) transition.[17] Notably, Congress reauthorizes the statutory copyright license for satellite carriage of SV stations and moves that license from the distant signal statutory copyright license provisions to the local signal statutory copyright license provisions.[18] The STELA is the fourth in a series of statutes that addresses satellite carriage of television broadcast stations.

5. In the 1988 Satellite Home Viewer Act ("1988 SHVA"), Congress established a statutory copyright license to enable satellite carriers to offer subscribers who could not receive the over-the-air signal of a broadcast station access to broadcast programming via satellite.[19] The 1988 SHVA was intended to protect the role of local broadcasters in providing over-the-air television by limiting satellite delivery of network broadcast programming to subscribers who were "unserved" by over-the-air signals. The 1988 SHVA also permitted satellite carriers to offer distant "superstations" to subscribers.[20]

6. In the 1999 Satellite Home Viewer Improvement Act ("SHVIA"), Congress expanded satellite carriers' ability to retransmit local broadcast television signals directly to subscribers.[21] A key element of the SHVIA was the grant to satellite carriers of a statutory copyright license to retransmit local broadcast programming, or "local-into-local" service, to subscribers. A satellite carrier provides "local-into-local" service when it retransmits a local television signal back into the local market of that television station for reception by subscribers.[22] Generally, a television station's "local market" is the DMA in which it is located.[23] Each satellite carrier providing local-into-local service pursuant to the statutory copyright license is generally obligated to carry any qualified local television station in the particular DMA that has made a timely election for mandatory carriage, unless the station's programming is duplicative of the programming of another station carried by the carrier in the DMA or the station does not provide a good quality signal to the carrier's local receive facility.[24] This is commonly referred to as the "carry one, carry all" requirement. The Commission implemented the SHVIA by adopting rules for satellite carriers with regard to carriage of broadcast signals, retransmission consent, and program exclusivity that paralleled the requirements for cable service.[25]

7. In the 2004 Satellite Home Viewer Extension and Reauthorization Act ("SHVERA"), Congress established the framework for satellite carriage of "significantly viewed" stations.[26] Specifically, the SHVERA expanded the statutory copyright license to allow satellite carriers to retransmit a distant (out-of-market) network station as part of their local service to subscribers in a local market where the Commission determined that distant station to be "significantly viewed" (based on over-the-air viewing).[27] In providing this authority to satellite carriers, Congress

[14] *See* 17 U.S.C. 119 and 122. 17 U.S.C. 119 contains the statutory copyright license for satellite carriage of "distant" network stations (limited to "unserved households") and 17 U.S.C. 122 contains the statutory copyright license for satellite carriage of "local" stations (generally defined as stations and subscribers in the same DMA but which now also includes SV stations that are treated as "local" for copyright purposes, even though such stations are not in the same DMA as the subscribers). The STELA also amended 17 U.S.C. 111, the statutory copyright license for cable carriage of broadcast stations.

[15] *See* 47 U.S.C. 325, 338, 339 and 340.

[16] *See* House Judiciary Committee Report dated Oct. 28, 2009, accompanying House Bill, H.R. 3570, 111th Cong. (2009), H.R. Rep. No. 111–319, at 4 ("*H.R. 3570 Report*"). There was no final Report issued to accompany the final version of the STELA bill (S. 3333) as it was enacted. *See* Senate Bill, S. 3333, 111th Cong. (2010) (enacted). Therefore, for the relevant legislative history, we look to the Reports accompanying the various predecessor bills (*e.g.,* H.R. 3570, H.R. 2994, and S. 1670). These Reports remain relevant with respect to those provisions that were unchanged, which is the case for the amendments to the "significantly viewed" provisions (*see* STELA secs. 203, 103). Finally, also relevant are certain remarks made in floor statements in passing the bill (S. 3333). *See* "House of Representatives Proceedings and Debates of the 111th Congress, Second Session," 156 Cong. Rec. H3317, H3328–3330 (daily ed. May 12, 2010) (statements of Reps. Conyers and Smith) ("*House Floor Debate*") and "Senate Proceedings and Debates of the 111th Congress, Second Session," 156 Cong. Rec. S3435, (daily ed. May 7, 2010) (statement of Sen. Leahy) ("*Senate Floor Debate*").

[17] *See H.R. 3570 Report* at 5. As of the June 12, 2009 statutory DTV transition deadline, all full-power television stations stopped broadcasting in analog and are broadcasting only digital signals. 47 U.S.C. 309(j)(14)(A).

[18] STELA sec. 103 (moving the SV signal statutory copyright license from 17 U.S.C. 119(a)(3) to 17 U.S.C. 122 (a)(2)). In doing so, Congress now defines SV signals as another type of local signal, rather than as an exception to distant signals. The move also means that Congress won't need to reauthorize the SV signal license in five years, when the distant signal license will expire.

[19] The Satellite Home Viewer Act of 1988 (SHVA), Pub. L. 100–667, 102 Stat. 3935, Title II (1988) (codified at 17 U.S.C. 111, 119). The 1988 SHVA was enacted on November 16, 1988, as an amendment to the copyright laws. The 1988 SHVA gave satellite carriers a statutory copyright license to offer distant signals to "unserved" households. 17 U.S.C. 119(a).

[20] *See id.* 119(a)(1) (2009). The STELA sec. 102(g) replaces the term "superstation" with the term "non-network station." This change in wording has no substantive impact on our rules. A non-network station (previously superstation) is defined as a television station, other than a network station, licensed by the Commission that is retransmitted by a satellite carrier. Non-network stations are still not considered "network stations" for copyright purposes. *See* 17 U.S.C. 119(d)(9).

[21] The Satellite Home Viewer Improvement Act of 1999 (SHVIA), Pub. L. 106–113, 113 Stat. 1501 (1999). The SHVIA was enacted on November 29, 1999, as Title I of the Intellectual Property and Communications Omnibus Reform Act of 1999 ("IPACORA") (relating to copyright licensing and carriage of broadcast signals by satellite carriers). In the SHVIA, Congress amended both the copyright laws, 17 U.S.C. 119 and 122, and the Communications Act, 47 U.S.C. 325, 338 and 339.

[22] 47 CFR 76.66(a)(6).

[23] *See* 17 U.S.C. 122(j)(2)(A); 47 U.S.C. 340(i)(1). DMAs, which describe each television market in terms of a unique geographic area, are established by Nielsen Media Research based on measured viewing patterns. *See* 17 U.S.C. 122(j)(2)(A) through (C).

[24] *See* 47 U.S.C. 338.

[25] *See SHVIA Signal Carriage Order,* 66 FR 7410, January 23, 2001; *OET SHVIA Report,* FCC 00–416 (rel. Nov. 29, 2000); *SHVIA Satellite Exclusivity Order,* 65 FR 68082, November 14, 2000; *SHVIA Retransmission Consent Enforcement Order;* 65 FR 10718, February 29, 2000; *SHVIA Good Faith Retransmission Consent Order,* 65 FR 15559, March 23, 2000.

[26] The Satellite Home Viewer Extension and Reauthorization Act of 2004 (SHVERA), Pub. L. 108–447, 118 Stat 2809 (2004) (codified in scattered sections of 17 and 47 U.S.C.). The SHVERA was enacted on December 8, 2004 as title IX of the "Consolidated Appropriations Act, 2005." The SHVERA contained additional mandates requiring Commission action, but not relevant to this proceeding, which concerns the carriage of SV stations. *See SHVERA Reciprocal Bargaining Order,* 70 FR 40216, July 13, 2005 (imposing a reciprocal good faith retransmission consent bargaining obligation on multichannel video programming distributors); *SHVERA Section 210 Order,* 70 FR 51658, August 31, 2005 (requiring satellite carriers to carry local TV broadcast stations in Alaska and Hawaii); *SHVERA Procedural Rules Order,* 70 FR 21669, April 27, 2005 (adopting procedural rules concerning satellite carriers' notifications to TV broadcast stations and obligations to conduct signal testing); *Public Notice,* "Media Bureau Seeks Comment For Inquiry Required By the on Rules Affecting Competition In the Television Marketplace," 70 FR 6593, February 8, 2005 (opening inquiry concerning the impact of certain rules and statutory provisions on competition in the television marketplace).

[27] In the SHVERA, Congress again amended both the Communications Act, 47 U.S.C. 325, 338, 339 and 340, and the copyright laws, 17 U.S.C. 119 and 122. In creating a statutory copyright license for satellite carriers to offer significantly viewed stations as part of their local service to subscribers, Congress distinguished between out-of-market stations that had significant over-the-air viewership in a local market (*i.e.,* significantly viewed stations) and truly "distant" stations.

sought to create parity with cable operators, who had already had such authority to offer SV stations to subscribers for more than 38 years.[28] The Commission implemented the SHVERA's significantly viewed provisions by publishing a list of SV stations and adopting rules for stations to attain eligibility for significantly viewed status and for subscribers to receive SV stations from satellite carriers. The SHVERA mandated that the Commission apply the same station eligibility requirements (*i.e.,* rules and procedures for parties to show that a station qualifies for significantly viewed status) to satellite carriers that already applied to cable operators.[29] However, to prevent a satellite carrier from favoring SV stations over traditional local market stations, the SHVERA also imposed subscriber eligibility requirements that applied only to satellite carriers.[30]

8. The SHVERA limited subscribers' eligibility to receive SV digital television stations from satellite carriers in two key ways. First, the SHVERA allowed a satellite carrier to offer SV stations only to subscribers that received the carrier's "local-into-local" service.[31] The Commission interpreted this provision to further require that the subscriber receive the specific local network station (as part of the carrier's "local-into-local" service) in order for that subscriber to also receive an SV station affiliated with the same network (called the receipt of the "same network affiliate" requirement).[32] Second, the SHVERA allowed a satellite carrier to offer an SV digital station to a subscriber only if the carrier also provided to that subscriber the affiliated local network station in a format that used either (1) An "equivalent" amount of bandwidth for the local and SV network station pair, or (2) the "entire" bandwidth of the local station (called the "equivalent or entire bandwidth" requirement).[33] The Commission interpreted this provision to require an objective comparison of each station's use of its bandwidth in terms of megabits per second (mbps) or bit rate.[34]

III. Discussion

9. STELA simplifies the significantly viewed provisions in Section 340(b) of the Communications Act to make it easier for satellite carriers to offer SV stations to subscribers.[35] The STELA makes two key changes to the significantly viewed provisions in Section 340(b) to ease the limitations on satellite subscriber eligibility to receive SV stations.[36] First, the STELA eliminates the equivalent or entire bandwidth requirement in Section 340(b)(2)(B).[37] In its place, the STELA permits a satellite carrier to carry in high definition (HD) format an SV network station, provided the satellite carrier also carries in HD format the local station in the market that is affiliated with the same network whenever the local station is available in HD format.[38] Second, the STELA strikes Section 340(b)(2)(A), the former digital service limitation which contained the "same network affiliate" limitation language, choosing, instead, to apply Section 340(b)(1), the former analog service limitation which contained only the "local-into-local" service limitation language, to digital stations.[39] Accordingly, we propose rules to implement the changes made to Section 340(b) of the Act and seek comment on them. Our discussion below addresses these two key changes to Section 340(b), and also considers the impact of these changes on the statutory exceptions to this section. We also propose some non-substantive, "housecleaning" rule changes. We seek comment on our proposals and tentative conclusions set forth herein, and also invite comment on any other issues that may be relevant to our implementation of the STELA's amendments to the significantly viewed provisions.

A. Proposed Elimination of "Equivalent or Entire Bandwidth" Requirement

10. In the 2004 SHVERA, Congress enacted the "equivalent" or "entire" bandwidth requirements to prevent a satellite carrier from using technological means to discriminate against a local network station in favor of the SV network affiliate.[40] The Commission codified these requirements in § 76.54(h) of the rules, which tracks the language of the statute.[41] In implementing this provision, the Commission strictly interpreted the statutory requirement for "equivalent bandwidth." As a result, satellite

[28] *See SHVERA Significantly Viewed Report and Order.* In 1972, the Commission adopted the concept of "significantly viewed" stations for cable television to differentiate between out-of-market television stations "that have sufficient audience to be considered local and those that do not." *Cable Television Report and Order.* The Commission concluded at that time that it would not be reasonable if choices on cable were more limited than choices over the air, and gave cable carriage rights to stations in communities where they had significant over-the-air (non-cable) viewing. *Id.*

[29] *See* 47 CFR 76.5, 76.7 and 76.54(a) through (d). As mandated by the SHVERA, the Commission required satellite carriers or broadcast stations seeking significantly viewed status for satellite carriage to follow the same petition process now in place for cable carriage.

[30] 47 U.S.C. 340(b) (2004). The eligibility requirements also addressed the different carriage requirements that apply to cable (*i.e.,* "must carry" for all cable systems) as compared with satellite (*i.e.,* "carry one, carry all").

[31] *See id.* at 340(b)(1) (analog service limitations) and (b)(2)(A) (digital service limitations) (2004). The Commission found that "subscriber receipt of 'local-into-local' service [was] unambiguously required by the statute." *SHVERA Significantly Viewed Report and Order.* The SHVERA provided for two exceptions to the local service limitations, contained in 47 U.S.C. 340(b)(3) and (4), respectively. Section 340(b)(3) allows satellite carriage of an SV network station to a subscriber when there is no local station affiliated with the same television network as the SV station present in the local market. Section 340(b)(4) allows a satellite carrier to privately negotiate with the local network station to obtain a waiver of the subscriber eligibility restrictions in Sections 340(b)(1) and 340(b)(2). While revising the eligibility limitations, the STELA retains these exceptions unchanged.

[32] The SHVERA's language differed with respect to the analog and digital service limitations. The Commission noted that, "[u]nlike the ambiguity in its sister analog provision [of 47 U.S.C. 340(b)(1) (2004)], Section 340(b)(2)(A) of the Act, 47 U.S.C. 340(b)(2)(A) (2004), is clear in requiring a subscriber to receive "the digital signal of a network station in the subscriber's local market that is affiliated with the same television network." *Id.*

[33] 47 U.S.C. 340(b)(2)(B) (2004). Congress sought to prevent satellite carriers from offering the local network station's digital signal "in a less robust format" than the significantly viewed affiliate station's digital signal). *SHVERA Significantly Viewed Report and Order.*

[34] *See id.*

[35] *See H.R. 3570 Report* at 4–5.

[36] STELA sec. 203(a) (amendments to be codified at 47 U.S.C. 340(b)(1) and (2)). We note that the subscriber eligibility limitations in 47 U.S.C. 340(b)(1) and (2), which are amended by the STELA sec. 203, do not apply to cable subscribers and that we do not propose to substantively amend our significantly viewed rules and procedures that satellite carriers share with cable operators. *See* 47 CFR 76.54(a) through (d). Furthermore, we note that the STELA sec. 203 does not amend the "significantly viewed" provisions in the Communications Act governing the eligibility of a television broadcast station to qualify for "significantly viewed" status. *See* 47 U.S.C. 340(a), (c) through (g). Therefore, we do not propose here any substantive (non-"housecleaning") changes to our rules and procedures implementing the significantly viewed station eligibility requirements. *See* 47 CFR 76.54(a) through (f), (j) and (k).

[37] The STELA sec. 203(a) removes the equivalent or entire bandwidth requirement in 47 U.S.C. 340(b)(2)(B) and the STELA sec. 204(c) strikes the definition of equivalent or entire bandwidth in 47 U.S.C. 340(i)(4).

[38] *See* 47 U.S.C. 340(b)(2) (2010), as amended by the STELA sec. 203(a).

[39] *See Id.* 340(b)(1) (2010), as amended by the STELA sec. 203(a).

[40] 47 U.S.C. 340(b)(2)(B) (2004). The law reflects Congress' intent to prevent a satellite carrier from offering the local digital station "in a less robust format" than the SV digital station). *SHVERA Significantly Viewed Report and Order.*

[41] 47 CFR 76.54(h) states: "Signals of significantly viewed network stations that originate as digital signals may not be retransmitted to subscribers unless the satellite carrier retransmits the digital signal of the local network station, which is affiliated with the same television network as the network station whose signal is significantly viewed, in either (1) At least the equivalent bandwidth of the significantly viewed station or (2) the entire bandwidth of the digital signal broadcast by such local station."

carriers must ensure virtually minute-by-minute comparisons between the satellite bandwidth allocated to carriage of the local station and the SV stations, making carriage of SV stations so burdensome that they are rarely carried.[42]

11. STELA eliminates the "equivalent or entire bandwidth" requirement from the statute,[43] changing the focus of the provision from "equivalent bandwidth" to "HD format." The STELA amends Section 340(b)(2) of the Act to read as follows: [44]

Service Limitations.—A satellite carrier may retransmit to a subscriber in high definition format the signal of a station determined by the Commission to be significantly viewed under subsection (a) only if such carrier also retransmits in high definition format the signal of a station located in the local market of such subscriber and affiliated with the same network whenever such format is available from such station.

12. In doing so, Congress intended to facilitate satellite carriage of SV stations, which Congress thought was thwarted by the Commission's implementation of the predecessor provision.[45] The legislative history also indicates an intent by Congress to simplify the law and increase service to satellite consumers.[46] Additionally, in reauthorizing the SHVERA and mostly retaining its framework for the carriage of SV stations, the STELA retains the key goals of its predecessor statute—those being to foster localism and promote parity between cable and satellite service.[47] The principal concern of Congress was simply to clarify that a satellite carrier may provide an SV station in HD format when the local network affiliate is broadcasting only in Standard Definition (SD) format, as long as the carrier provides the local station in HD format whenever such format is available.[48] Moreover, in moving the statutory copyright license into the "local" license, we believe Congress recognized the "local" nature of an SV station, and that carriage of an SV network station, in itself, promotes localism, as long as such station is not favored over the in-market (local) affiliate. Therefore, we tentatively conclude that, in revising the law, Congress intended for the Commission to create a workable framework that would generally provide for the satellite carriage of SV stations, while ensuring that the SV network station is not retransmitted in HD format unless the in-market affiliate is also retransmitted in HD format when so broadcast.

13. Accordingly, we propose to revise our rule in § 76.54(h), which we now move to § 76.54(g)(2), to eliminate the "equivalent or entire bandwidth" requirement and to provide that a satellite carrier may retransmit the HD signal of an SV station to a subscriber only if such carrier also retransmits the HD signal of the local station affiliated with the same network whenever that signal is available in HD format.[49] Our proposed rule tracks the revised language in Section 340(b)(2).[50] We also tentatively conclude that Section 340(b)(2), by its terms, only limits satellite carriage of an SV station with respect to HD format; it does not apply if the satellite carrier only carries the SV station in SD format.[51] Finally, we note that the Advanced Television Systems Committee ("ATSC"), a non-profit organization that develops voluntary standards for digital television, including HDTV, defines "high definition" television as having a screen resolution of 720p, 1080i, or higher, and believe that no further definition of "HD format" is needed to implement the statute.[52] We seek comment on our statutory interpretation, proposed rule and tentative conclusions. We also seek comment on whether satellite carriers will face any technical problems in order to comply with our proposed rule.

14. Section 340(b)(2) permits retransmission of an SV network station in HD "*only if such carrier also retransmits in high definition format the signal of a station located in the local market of such subscriber and affiliated with the same network whenever such format is available from such station.*" [53] We seek comment on the significance of this requirement. What is required by this language in the event a satellite carrier wants to retransmit an SV network affiliate and there is an in-market (local) station that is multicasting in HD format and airing programming affiliated with the same network in HD on a secondary stream? Is the satellite carrier required to carry this secondary stream in HD in order to be permitted to retransmit the SV station in HD even if the in-market station's primary stream is affiliated with another network? We also seek information on the extent to which stations are broadcasting HD programming from two different networks, and whether this is sufficiently rare that it can be addressed on a case-by-case basis, rather than in a rule or order.

B. Proposed Elimination of Requirement To Receive Specific Local Affiliate of the Same Network

15. We propose to amend our rules regarding subscriber eligibility to address STELA's change to Sections 340(b)(1) and 340(b)(2)(A) that eliminates the reference to receiving a

[42] In a House Energy and Commerce Committee Report, Congress noted that the "equivalent bandwidth" requirement "has generally served to discourage satellite carriers from using Section 340 to provide significantly viewed signals to qualified households." *See* House Energy and Commerce Committee Report dated Dec. 12, 2009, accompanying House Bill, H.R. 2994, 111th Cong. (2009), H.R. Rep. No. 111–349, at 16 ("*H.R. 2994 Report*"). *See also* Testimony of Bob Gabrielli, Senior Vice President, Broadcasting Operations and Distribution, DIRECTV, Inc., before the U.S. House of Representatives Subcommittee on Communications, Technology and the Internet, Hearing on Reauthorization of the of the Satellite Home Viewer Extension and Reauthorization Act, at 9 (Feb. 24, 2009) (asserting that it is "infeasible" for DIRECTV to "carry local stations in the same format as SV stations every moment of the day").

[43] We note that DIRECTV, Inc. ("DIRECTV") and EchoStar Satellite LLC ("EchoStar") filed a joint petition, which remains pending, seeking reconsideration of two decisions in the 2005 *SHVERA Significantly Viewed Report and Order.* The first decision challenged by the petition is the Commission's interpretation of the "equivalent bandwidth" requirement. *See* DIRECTV and EchoStar Joint Petition for Reconsideration in MB Docket No. 05–49 (filed Jan. 26, 2006) ("*DIRECTV/EchoStar Joint Petition*"). As a result of the STELA's elimination of this requirement, we believe the petition on this first issue is now moot. The second issue relates to the receipt of the local analog station affiliate requirement, which we also believe is moot. We expect to dismiss the petition soon after we issue final rules in this proceeding.

[44] 47 U.S.C. 340(b)(2) (2010), as amended by the STELA sec. 203(a).

[45] *See H.R. 2994 Report* at 16.

[46] *See H.R. 3570 Report* at 4–5. Congress wanted to clarify that a satellite carrier may provide an SV station in HD format, when the local network affiliate is broadcasting only in Standard Definition (SD) format, as long as the carrier provides the local station in HD format whenever such format is available. *H.R. 2994 Report* at 16.

[47] *See SHVERA Significantly Viewed Report and Order.*

[48] *H.R. 2994 Report* at 16. The Commission interpreted the "equivalent bandwidth" requirement to include multicast signals. *SHVERA Significantly Viewed Report and Order.* (concluding that "if the SV station transmits in HD and the local station transmits multiplexed (multicast) signal, then a satellite carrier may carry the SV station's HD signal, provided it also carries as many of the local station's multicast channels as necessary to match the bandwidth provided to the SV station."). However, the STELA's change to 47 U.S.C. 340(b)(2) appears to refocus the comparison of the local and SV network station pair on HD format.

[49] *See* Proposed rule 47 CFR 76.54(g)(2).

[50] *Id.*

[51] We propose including a sentence in our proposed rule to clarify this point. *See* Proposed rule 47 CFR 76.54(g)(2).

[52] *See, e.g., Local Broadcast Signal Carriage First Report and Order,* 66 FR 16533, March 26, 2001 (discussing several formats that are considered "high definition"); *Local Broadcast Signal Carriage Second Report and Order,* 73 FR 24502, May 5, 2008. *See also, e.g.,* Newton's Telecom Dictionary definition of HDTV at 389 (20th ed. 2004) and the Commission's "DTV Shopping Guide" for consumers at *http://www.dtv.gov/shopgde.html.*

[53] *See* 47 U.S.C. 340(b)(2) (2010), as amended by the STELA sec. 203(a).

specific local station affiliated with the same network as the SV station.[54] In the 2004 SHVERA, Congress authorized satellite carriers to offer SV stations to subscribers, but crafted Sections 340(b)(1) and 340(b)(2)(A) of the Act to protect localism by requiring that these subscribers also receive the carrier's local service.[55] These two provisions, however, contained different language. Whereas Section 340(b)(1),[56] the provision related to analog service, required only that the analog subscriber receive local service "pursuant to Section 338"—referring to the "carry one, carry all" carriage requirements that pertain to local stations,[57] Section 340(b)(2)(A),[58] the provision related to digital service, contained additional language that expressly required the digital subscriber to receive the local station that was specifically "affiliated with the same television network" as the SV station (hereinafter referred to as the "same network affiliate" language). Thus, while each of these provisions clearly required a subscriber to at least receive the satellite carrier's local-into-local service before that subscriber could receive an SV station, it was unclear whether Section 340(b)(1) also required an analog subscriber to receive the specific local network station before that subscriber could receive the SV station affiliated with the same network.[59] For example, the statute did not address the situation where there is a local network station in the local market, but such station fails to request local carriage, refuses to grant retransmission consent, or is otherwise ineligible for local carriage.[60]

16. Ultimately, in the 2005 *SHVERA Significantly Viewed Report and Order,* the Commission interpreted both Sections 340(b)(1) and 340(b)(2)(A) to require that the subscriber receive the specific local station that is affiliated with the same network as the SV station.[61] Although Section 340(b)(1) lacked the express "same network affiliate" language as contained in Section 340(b)(2)(A), the Commission read the two provisions together and interpreted Section 340(b)(1) to also contain the "same network affiliate" requirement, based largely on the notion that Congress intended the two provisions to achieve similar ends.[62] Accordingly, the Commission adopted § 76.54(g) of the rules, based on the "same network affiliate" language in Section 340(b)(2)(A).[63]

17. In the STELA, Congress strikes Section 340(b)(2)(A), which governed digital stations and included the "same network affiliate" language,[64] and removes the references to analog in Section 340(b)(1) because of the completion of the DTV transition.[65] Specifically, the STELA amends Section 340(b)(1) of the Act to read as follows:[66]

> Service Limited to Subscribers Taking Local-Into-Local Service.—This section shall apply only to retransmissions to subscribers of a satellite carrier who receive retransmissions of a signal from that satellite carrier pursuant to section 338.

This provision, as amended, still contains the local-into-local service requirement,[67] but no longer requires carriage of the local affiliate of the same network. We presume that Congress acted intentionally and purposely when it chose to discard the "same network affiliate" language in Section 340(b)(2)(A), which language the Commission had relied upon for its more restrictive interpretation of Section 340(b)(1).[68]

18. Accordingly, we propose to revise our rule in § 76.54(g) to reflect the amended statutory language in Section 340(b)(1).[69] We tentatively conclude that, by striking Section 340(b)(2)(A), Congress intended to eliminate the requirement that a subscriber receive the specific local station that is affiliated with the same network as the SV station. Therefore, our proposed rule requires only that a subscriber receive the satellite carrier's local-into-local service as a pre-condition for the subscriber to receive SV stations. We

[54] *See* 47 U.S.C. 340(b)(1) (2010), as amended by the STELA sec. 203(a).

[55] 47 U.S.C. 340(b)(1) and (b)(2)(A) (2004). Congress intended for these provisions to protect localism "by helping ensure that the satellite operator cannot retransmit into a market a significantly viewed digital signal of a network broadcast station from a distant market without also retransmitting into the market a digital signal of any local affiliate from the same network." *SHVERA Significantly Viewed Report and Order.*

[56] 47 U.S.C. 340(b)(1) (2004), as established in 2004, stated: "With respect to a signal that originates as an analog signal of a network station, this section shall apply only to retransmissions to subscribers of a satellite carrier who receive retransmissions of a signal that originates as an analog signal of a local network station from that satellite carrier pursuant to section 338."

[57] 47 U.S.C. 338.

[58] 47 U.S.C. 340(b)(2)(A) (2004), as established in 2004, stated: "With respect to a signal that originates as a digital signal of a network station, this section shall apply only if—(A) the subscriber receives from the satellite carrier pursuant to section 338 the retransmission of the digital signal of a network station in the subscriber's local market that is affiliated with the same television network * * *."

[59] *SHVERA Significantly Viewed Report and Order.*

[60] *See id.*

[61] *Id.* This is the second decision challenged by the pending 2006 *DIRECTV/EchoStar Joint Petition.* The petition challenged only the Commission's interpretation of the *analog* service limitation provision in 47 U.S.C. 340(b)(1), essentially conceding the meaning of the plain language in the digital provision in 47 U.S.C. 340(b)(2)(A). With the end of analog full-power broadcasting (due to the completion of DTV transition), we believe this second issue in the petition is also moot, and we expect to dismiss the petition soon after we issue final rules in this proceeding.

[62] *See SHVERA Significantly Viewed Report and Order.* We note that the Commission also stated that its interpretation of Section 340(b)(1) was necessary to give meaning to the statutory exceptions in Sections 340(b)(3) and (4). As discussed in more detail later, we believe the statutory exceptions remain meaningful to, and are consistent with, our proposed interpretation of Section 340(b)(1) as amended by STELA.

[63] 47 CFR 76.54(g) states: "(g) Signals of analog or digital significantly viewed television broadcast stations may not be retransmitted by satellite carriers to subscribers who do not receive local-into-local service, including a station affiliated with the same network as the significantly viewed station, pursuant to § 76.66 of this chapter; except that a satellite carrier may retransmit a significantly viewed signal of a television broadcast station to a subscriber who receives local-into-local service but does not receive a local station affiliated with the same network as the significantly viewed station, if: (1) There is no station affiliated with the same television network as the station whose signal is significantly viewed; or (2) The station affiliated with the same television network as the station whose signal is significantly viewed has granted a waiver in accordance with 47 U.S.C. 340(b)(4)."

[64] 47 U.S.C 340(b)(2)(A) (2004). The digital local service provision provided: "With respect to a signal that originates as a digital signal of a network station, this section shall apply only if—(A) the subscriber receives from the satellite carrier pursuant to section 338 of this title the retransmission of the digital signal of a network station in the subscriber's local market *that is affiliated with the same television network;* and" (B) the retransmission complies with either the (i) equivalent or (ii) entire bandwidth requirement. (Emphasis added.)

[65] 47 U.S.C. 340(b)(1) (2004). The analog local service provision provided: "With respect to a signal that originates as an analog signal of a network station, this section shall apply only to retransmissions to subscribers of a satellite carrier who receive retransmissions of a signal that originates as an analog signal of a local network station from that satellite carrier pursuant to section 338 of this title."

[66] 47 U.S.C. 340(b)(1) (2010), as amended by the STELA sec. 203(a).

[67] The provision limits subscriber eligibility for SV stations to those subscribers that receive retransmissions from their satellite carrier pursuant to the "carry one, carry all" requirement in 47 U.S.C. 338.

[68] *See, e.g., Moshe Gozlon-Peretz* v. *United States,* 498 U.S. 395, 404 (1990) ("[Where] Congress includes particular language in one section of a statute but omits it in another section of the same Act, it is generally presumed that Congress acts intentionally and purposely in the disparate inclusion or exclusion.") (internal citations omitted); *Russello* v. *United States,* 464 U.S. 16, 23 (1983) (same); *Estate of Bell* v. *Commissioner,* 928 F.2d 901, 904 (9th Cir. 1991) ("Congress is presumed to act intentionally and purposely when it includes language in one section but omits it in another."); *Arizona Elec. Power Co-op.* v. *United States,* 816 F.2d 1366, 1375 (9th Cir. 1987) ("When Congress includes a specific term in one section of a statute but omits in another section of the same Act, it should not be implied where it is excluded.").

[69] *See* Proposed rule 47 CFR 76.54(g)(1).

note that this interpretation would allow a satellite carrier to carry an SV station affiliated with a particular network if the local in-market station affiliated with the same network does not grant retransmission consent. We seek comment on our proposed rule and tentative conclusions.

C. Statutory Exceptions to the Subscriber Eligibility Limitations

19. While revising the subscriber eligibility limitations in Sections 340(b)(1) and 340(b)(2), the STELA retains without change the statutory exceptions in Sections 340(b)(3) and 340(b)(4) to these restrictions.[70] As noted above, the Section 340(b)(3) exception to the subscriber eligibility limitations permits a satellite carrier to offer an SV network station to a subscriber when there is no local network affiliate present in the local market.[71] The Section 340(b)(4) exception permits a satellite carrier to privately negotiate with the local network station to obtain a waiver of the eligibility restrictions.[72] These two exceptions provide as follows:

(b)(3) The limitations in paragraphs (1) and (2) shall not prohibit a retransmission under this section to a subscriber located in a local market in which there are no network stations affiliated with the same television network as the station whose signal is being retransmitted pursuant to this section.

(b)(4) Paragraphs (1) and (2) shall not prohibit a retransmission of a network station to a subscriber if and to the extent that the network station in the local market in which the subscriber is located, and that is affiliated with the same television network, has privately negotiated and affirmatively granted a waiver from the requirements of paragraph (1) and (2) to such satellite carrier with respect to retransmission of the significantly viewed station to such subscriber.

We tentatively conclude that these statutory exceptions will continue to apply as they have before and are consistent with our proposed interpretations of the amended subscriber limitation provisions in Sections 340(b)(1)–(2). We believe the statutory exceptions in Sections 340(b)(3)–(4) will continue to have meaning, and would not be superfluous, to our proposed interpretation of Section 340(b)(1).[73] For example, the statutory exceptions in Sections 340(b)(3)–(4) would still apply where local-into-local service is not available to a subscriber for technical reasons (such as the spot beam does not cover the DMA or its reception is blocked for an individual subscriber by terrain or foliage) or if local-into-local service is not yet offered by the satellite carrier to a subscriber's market. We seek comment on our tentative conclusions. We also invite comment on whether application of these unchanged statutory exceptions to the amended subscriber limitation provisions raise any issues that may be relevant to our implementation of the Section 340(b) significantly viewed provisions as a whole.

D. Housecleaning Rule Changes

20. In this section, we propose non-substantive changes to update our significantly viewed rules. We seek comment on these proposed rule changes.

21. *47 CFR 76.5(i).* We propose to amend § 76.5(i) of the rules to replace its references to the term "non-cable" with the term "over-the-air."[74] In the 2005 *SHVERA Significantly Viewed Report and Order,* the Commission made this change to § 76.54 to reflect the rule's true meaning, that being to indicate over-the-air viewing.[75] The Commission explained that, in the *1972 Order,* the concept of significant viewing was adopted to apply to over-the-air households, which at the time essentially meant households without cable (*i.e.,* non-cable households).[76] Thus, amending § 76.5(i) to change "non-cable" to "over-the-air" reflects the true intent of the rule as it was in 1976, and is more consistent with the statute's intent to establish parity between cable and satellite.

22. *47 CFR 76.54(c).* We propose to amend § 76.54(c) of the rules to strike the outdated reference to the analog Grade B contour.[77] In the 2004 *SHVERA Significantly Viewed Report and Order,* the Commission revised this rule to add the appropriate service contour relevant for a station's digital signal—that being the noise limited service contour ("NLSC").[78] With the completion of the transition, we now propose to eliminate this reference to Grade B contour.

IV. Conclusion

23. In conclusion, in this NPRM, we propose to simplify our satellite TV significantly viewed rules, as mandated by Congress. To implement Section 203 of the STELA, we propose changes to § 76.54 of our rules. Our proposed rule changes—shown, below, in the Proposed Rule Changes section of this document—are modeled on the amended language in the statute. Specifically, we propose to eliminate both the "equivalent or entire bandwidth" requirement and the requirement for a subscriber to receive the specific local affiliate of the SV station.

V. Procedural Matters

A. Initial Regulatory Flexibility Act Analysis

24. As required by the Regulatory Flexibility Act of 1980, as amended ("RFA")[79] the Commission has prepared this present Initial Regulatory Flexibility Analysis ("IRFA") concerning the possible significant economic impact on small entities by the policies and rules proposed in this *NPRM.* Written public comments are requested on this IRFA. Comments must be identified as responses to the IRFA and must be filed by the deadlines for comments provided in Section V.D. of the *NPRM.* The Commission will send a copy of the *NPRM,* including this IRFA, to the Chief Counsel for Advocacy of the Small Business Administration ("SBA").[80] In addition, the *NPRM* and IRFA (or summaries thereof) will be published in the **Federal Register.**[81]

1. Need for, and Objectives of, the Proposed Rule Changes

25. This document proposes changes to the Commission's satellite television "significantly viewed" rules to implement Section 203 of the Satellite Television Extension and Localism Act of 2010 (STELA).[82] The STELA requires

[70] 47 U.S.C. 340(b)(3) and (4). We note that the STELA sec. 103 does amend the waiver provision in the corresponding satellite statutory copyright license in 17 U.S.C. 122(a)(2) to eliminate the "sunset" provision and replace the term "superstation" with "non-network station."

[71] *Id.* at 340(b)(3).

[72] *Id.* at 340(b)(4).

[73] *See SHVERA Significantly Viewed Report and Order.* The Commission stated that if Section 340(b)(1) only required receipt of any local-into-local service as a prerequisite to receiving an SV network affiliate, as opposed to receiving the specific local affiliate of the same network as the SV station, then there would be no need for the statutory exceptions in Sections 340(b)(3) and (4) to apply to Section 340(b)(1). *Id.*

[74] *See* Proposed rule change to 47 CFR 76.5(i).

[75] *SHVERA Significantly Viewed Report and Order.*

[76] *Id.* (citing to *Cable Television Report and Order*).

[77] *See* Proposed rule change to 47 CFR 76.54(c).

[78] *SHVERA Significantly Viewed Report and Order.* (The digital NLSC is defined in 47 CFR 73.622(e).)

[79] *See* 5 U.S.C. 603. The RFA, *see* 5 U.S.C. 601 *et. seq.,* has been amended by the Contract With America Advancement Act of 1996, Pub. L. 104–121, 110 Stat. 847 (1996) (CWAAA). Title II of the CWAAA is the Small Business Regulatory Enforcement Fairness Act of 1996 (SBREFA).

[80] *See* 5 U.S.C. 603(a).

[81] *See id.*

[82] The Satellite Television Extension and Localism Act of 2010 (STELA) sec. 203, Pub. L. 111–175, 124 Stat 1218, 1245 (2010) (sec. 203 codified as amended at 47 U.S.C. 340, other STELA amendments codified in scattered sections of 17 and 47 U.S.C.).

the Commission to issue final rules in this proceeding on or before Wednesday, November 24, 2010.[83]

26. Section 203 of the STELA amends Section 340 of the Communications Act, which gives satellite carriers the authority to offer out-of-market but "significantly viewed" broadcast television network stations as part of their local service to subscribers.[84] The designation of "significantly viewed" status allows a station assigned to one DMA to be treated as a "local" station with respect to a particular cable or satellite community in another DMA, and, thus, enables cable or satellite carriage into said community in that other DMA. Whereas cable operators have had carriage rights for "significantly viewed" ("SV") stations since 1972, satellite carriers have had such authority only since the 2004 Satellite Home Viewer Extension and Reauthorization Act of 2004 (SHVERA) and may only retransmit SV network stations to "eligible" satellite subscribers. The satellite subscriber eligibility rules impose conditions on when satellite carriers may retransmit SV stations to subscribers. These conditions are intended to prevent satellite carriers from favoring an SV network station over the in-market (local) station affiliated with the same network. We note that the nature of SV carriage under Section 340 is permissive (and not mandatory), meaning the statute applies when a satellite carrier chooses to carry an SV station and has obtained retransmission consent from such SV station.[85]

27. Section 203 of the STELA amends the SHVERA's Section 340(b) satellite subscriber eligibility rules in two ways. First, it eliminates the former requirement that satellite carriers devote "equivalent bandwidth" to the carriage of the in-market (local) station as compared with the bandwidth devoted to carriage of the out-of-market SV station.[86] In its place, the STELA requires a satellite carrier to retransmit "in high definition format the signal of a station located in the local market of such subscriber and affiliated with the same network whenever such format is available from such station."[87] Second, STELA revises the subscriber eligibility requirements by eliminating the SHVERA requirement that the subscriber receive the local station affiliated with the same network as the SV station and requires only that the subscriber receive the local-into-local package from the satellite carrier.[88] The STELA does not amend the SHVERA's Section 340(a) station eligibility requirements, which govern the eligibility of a television broadcast station to qualify for "significantly viewed" status.[89]

28. To implement the STELA's two amendments to Section 340(b), the NPRM proposes the following changes to our satellite subscriber eligibility rules:

- The document proposes to eliminate the requirement that satellite carriers offer "equivalent bandwidth" to the local and SV network station pair, and to require instead carriage of the local network affiliate in high definition (HD) as a precondition to satellite carriage of the HD programming of an SV station affiliated with the same network.
- The document proposes to eliminate the requirement that a subscriber receive the specific local network station (as part of the satellite carrier's "local-into-local" service) in order for that subscriber to also receive an SV station affiliated with the same network and to require instead that the subscriber receive local-into-local satellite service.

Finally, the document also seeks comment on the proposals and tentative conclusions set forth in the NPRM, and invites comment on any other issues that may be relevant to the Commission's implementation of the STELA's amendments to the significantly viewed provisions.

2. Legal Basis

29. The proposed action is authorized pursuant to Section 203 of the Satellite Television Extension and Localism Act of 2010, and Sections 1, 4(i) and (j), and 340 of the Communications Act, as amended, 47 U.S.C. 151, 154(i) and (j), and 340.

3. Description and Estimate of the Number of Small Entities to Which the Proposed Rules Will Apply

30. The RFA directs agencies to provide a description of and, where feasible, an estimate of the number of small entities that may be affected by the proposed rules, if adopted.[90] The RFA generally defines the term "small entity" as having the same meaning as the terms "small business," "small organization," and "small governmental jurisdiction."[91] In addition, the term "small business" has the same meaning as the term "small business concern" under the Small Business Act.[92] A small business concern is one which: (1) Is independently owned and operated; (2) is not dominant in its field of operation; and (3) satisfies any additional criteria established by the SBA.[93] Below, we provide a description of such small entities, as well as an estimate of the number of such small entities, where feasible.

31. *Satellite Carriers.* The term "satellite carrier" means an entity that uses the facilities of a satellite or satellite service licensed under Part 25 of the Commission's rules to operate in the Direct Broadcast Satellite (DBS) service or Fixed-Satellite Service (FSS) frequencies.[94] As a general practice (not mandated by any regulation), DBS licensees usually own and operate their own satellite facilities as well as package the programming they offer to their subscribers. In contrast, satellite carriers using FSS facilities often lease capacity from another entity that is licensed to operate the satellite used to provide service to subscribers. These entities package their own programming and may or may not be Commission licensees themselves. In addition, a third situation may include an entity using a non-U.S. licensed satellite to provide programming to subscribers in the United States pursuant to a blanket

[83] STELA sec. 203(b).

[84] 47 U.S.C. 340.

[85] *Id.* at 340(d).

[86] 47 U.S.C. 340(b)(2)(B) (2004).

[87] 47 U.S.C. 340(b)(2) (2010), as amended by the STELA sec. 203(a).

[88] *Id.* at 340(b)(1) (2010), as amended by the STELA sec. 203(a). In the NPRM, the Commission explains that "a satellite carrier provides 'local-into-local' service when it retransmits a local television signal back into the local market of that television station for reception by subscribers."

[89] 47 U.S.C. 340(a). Accordingly, the NPRM does not propose any changes to such station eligibility requirements; *see* 47 CFR 76.54(a) through (f), (j) and (k).

[90] 5 U.S.C. 603(b)(3).

[91] 5 U.S.C. 601(6).

[92] 5 U.S.C. 601(3) (incorporating by reference the definition of "small business concern" in 15 U.S.C. 632). Pursuant to 5 U.S.C. 601(3), the statutory definition of a small business applies "unless an agency, after consultation with the Office of Advocacy of the Small Business Administration and after opportunity for public comment, establishes one or more definitions of such term which are appropriate to the activities of the agency and publishes such definition(s) in the **Federal Register**." 5 U.S.C. 601(3).

[93] 15 U.S.C. 632. Application of the statutory criteria of dominance in its field of operation and independence are sometimes difficult to apply in the context of broadcast television. Accordingly, the Commission's statistical account of television stations may be over-inclusive.

[94] The Communications Act defines the term "satellite carrier" by reference to the definition in the copyright laws in title 17. *See* 47 U.S.C. 340(i)(1) and 338(k)(3); 17 U.S.C. 119(d)(6). Part 100 of the Commission's rules was eliminated in 2002 and now both FSS and DBS satellite facilities are licensed under Part 25 of the rules. *Policies and Rules for the Direct Broadcast Satellite Service,* 67 FR 51110, August 7, 2002; 47 CFR 25.148.

earth station license.[95] In the *SHVERA Significantly Viewed Report and Order,* the Commission concluded that the definition of "satellite carrier" includes all three of these types of entities.[96]

32. *Direct Broadcast Satellite ("DBS") Service.* DBS service is a nationally distributed subscription service that delivers video and audio programming via satellite to a small parabolic "dish" antenna at the subscriber's location. DBS, by exception, is now included in the SBA's broad economic census category, "Wired Telecommunications Carriers,"[97] which was developed for small wireline firms. Under this category, the SBA deems a wireline business to be small if it has 1,500 or fewer employees.[98] However, the data we have available as a basis for estimating the number of such small entities were gathered under a superseded SBA small business size standard formerly titled "Cable and Other Program Distribution." The definition of Cable and Other Program Distribution provided that a small entity is one with $12.5 million or less in annual receipts.[99] Currently, only two entities provide DBS service, which requires a great investment of capital for operation: DIRECTV and EchoStar Communications Corporation ("EchoStar") (marketed as the DISH Network).[100] Each currently offer subscription services. DIRECTV[101] and EchoStar[102] each report annual revenues that are in excess of the threshold for a small business. Because DBS service requires significant capital, we believe it is unlikely that a small entity as defined by the SBA would have the financial wherewithal to become a DBS service provider. We seek comments that have data on the annual revenues and number of employees of DBS service providers.

33. *Fixed-Satellite Service ("FSS").* The FSS is a radiocommunication service between earth stations at a specified fixed point or between any fixed point within specified areas and one or more satellites.[103] The FSS, which utilizes many earth stations that communicate with one or more space stations, may be used to provide subscription video service. FSS, by exception, is now included in the SBA's broad economic census category, "Wired Telecommunications Carriers,"[104] which was developed for small wireline firms. Under this category, the SBA deems a wireline business to be small if it has 1,500 or fewer employees.[105] However, the data we have available as a basis for estimating the number of such small entities were gathered under a superseded SBA small business size standard formerly titled "Cable and Other Program Distribution." The definition of Cable and Other Program Distribution provided that a small entity is one with $12.5 million or less in annual receipts.[106] Although a number of entities are licensed in the FSS, not all such licensees use FSS frequencies to provide subscription services. The two DBS licensees (EchoStar and DirecTV) have indicated interest in using FSS frequencies to broadcast signals to subscribers. It is possible that other entities could similarly use FSS frequencies, although we are not aware of any entities that might do so.

34. *Television Broadcasting.* The SBA defines a television broadcasting station as a small business if such station has no more than $14.0 million in annual receipts.[107] Business concerns included in this industry are those "primarily engaged in broadcasting images together with sound."[108] The Commission has estimated the number of licensed commercial television stations to be 1,392.[109] According to Commission staff review of the BIA/Kelsey, MAPro Television Database ("BIA") as of April 7, 2010, about 1,015 of an estimated 1,380 commercial television stations[110] (or about 74 percent) have revenues of $14 million or less and, thus, qualify as small entities under the SBA definition. The Commission has estimated the number of licensed noncommercial educational (NCE) television stations to be 390.[111] We note, however, that, in assessing whether a business concern qualifies as small under the above definition, business (control) affiliations[112] must be included. Our estimate, therefore, likely overstates the number of small entities that might be affected by our action, because the revenue figure on which it is based does not include or aggregate revenues from affiliated companies. The Commission does not compile and otherwise does not have access to information on the revenue of NCE stations that would permit it to determine how many such stations would qualify as small entities.

35. In addition, an element of the definition of "small business" is that the entity not be dominant in its field of operation. We are unable at this time to define or quantify the criteria that would establish whether a specific

[95] *See, e.g., DIRECTV 5 Blanket Earth Station License,* DA 04–2526, August 12, 2004.

[96] *SHVERA Significantly Viewed Report and Order.*

[97] *See* 13 CFR 121.201, NAICS code 517110 (2007). The 2007 North American Industry Classification System ("NAICS") defines the category of "Wired Telecommunications Carriers" as follows: "This industry comprises establishments primarily engaged in operating and/or providing access to transmission facilities and infrastructure that they own and/or lease for the transmission of voice, data, text, sound, and video using wired telecommunications networks. Transmission facilities may be based on a single technology or a combination of technologies. Establishments in this industry use the wired telecommunications network facilities that they operate to provide a variety of services, such as wired telephony services, including VoIP services; wired (cable) audio and video programming distribution; and wired broadband Internet services. *By exception, establishments providing satellite television distribution services using facilities and infrastructure that they operate are included in this industry.*" (*Emphasis* added to text relevant to satellite services.) U.S. Census Bureau, 2007 NAICS Definitions, "517110 Wired Telecommunications Carriers"; *http://www.census.gov/naics/2007/def/ND517110.HTM.*

[98] 13 CFR 121.201, NAICS code 517110 (2007).

[99] 13 CFR 121.201, NAICS code 517510 (2002).

[100] *See Thirteenth Annual Cable/MVPD Competition Report,* 74 FR 11102, March 16, 2009. We note that, in 2007, EchoStar purchased the licenses of Dominion Video Satellite, Inc. ("Dominion") (marketed as Sky Angel). *See* Public Notice, "Policy Branch Information; Actions Taken," Report No. SAT–00474, DA 07–4164 (IB rel. Oct. 5, 2007).

[101] As of June 2006, DIRECTV is the largest DBS operator and the second largest MVPD, serving an estimated 16.20% of MVPD subscribers nationwide. *See Thirteenth Annual Cable/MVPD Competition Report.*

[102] As of June 2006, DISH Network is the second largest DBS operator and the third largest MVPD, serving an estimated 13.01% of MVPD subscribers nationwide. *Id.* As of June 2006, Dominion served fewer than 500,000 subscribers, which may now be receiving "Sky Angel" service from DISH Network. *See id.*

[103] *See* 47 CFR 2.1(c).

[104] *See* 13 CFR 121.201, NAICS code 517110 (2007).

[105] *Id.*

[106] 13 CFR 121.201, NAICS code 517510 (2002).

[107] *See* 13 CFR 121.201, NAICS Code 515120 (2007).

[108] *Id.* This category description continues, "These establishments operate television broadcasting studios and facilities for the programming and transmission of programs to the public. These establishments also produce or transmit visual programming to affiliated broadcast television stations, which in turn broadcast the programs to the public on a predetermined schedule. Programming may originate in their own studios, from an affiliated network, or from external sources." Separate census categories pertain to businesses primarily engaged in producing programming. *See* Motion Picture and Video Production, NAICS code 512110; Motion Picture and Video Distribution, NAICS Code 512120; Teleproduction and Other Post-Production Services, NAICS Code 512191; and Other Motion Picture and Video Industries, NAICS Code 512199.

[109] *See* News Release, "Broadcast Station Totals as of December 31, 2009," 2010 WL 676084 (F.C.C.) (dated Feb. 26, 2010) ("*Broadcast Station Totals*"); also available at *http://hraunfoss.fcc.gov/edocs_public/attachmatch/DOC-296538A1.pdf.*

[110] We recognize that this total differs slightly from that contained in *Broadcast Station Totals;* however, we are using BIA's estimate for purposes of this revenue comparison.

[111] *See Broadcast Station Totals.*

[112] "[Business concerns] are affiliates of each other when one concern controls or has the power to control the other or a third party or parties controls or has to power to control both." 13 CFR 121.103(a)(1).

television station is dominant in its field of operation. Accordingly, the estimate of small businesses to which rules may apply do not exclude any television station from the definition of a small business on this basis and are therefore over-inclusive to that extent. Also, as noted, an additional element of the definition of "small business" is that the entity must be independently owned and operated. We note that it is difficult at times to assess these criteria in the context of media entities and our estimates of small businesses to which they apply may be over-inclusive to this extent.

36. *Satellite Master Antenna Television (SMATV) Systems, also known as Private Cable Operators (PCOs).* SMATV systems or PCOs are video distribution facilities that use closed transmission paths without using any public right-of-way. They acquire video programming and distribute it via terrestrial wiring in urban and suburban multiple dwelling units such as apartments and condominiums, and commercial multiple tenant units such as hotels and office buildings. SMATV systems or PCOs are now included in the SBA's broad economic census category, "Wired Telecommunications Carriers," [113] which was developed for small wireline firms.[114] Under this category, the SBA deems a wireline business to be small if it has 1,500 or fewer employees.[115] However, the data we have available as a basis for estimating the number of such small entities were gathered under a superseded SBA small business size standard formerly titled "Cable and Other Program Distribution." The definition of Cable and Other Program Distribution provided that a small entity is one with $12.5 million or less in annual receipts.[116] As of June 2004, there were approximately 135 members in the Independent Multi-Family Communications Council (IMCC), the trade association that represents PCOs.[117] The IMCC indicates that, as of June 2006, PCOs serve about 1 to 2 percent of the multichannel video programming distributors (MVPD) marketplace.[118] Individual PCOs often serve approximately 3,000–4,000 subscribers, but the larger operations serve as many as 15,000–55,000 subscribers. In total, as of June 2006, PCOs serve approximately 900,000 subscribers.[119] Because these operators are not rate regulated, they are not required to file financial data with the Commission. Furthermore, we are not aware of any privately published financial information regarding these operators. Based on the estimated number of operators and the estimated number of units served by the largest 10 PCOs, we believe that a substantial number of PCOs may have been categorized as small entities under the now superseded SBA small business size standard for Cable and Other Program Distribution.[120]

4. Description of Projected Reporting, Recordkeeping, and Other Compliance Requirements

37. The NPRM's proposed rules do not impose any new reporting, recordkeeping or other compliance requirements.

5. Steps Taken to Minimize Significant Economic Impact on Small Entities, and Significant Alternatives Considered

38. The RFA requires an agency to describe any significant alternatives that it has considered in reaching its proposed approach, which may include the following four alternatives (among others): (1) The establishment of differing compliance or reporting requirements or timetables that take into account the resources available to small entities; (2) the clarification, consolidation, or simplification of compliance or reporting requirements under the rule for small entities; (3) the use of performance, rather than design, standards; and (4) an exemption from coverage of the rule, or any part thereof, for small entities.[121]

39. We invite comment on whether there are any alternatives we should consider to our proposed implementation of the statutory amendments to Section 340(b) that would minimize any adverse impact on small businesses, but which are consistent with the statute and its goals and also maintain the benefits of our proposals. As discussed in the NPRM, STELA's amendments to Section 340(b) intend to facilitate satellite carriage of SV stations, with the expectation that this will increase satellite TV service to consumers and promote regulatory parity between cable and satellite service.[122] We believe our proposed rule changes implement the statute in the way that is most consistent with the plain language of the statute.[123] We also note that the plain language of the statute does not appear to give us discretion to treat small entities differently from larger ones, but seek comment on this question.

40. As was the intent of Congress, we believe our proposed rules will benefit satellite carriers and the SV stations which they would carry,[124] as well as consumers of satellite TV service.[125] We believe that adverse impact to these entities is unlikely because SV carriage under Section 340 is permissive (and not mandatory); that is, the satellite carrier chooses to carry an SV station and the SV station must grant its consent to be carried.[126] We do not have data to measure whether small TV stations on the whole, including in-market network affiliates, are more or less likely to benefit from satellite carriage of SV stations, so we invite small stations to comment on this issue.

6. Federal Rules That May Duplicate, Overlap, or Conflict With the Proposed Rule

41. None.

B. Initial Paperwork Reduction Act of 1995 Analysis

42. This NPRM has been analyzed with respect to the Paperwork Reduction Act of 1995 ("PRA"),[127] and does not propose any new or modified information collection requirements.[128] In addition, therefore, it does not contain any new or modified "information collection burden for small business concerns with fewer than 25 employees," pursuant to the Small

[113] *See* 13 CFR 121.201, NAICS code 517110 (2007).

[114] Although SMATV systems often use DBS video programming as part of their service package to subscribers, they are not included in Section 340's definition of "satellite carrier." *See* 47 U.S.C. 340(i)(1) and 338(k)(3); 17 U.S.C.119(d)(6).

[115] 13 CFR 121.201, NAICS code 517110 (2007).

[116] 13 CFR 121.201, NAICS code 517510 (2002).

[117] *See Eleventh Annual Cable/MVPD Competition Report,* FCC 05–13 (rel. Feb. 4, 2005).

[118] *See Thirteenth Annual Cable/MVPD Competition Report.*

[119] *Id.*

[120] 13 CFR 121.201, NAICS code 517510 (2002).

[121] 5 U.S.C. 603(c)(1) through (4).

[122] *See H.R. 3570 Report* at 4–5; *H.R. 2994 Report* at 16. In the NPRM, we stated that, in revising the law, Congress intended for the Commission to create a framework that would generally provide for the satellite carriage of SV stations.

[123] Our proposed rules are based on, and largely track, the amended language of the statute.

[124] For example, small broadcast stations will benefit from the opportunity to be delivered as an SV station to more viewers.

[125] *See H.R. 3570 Report* at 4–5.

[126] *See* 47 U.S.C. 340(d).

[127] The Paperwork Reduction Act of 1995 ("PRA"), Pub. L. 104–13, 109 Stat 163 (1995) (codified in Chapter 35 of title 44 U.S.C.).

[128] The Commission does not propose to modify the existing information collections that relate to the Commission's significantly viewed rules and procedures: OMB Control Nos. 3060–0311 (47 CFR 76.54), 3060–0960 (47 CFR 76.122, 76.123, 76.124, 76.127), and 3060–0888 (47 CFR 76.7). The Commission will continue to maintain these collections and seek extensions at the appropriate time.

Business Paperwork Relief Act of 2002.[129]

C. Ex Parte Rules

43. *Permit-But-Disclose.* This proceeding will be treated as a "permit-but-disclose" proceeding subject to the "permit-but-disclose" requirements under section 1.1206(b) of the Commission's rules.[130] *Ex parte* presentations are permissible if disclosed in accordance with Commission rules, except during the Sunshine Agenda period when presentations, *ex parte* or otherwise, are generally prohibited. Persons making oral *ex parte* presentations are reminded that a memorandum summarizing a presentation must contain a summary of the substance of the presentation and not merely a listing of the subjects discussed. More than a one- or two-sentence description of the views and arguments presented is generally required.[131] Additional rules pertaining to oral and written presentations are set forth in section 1.1206(b).

D. Filing Requirements

44. *Comments and Replies.* Pursuant to Sections 1.415 and 1.419 of the Commission's rules,[132] interested parties may file comments and reply comments on or before the dates indicated on the first page of this document. Comments may be filed using: (1) The Commission's Electronic Comment Filing System ("ECFS"), (2) the Federal Government's eRulemaking Portal, or (3) by filing paper copies.[133]

- *Electronic Filers:* Comments may be filed electronically using the Internet by accessing the ECFS: *http://www.fcc.gov/cgb/ecfs/* or the Federal eRulemaking Portal: *http://www.regulations.gov.*
- *Paper Filers:* Parties who choose to file by paper must file an original and four copies of each filing. If more than one docket or rulemaking number appears in the caption of this proceeding, filers must submit two additional copies for each additional docket or rulemaking number.

Filings can be sent by hand or messenger delivery, by commercial overnight courier, or by first-class or overnight U.S. Postal Service mail. All filings must be addressed to the Commission's Secretary, Office of the Secretary, Federal Communications Commission.

○ All hand-delivered or messenger-delivered paper filings for the Commission's Secretary must be delivered to FCC Headquarters at 445 12th St., SW., Room TW–A325, Washington, DC 20554. All hand deliveries must be held together with rubber bands or fasteners. Any envelopes must be disposed of *before* entering the building. The filing hours are 8 a.m. to 7 p.m.

○ Commercial overnight mail (other than U.S. Postal Service Express Mail and Priority Mail) must be sent to 9300 East Hampton Drive, Capitol Heights, MD 20743.

○ U.S. Postal Service first-class, Express, and Priority mail must be addressed to 445 12th Street, SW., Washington DC 20554.

45. *Availability of Documents.* Comments, reply comments, and *ex parte* submissions will be available for public inspection during regular business hours in the FCC Reference Center, Federal Communications Commission, 445 12th Street, SW., CY–A257, Washington, DC, 20554. These documents will also be available via ECFS. Documents will be available electronically in ASCII, Microsoft Word, and/or Adobe Acrobat.

46. *Accessibility Information.* To request information in accessible formats (computer diskettes, large print, audio recording, and Braille), send an e-mail to *fcc504@fcc.gov* or call the FCC's Consumer and Governmental Affairs Bureau at (202) 418–0530 (voice), (202) 418–0432 (TTY). This document can also be downloaded in Word and Portable Document Format (PDF) at: *http://www.fcc.gov.*

47. *Additional Information.* For additional information on this proceeding, contact Evan Baranoff, *Evan.Baranoff@fcc.gov*, of the Media Bureau, Policy Division, (202) 418–2120.

VI. Ordering Clauses

48. Accordingly, *it is ordered* that pursuant to Section 203 of the Satellite Television Extension and Localism Act of 2010, and Sections 1, 4(i) and (j), and 340 of the Communications Act of 1934, as amended, 47 U.S.C. 151, 154(i) and (j), and 340, *notice is hereby given* of the proposals and tentative conclusions described in this Notice of Proposed Rulemaking.

49. *It is further ordered* that the Reference Information Center, Consumer Information Bureau, shall send a copy of this Notice of Proposed Rulemaking, including the Initial Regulatory Flexibility Analysis, to the Chief Counsel for Advocacy of the Small Business Administration.

List of Subjects in 47 CFR Part 76

Satellite television.

Federal Communications Commission.

Marlene H. Dortch,

Secretary.

Proposed Rule Changes

For the reasons discussed in the preamble, the FCC proposes to amend 47 CFR part 76 as follows:

PART 76—MULTICHANNEL VIDEO AND CABLE TELEVISION SERVICE.

1. The authority citation for part 76 continues to read as follows:

Authority: 47 U.S.C. 151, 152, 153, 154, 301, 302, 302a, 303, 303a, 307, 308, 309, 312, 315, 317, 325, 339, 340, 341, 503, 521, 522, 531, 532, 534, 535, 536, 537, 543, 544, 544a, 545, 548, 549, 552, 554, 556, 558, 560, 561, 571, 572, 573.

2. Amend § 76.5(i) by removing the words "other than cable television" and adding in their place the words "over-the-air" and in the Note following paragraph (i) remove the word "noncable" each place it appears and add in its place the words "over-the-air".

3. Amend § 76.54 by revising the first sentence in paragraph (c), revising paragraph (g) and by removing and reserving paragraph (h) to read as follows:

§ 76.54 Significantly viewed signals; method to be followed for special showings.

* * * * *

(c) Notice of a survey to be made pursuant to paragraph (b) of this section shall be served on all licensees or permittees of television broadcast stations within whose predicted noise limited service contour, as defined in § 73.622(e) of this chapter, the cable or satellite community or communities are located, in whole or in part, and on all other system community units, franchisees, and franchise applicants in the cable community or communities at least (30) days prior to the initial survey period. * * *

* * * * *

(g) *Limitations on satellite subscriber eligibility.* A satellite carrier may retransmit a significantly viewed network station to a subscriber, provided the subscriber satisfies the conditions in paragraphs (g)(1) and (g)(2) of this section or qualifies for one of the two exceptions to these conditions provided in paragraphs (g)(3) and (g)(4) of this section.

(1) *Receipt of local-into-local service.* A satellite carrier may retransmit to a

[129] The Small Business Paperwork Relief Act of 2002 ("SBPRA"), Pub. L. 107–198, 116 Stat 729 (2002) (codified in Chapter 35 of title 44 U.S.C.); *see* 44 U.S.C. 3506(c)(4).

[130] *See* 47 CFR 1.1206(b); *see also id.* 1.1202, 1.1203.

[131] *See id.* 1.1206(b)(2).

[132] *See id.* 1.415, 1419.

[133] *See Electronic Filing of Documents in Rulemaking Proceedings,* Report and Order, 63 FR 24121, May 1, 1998.

subscriber the signal of a significantly viewed station only if that subscriber receives local-into-local service, pursuant to § 76.66.

(2) *Receipt in HD format.* A satellite carrier may retransmit to a subscriber in high definition (HD) format the signal of a significantly viewed station only if such carrier also retransmits in HD format the signal of a station located in the local market of such subscriber and affiliated with the same network whenever such format is available from such station. This condition does not apply to, nor prohibit, the retransmission to a subscriber of a significantly viewed station in standard definition (SD) format.

(3) *Exception if no network affiliate in local market.* The limitations in paragraphs (g)(1) and (g)(2) of this section will not prohibit a satellite carrier from retransmitting a significantly viewed network station to a subscriber located in a local market in which there are no network stations affiliated with the same television network as the significantly viewed station.

(4) *Exception if waiver granted by local station.* The limitations in paragraphs (g)(1) and (g)(2) of this section will not apply if, and to the extent that, the local network station affiliated with the same television network as the significantly viewed station has granted a waiver in accordance with 47 U.S.C. 340(b)(4).

* * * * *

[FR Doc. 2010–18538 Filed 7–27–10; 8:45 am]

BILLING CODE 6712–01–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

50 CFR Parts 600 and 622

[Docket No. 0907201152–91188–01]

RIN 0648–AY05

Fisheries of the Caribbean, Gulf of Mexico, and South Atlantic; Regulatory Amendment to the Fishery Management Plan for the Reef Fish Fishery of Puerto Rico and the U.S. Virgin Islands

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

ACTION: Proposed rule; request for comments.

SUMMARY: NMFS issues this proposed rule that would implement a regulatory amendment to the Fishery Management Plan for the Reef Fish Fishery of Puerto Rico and the U.S. Virgin Islands (FMP) prepared by the Caribbean Fishery Management Council (Council). This proposed rule would modify the Bajo de Sico seasonal closure from a 3-month closure to a 6-month closure, and prohibit fishing for and possession of Caribbean reef fish in or from the exclusive economic zone (EEZ) portion of Bajo de Sico during the closure. The proposed rule would also prohibit anchoring in the EEZ portion of Bajo de Sico year-round. In addition to the measures contained in the regulatory amendment, this proposed rule would also add spear to the list of allowable gears in the commercial sector of the Caribbean reef fish fishery. The intended effect of this proposed rule is to provide further protection for red hind spawning aggregations and large snappers and groupers, and better protect the essential fish habitat (EFH) where these species reside.

DATES: Written comments must be received on or before August 27, 2010.

ADDRESSES: You may submit comments on the proposed rule identified by 0648–AY05, by any of the following methods:

- Electronic Submissions: Submit all electronic public comments via the Federal e-Rulemaking Portal: *http://www.regulations.gov*. Follow the instructions for submitting comments.
- Mail: Britni Tokotch, Southeast Regional Office, NMFS, 263 13th Avenue South, St. Petersburg, FL 33701.
- Fax: 727–824–5308; Attention: Britni Tokotch.

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 wish to remain anonymous). You may submit attachments to electronic comments in Microsoft Word, Excel, WordPerfect, or Adobe PDF file formats only.

Copies of the regulatory amendment--which includes an Environmental Assessment (EA), an initial regulatory flexibility analysis (IRFA), and a regulatory impact review (RIR)--may be obtained from Britni Tokotch, Southeast Regional Office, NMFS, 263 13th Avenue South, St. Petersburg, FL 33701 or may be downloaded from the Southeast Regional Office website at *http://sero.nmfs.noaa.gov*.

FOR FURTHER INFORMATION CONTACT: Britni Tokotch, 727–824–5305.

SUPPLEMENTARY INFORMATION: The Caribbean reef fish fishery is managed under the FMP. The FMP was prepared by the Council and is implemented through regulations at 50 CFR part 622 under the authority of the Magnuson-Stevens Fishery Conservation and Management Act (Magnuson-Stevens Act).

Background

The Bajo de Sico area closure was first implemented in 1996 to protect spawning aggregations of red hind. Currently, the EEZ portion of Bajo de Sico is closed to all fishing activities from December 1 through the end of February, each year. Within the EEZ portion of the Bajo de Sico closed area, the use of bottom-tending gear, including traps, pots, gillnets, trammel nets, and bottom longlines, is prohibited year-round.

Recently, Bajo de Sico has been identified as an important spawning site, especially for red hind, and possibly for other resident groupers, including Nassau and yellowfin groupers. Bajo de Sico is also an important foraging site for these and other Caribbean reef fish. The Bajo de Sico closed area has been described as a well developed and diverse coral and sponge habitat, which provides EFH for Caribbean reef fish within Bajo de Sico. The purpose of this proposed rule is to protect red hind spawning aggregations and large snappers and groupers from directed fishing mortality to achieve a more natural sex ratio, age, and size structure, and to protect associated EFH, while minimizing adverse social and economic effects.

Management Measures Contained in this Proposed Rule

Within the EEZ portion of Bajo de Sico, this proposed rule would establish a seasonal closure from October 1 through March 31, each year, during which fishing for and possession of Caribbean reef fish in or from the area would be prohibited. The proposed revision of the Bajo de Sico closure would provide additional protection for Caribbean reef fish inhabiting Bajo de Sico.

This proposed rule would also prohibit anchoring by fishing vessels year-round while in the EEZ portion of the Bajo de Sico closed area. Prohibiting

anchoring will provide added protection to the EFH utilized by Caribbean reef fish. This measure will minimize potential damage to coral reef populations and will protect reef fish and habitat important to the overall health of Bajo de Sico.

Additional Measures Contained in this Proposed Rule

This rule proposes to add spear to the list of allowable gears in § 600.725 for the commercial sector of the Caribbean reef fish fishery. At its March 2009 Caribbean Council meeting, the Council voted to add spear to the list of allowable gears for this fishery, and in a letter dated May 27, 2009, the Council requested that NMFS implement this measure. Spear is currently on the list of allowable gears for the recreational sector, and this rule would implement the same measure for the commercial sector.

NMFS proposes to revise the title for the FMP in the list of authorized fisheries and gears. In § 600.725, the FMP is incorrectly named the "Shallow Water Reef Fish Fishery FMP." Amendment 2 to the FMP renamed the FMP, from the "Shallow Water Reef Fish Fishery FMP" to the "Reef Fish Fishery FMP," however, this title was not revised in the part 600 regulations. This rule corrects the FMP title. These minor revisions are unrelated to the actions contained in the Bajo de Sico regulatory amendment.

Classification

Pursuant to section 304(b)(1)(A) of the Magnuson-Stevens Act, the Assistant Administrator has determined that this proposed rule is consistent with the regulatory amendment, other provisions of the Magnuson-Stevens Act, and other applicable law, subject to further consideration after public comment.

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

NMFS prepared an IRFA, as required by section 603 of the Regulatory Flexibility Act, for this proposed rule. The IRFA describes the economic impact this proposed rule, if adopted, would have on small entities. A description of the action, why it is being considered, and the objectives of, and legal basis for this action are contained at the beginning of this section in the preamble and in the **SUMMARY** section of the preamble. A copy of the full analysis is available from the NMFS (see **ADDRESSES**). A summary of the IRFA follows.

The Magnuson-Stevens Act provides the statutory basis for the proposed rule. The proposed rule would modify the Bajo de Sico seasonal closure by extending it from a 3-month closure to a 6-month closure, and prohibit fishing for and possession of Caribbean reef fish in or from the EEZ portion of Bajo de Sico during the closure. The proposed rule would also prohibit anchoring by fishing vessels in the EEZ portion of Bajo de Sico year-round. This rule also proposes minor revisions to the codified text, including adding spear to the list of allowable gears in the commercial sector of the reef fish fishery, and revising the title of the FMP in the list of authorized fisheries and gears in § 600.725. The purposes of this proposed rule are to provide further protection for red hind spawning aggregations and large snappers and groupers from directed fishing mortality to achieve a more natural sex ratio, age, and size structure, and to better protect the EFH where these species reside.

No duplicative, overlapping or conflicting Federal rules have been identified.

At present, Federal permits are not required to participate in Council-managed fisheries on Puerto Rico's west coast, and, therefore, it is unknown how many fishermen or vessels participate in the Federal component of these fisheries. However, landings data from Puerto Rico's trip ticket program indicate that 294 fishermen had commercial landings on Puerto Rico's west coast in 2007. Some of these fishermen do not possess commercial fishing licenses, and the vessels used by these fishermen are not identified in the landings data. Preliminary fisherman Census data for 2008 indicates that 95 percent of commercial fishermen own one vessel, and thus it is assumed for current purposes that each commercial fisherman represents a single commercial fishing vessel. Further, all charter and headboat vessels used to fish for, take, retain, or possess Atlantic billfish, tunas, swordfish, or sharks must possess an Atlantic Highly Migratory Species (HMS) charter/headboat permit. In 2008, eight charter vessels on Puerto Rico's west coast held HMS charter/headboat permits.

In Puerto Rico's west coast fisheries, commercial fishing vessels average 20 ft (6.3 m) in length, but range between 12 to 51 ft (3.8–15.9 m), with the vast majority being between 15 and 25 ft (4.7–7.8 m). These vessels have an average horsepower (HP) of approximately 77, though considerable variability exists within the fleet, even among vessels of comparable length. The age of these vessels is approximately 19 years on average. The majority of vessels are made of fiberglass (63 percent), though wood hulls and wood and fiberglass composite hulls are relatively common, accounting for 19 percent and 18 percent of the fleet, respectively. On average, each vessel carries two individuals, the captain and one crewman.

According to the 2008 fisherman Census, 72 percent of Puerto Rico's west coast commercial fishermen possess some type of commercial fishing license while 28 percent do not. Of those fishermen who hold a commercial fishing license, the vast majority (78 percent) possess a full-time license, while the others possess either a beginner's license (18 percent) or a part-time license (4 percent). These fishermen are approximately 47 years old on average and have nearly 27 years of commercial fishing experience. Each fisherman supports approximately three dependents on average, which translates to an average household family size of four persons. Each fisherman spends an average of approximately 51 hours per week on commercial fishing related activities. These individuals are highly dependent on income from commercial fishing, which represents more than 85 percent of their household income on average. More than half of these fishermen (54 percent) have less than a high school level of education, 35 percent have a high school level of education, and 11 percent have some additional education beyond high school.

As a result of non-reporting, reported landings and, thus, revenue for Puerto Rico's commercial fisheries underestimate actual landings and revenue. Therefore, landings and revenue must be adjusted in order to generate more accurate estimates. Based on corrected landings estimates, average gross revenue per commercial fisherman was $5,431 and $9,168 in 2006 and 2007 respectively, or $7,076 across both years. The maximum gross revenue for a single commercial fisherman in either year was approximately $138,000. Commercial fishermen are mainly dependent on revenue from spiny lobster, queen conch, and reef fish, particularly queen snapper and silk snapper. However, harvest of queen conch is prohibited in the EEZ around Puerto Rico and bottom-tending gear (e.g, fish traps, lobster traps, and bottom longline) is prohibited in Bajo de Sico. Scuba diving and bottom line are the predominant gears used by commercial fishermen. The bottom line fishery for reef fish is most relevant for the actions in this proposed rule.

In 2008, eight vessels on Puerto Rico's west coast possessed HMS charter/headboat permits. All eight charter

vessels are made of fiberglass. The majority of the HMS charter vessels (seven) use rod and reel gear, while one vessel uses handline gear. Furthermore, these vessels are 27 ft (8.4 m) in length and have 358 HP on average and thus are slightly longer and considerably more powerful on average than commercial fishing vessels. These vessels are approximately 8 years old on average and are thus also much newer on average than commercial fishing vessels. Charter vessels also typically carry more individuals in terms of crew and passengers (approximately seven on average) than commercial vessels. Charter vessels most frequently target dolphin, blue marlin, wahoo, and yellowfin tuna. Charter fishermen have approximately 25 years of fishing experience on average. Charter vessels in Puerto Rico take approximately 190 trips per year, though recent survey data suggest that charter vessels on the west coast may average only 150–160 trips per year. These data also suggest that west coast charter vessels specialize in half-day trips rather than full-day trips, the latter of which was reported to cost $526 on average in 2005. Annual landings and revenue data for west coast charter vessels are not presently available. However, the available information regarding number of trips per year and cost per trip indicates that these charter operations are similar to those in the Gulf of Mexico and South Atlantic regions. Therefore, it is assumed that these vessels' maximum and average annual revenues are also similar to those operating in the Gulf of Mexico and South Atlantic regions.

The Small Business Administration defines a small business in the commercial fishing industry as an entity that is independently owned and operated, is not dominant in its field of operation (including its affiliates), and has combined annual receipts not in excess of $4.0 million annually (NAICS codes 114111 and 114112, finfish and shellfish fishing). For charter vessels, the other qualifiers apply and the annual receipts threshold is $6.5 million (NAICS code 713990, recreational industries). Based on the annual revenue and related information for the fisheries provided above, all vessels expected to be directly impacted by this proposed rule are determined, for the purpose of this analysis, to be small entities.

The action to modify the Bajo de Sico closure is expected to directly benefit all eight charter vessels on Puerto Rico's west coast by giving them access to Bajo de Sico's HMS and pelagic resources during the 3 months (December, January, and February) the area is currently closed to all fishing. The magnitude of these economic benefits depends on the extent to which these vessels take additional trips to Bajo de Sico as opposed to reallocating current trips from other areas. An estimate of how many additional trips these charter vessels might take is not currently available. However, additional trips would be expected to result in higher revenue and thus higher profit.

Conversely, 64 of the 294 (22 percent) commercial fishing vessels actively participating in Puerto Rico's west coast fisheries in 2007 are expected to experience direct, adverse economic effects as a result of the action to modify the Bajo de Sico closure. Specifically, since these vessels will experience additional loss of access to Bajo de Sico's fisheries resources, particularly reef fish, during the months of October, November, and March under this action, their landings, revenue, and, therefore, profit are expected to decrease. Based on an extrapolation of landings data from Puerto Rico's trip ticket data, the 64 directly affected vessels averaged approximately 6,400 lb (2,303 kg) in landings and $17,300 in gross revenue in 2007. Detailed cost data and, therefore, profit estimates are not currently available for these commercial vessels. Therefore, the reduction in profit arising from this action cannot be directly estimated for the directly affected vessels.

However, surveys of the directly affected commercial fishermen indicate that these vessels are expected to experience a 48–percent reduction in landings and a 47–percent reduction in gross revenue, or approximately $8,130 per vessel. Most of these losses are due to reductions in the harvest of reef fish, particularly deepwater snappers. However, the harvest of other species (e.g. baitfish) caught on trips that target reef fish are also expected to be foregone. Since these relatively small vessels will not be able to transit through Bajo de Sico with reef fish on board and may have to travel to more distant fishing grounds in order to harvest deepwater snappers, operating costs are expected to increase by 57 percent. Further, the affected fishermen are expected to experience a 55–percent reduction in household income. Since the fisherman's household income is generally indicative of net revenue or profit to the vessel, this figure represents the best available estimate of the expected percentage reduction in profit for these entities.

On the other hand, since October and November are off-season for many commercial vessels due to poor weather and sea conditions, and given that the harvest of their primary target species, silk snapper, is already prohibited during these months, the reductions in landings, revenue, household income and, therefore, profit are likely overestimated. Furthermore, vessels with the appropriate gear, the number of which cannot be determined with available data, may be able to partially mitigate these losses by reallocating some of their fishing effort out of the bottom line fishery for reef fish into the troll line fishery for HMS and pelagic species during the months that Bajo de Sico will be closed to fishing for Caribbean reef fish.

The action to prohibit anchoring by fishing vessels in Bajo de Sico year-round is not expected to generate adverse economic impacts on the eight charter vessels because they use troll or handline gear and do not drop anchor when fishing. It is possible, though not likely, that a few of the commercial vessels expected to be affected by the proposed action to modify the Bajo de Sico closure may experience additional minimal adverse economic effects as a result of the proposed anchoring prohibition. Though it is not necessary for vessels using bottom line gear to drop anchor when fishing, such behavior may occur on occasion. Since dropping anchor in Bajo de Sico would no longer be permissible under the proposed action, vessels would be required to move out of the area, and thereby expend additional fuel, if they want to drop anchor. The effects resulting from the occasional need for a few vessels to expend additional fuel would likely be imperceptible and, therefore, probably have no impact on these vessels' profitability.

The action to add spear to the list of allowable gears in the commercial sector of the reef fish fishery is not expected to generate any adverse economic effects on commercial reef fish vessels. This action is administrative in nature, the purpose of which is to correct an oversight with respect to the current list of allowable gears for the commercial reef fish fishery. Since spear is and has been an historically used gear in the commercial reef fish fishery, the Council intended for it to be included in the list of allowable gears. This action would formally legalize its use in the fishery but have no effect on its current or expected future use in the fishery and thus, in turn, have no effect on the operations of commercial reef fish vessels.

Four alternatives, including the status quo, were considered for the action to modify the Bajo de Sico seasonal closure. Three of the alternatives include multiple options that determine

which species and specific activities are covered by the closure. The first alternative, the status quo, would not have modified the seasonal closure for Bajo de Sico or prohibited possession of reef fish onboard when transiting through the area during the closure. Further, the seasonal closure would have continued to apply to all fishing, including fishing for non-reef fish species such as HMS and pelagics. The status quo alternative is inconsistent with the Council's objective of providing greater protection for spawning aggregations of reef fish in the area as well as well developed coral that provide critical habitat for these species.

The second alternative, which would extend the seasonal closure by 3 months to the months of October, November, and March, had three options other than the proposed action. The first option would have prohibited fishing for all species, including those not managed by the Council, during the closure. The second option would have prohibited fishing for and possession of all species, including those not managed by the Council, during the closure. The third option would have prohibited fishing for reef fish during the closure. The first two options were not selected because fishing for HMS and pelagic species using troll, rod and reel, and handline gear near the surface is not expected to result in the incidental harvest of reef fish or damage to coral. As such, prohibiting fishing for and possession of these species would generate unnecessary economic and social impacts on charter, private recreational, and commercial vessels. The third option was not selected because it would still effectively allow transit through Bajo de Sico during the closure with reef fish onboard. Allowing possession of reef fish onboard would make it difficult to prove where they were harvested from, which would in turn cause enforcement of the closure to be more difficult and thereby less effective.

The third alternative, which would extend the seasonal closure by 3 months to the months of March, April, and May, had four options. Although this alternative would close Bajo de Sico for 6 months, and thereby generate comparable biological benefits in terms of protecting red hind spawning aggregations and larger individuals of snapper and grouper, as well as protecting well developed coral and sponge habitat (EFH), it would create greater adverse social and economic impacts on commercial vessels and associated onshore businesses since commercial fishing activity is considerably greater in March, April, and May than in October, November, and March. Thus, this alternative would result in lower net benefits to society compared to the proposed action.

The fourth alternative, which would implement a year-round closure of Bajo de Sico, had four options. This alternative would have generated greater biological benefits with respect to protecting coral and reef fish populations. However, the additional benefits of a year-round closure to reef fish spawning aggregations were not believed to be significantly greater compared to a 6-month closure, and additional protections to coral habitat are being accomplished by the proposed anchoring prohibition. Further, by completely prohibiting access to Bajo de Sico's reef fish and, in effect, baitfish resources, this alternative would have generated much greater adverse social and economic impacts on commercial and charter vessels and associated onshore businesses. Given the proposed rule's objectives, the Council concluded these considerably larger social and economic costs outweighed the additional biological benefits and, thus, would have resulted in lower net benefits to society compared to the proposed action.

Three alternatives, including the status quo, were considered for the action to prohibit anchoring in Bajo de Sico. The first alternative, the status quo, would not have implemented any restrictions on anchoring in Bajo de Sico. Anchoring is thought to cause substantial and long lasting damage to coral populations. Anchoring can also indirectly impact the long-term growth of coral populations. Coral populations are an essential part of the ecology of reef environments. If coral populations are decreased, reef fish populations could also be indirectly impacted by lack of essential habitat. Thus, this alternative is contrary to the Council's objective of providing additional protections to important coral habitat.

The second alternative would have prohibited anchoring for 6 months. Anchoring has a high probability of damaging essential coral reef populations. These coral populations are very vulnerable and slow growing, and even slight damage can require years of recovery. Anchoring during the open season could damage coral beyond recovery. Coral populations are an essential part of the ecology of reef environments. If coral populations are decreased, reef fish populations could also be indirectly impacted by lack of essential habitat. Thus, this alternative is contrary to the Council's objective of providing additional protections to important coral habitat.

Copies of the RIR and IRFA are available from NMFS (see **ADDRESSES**).

List of Subjects

50 CFR Part 600

Administrative practice and procedures, Confidential business information, Fisheries, Fishing, Fishing vessels, Foreign relations, Intergovernmental relations, Penalties, Reporting and recordkeeping requirements, Statistics.

50 CFR Part 622

Fisheries, Fishing, Puerto Rico, Reporting and recordkeeping requirements, Virgin Islands.

Dated: July 23, 2010.

Samuel D. Rauch III,

Deputy Assistant Administrator for Regulatory Programs, National Marine Fisheries Service.

For the reasons set out in the preamble, 50 CFR parts 600 and 622 are proposed to be amended as follows:

PART 600—MAGNUSON–STEVENS ACT PROVISIONS

1. The authority citations for part 600 continue to read as follows:

Authority: 5 U.S.C. 561 and 16 U.S.C. 1801 *et seq.*

2. In § 600.725, in paragraph (v), in the table under heading "V. Caribbean Fishery Management Council," the heading for entry 2. is revised, and a new entry 2.D. is added to read as follows:

§ 600.725 General prohibitions.

* * * * *

(v) * * *

Fishery	Authorized gear types
* * * * *	
V. Caribbean Fishery Management Council	
* * * * *	
2. Caribbean Reef Fish Fishery (FMP)	
* * * * *	
D. Other commercial fishery.	D. Spear.
* * * * *	

PART 622—FISHERIES OF THE CARIBBEAN, GULF, AND SOUTH ATLANTIC

3. The authority citation for part 622 continues to read as follows:

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

4. In § 622.33, paragraph (a)(2)(ii)(A) is removed and reserved, introductory

paragraph (a) is revised and paragraph (a)(8) is added to read as follows:

§ 622.33 Caribbean EEZ seasonal and/or area closures.

(a) *Seasonal closures.* In addition to the other restrictions specified in this paragraph (a), fishing with pots, traps, bottom longlines, gillnets or trammel nets is prohibited year-round in the closed areas specified in paragraphs (a)(1), (a)(2), (a)(3), and (a)(8) of this section.

* * * * *

(8) *Bajo de Sico closed area.* The Bajo de Sico closed area is bounded by rhumb lines connecting, in order the following points:

Point A	North lat.	West long.
A	18°15.7′	67°26.4′
B	18°15.7′	67°23.2′
C	18°12.7′	67°23.2′
D	18°12.7′	67°26.4′
A	18°15.7′	67°26.4′

(ii) From October 1 through March 31, each year, no person may fish for or possess any Caribbean reef fish, as listed in Table 2 of Appendix A to part 622, in or from those parts of the Bajo de Sico closed area that are in the EEZ. The prohibition on possession does not apply to such Caribbean reef fish harvested and landed ashore prior to the closure.

(iii) Anchoring, by fishing vessels, is prohibited in those parts of the Bajo de Sico closed area that are in the EEZ year-round.

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[FR Doc. 2010–18537 Filed 7–27–10; 8:45 am]

BILLING CODE 3510–22–S

Notices

Federal Register

Vol. 75, No. 144

Wednesday, July 28, 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

Natural Resources Conservation Service

Notice of Meeting of the Agricultural Air Quality Task Force

AGENCY: Natural Resources Conservation Service, United States Department of Agriculture.

ACTION: Notice of meeting.

SUMMARY: The Agricultural Air Quality Task Force (AAQTF) will meet to continue discussions on air quality issues relating to agriculture. Additionally, the Livestock and Poultry Subcommittee of the AAQTF will conduct a pre-meeting *Livestock and Poultry Air Emissions Standardization (LPAES) Workshop* to discuss livestock and poultry air emissions monitoring data/research obtained from the National Animal Air Emissions Monitoring Study (NAAEMS).

DATES: The LPAES workshop will convene at 2 p.m. on Monday, September 27, 2010, and conclude at 6 p.m., and convene at 8 a.m. on Tuesday, September 28, 2010, and conclude at 5 p.m.

The AAQTF meeting will convene at 8 a.m. on Wednesday, September 29 and Thursday, September 30, and conclude at 5 p.m. each day. A public comment period for the AAQTF meeting will be held on September 30, 2010. Individuals making oral presentations should register in person at the AAQTF meeting site and must bring with them 50 copies of any materials they would like distributed.

ADDRESSES: The LPAES workshop will be held at the Hilton Raleigh-Durham Airport at Research Triangle Park Hotel located at 4810 Page Creek Lane, Durham, North Carolina 27703: (919) 941–6000.

The AAQTF meeting will be held on the campus of the U.S. Environmental Protection Agency Headquarters, Room C111 A–B–C, located at 109 TW Alexander Drive, Research Triangle Park, North Carolina 27711: (919) 541–5400.

FOR FURTHER INFORMATION CONTACT: Questions and comments should be directed to Jeff Schmidt, Acting Designated Federal Official. Mr. Schmidt may be contacted at Department of Agriculture, Natural Resources Conservation Service, 420 South State Road 7, Suite 160, Royal Palm Beach, Florida 33414; telephone: (561) 242–5520 x3748; e-mail: *jeff.schmidt@fl.usda.gov*.

SUPPLEMENTARY INFORMATION: Notice of this meeting is given under the Federal Advisory Committee Act, 5 U.S.C. App. 2. Additional information for the LPAES workshop and AAQTF meeting may be found on the World Wide Web at *http://www.airquality.nrcs.usda.gov/AAQTF/*. Please be advised RSVPs are recommended for the LPAES workshop.

Draft Agenda

2010 Livestock and Poultry Air Emissions Standardization Workshop

September 27–28, 2010

A. The Importance of Standardization.

B. Presentations and discussion on each principle—overview/recommendations.

(1) Prin. #1: Recommended units for reporting emissions for livestock and poultry.

(2) Prin. #2: Data collection to support the proper units of emissions reporting.

(3) Prin. #3: Methodologies and protocols for determining emissions from raw data.

(4) Prin. #4: Consistency in reporting mitigation practices.

C. EPA presentation: NAEMS data analysis, interpretation, and emissions estimating methodologies under consideration.

Draft Agenda

Meeting of the AAQTF

September 29–30, 2010

A. Welcome to Research Triangle Park/EPA.

B. Discussion of Minutes from Previous Meeting.

C. Discussion of Documents to be Approved by the End of the Meeting.

D. Preliminary Discussion of Recommendations for Standardization of Monitoring Data from National Animal Agricultural Emissions Monitoring Study (NAAEMS).

E. Scientific and Subcommittee Presentations.

(1) Agricultural Equipment Subcommittee Report.

(2) Air Quality Standards Subcommittee Report.

(3) Greenhouse Gases and Bioenergy Subcommittee Report.

(4) Livestock and Poultry Subcommittee Report.

(5) Reactive Nitrogen Subcommittee Report.

F. Department of Agriculture Update.

G. Environmental Protection Agency Update.

H. Discussion of Subcommittee Recommendations.

I. Next Meeting, Time, and Place.

* Please note that the timing of events in this agenda is subject to change to accommodate changing schedules of expected speakers.

Procedural

The LPAES workshop and AAQTF meeting are open to the public. At the discretion of the Chair, members of the public may give oral presentations during the AAQTF meeting. Those persons wishing to make oral presentations should register in person at the meeting site. Those wishing to distribute written materials at the AAQTF meeting (in conjunction with spoken comments) must bring 50 copies of the materials with them. Written materials for distribution to AAQTF members prior to the meeting must be received by Jeff Schmidt no later than Friday, September 10, 2010.

Information on Services for Individuals With Disabilities

For information on facilities or services for individuals with disabilities, or to request special assistance at the meeting, please contact Mr. Schmidt. The Department of Agriculture (USDA) prohibits discrimination in its programs and activities on the basis of race, color, national origin, gender, religion, age, sexual orientation, or disability. Additionally, discrimination on the basis of political beliefs and marital or family status is also prohibited by statutes enforced by USDA (not all prohibited bases apply to all programs). Persons with disabilities who require alternate means for communication of program information (Braille, large print, audio tape, *etc.*) should contact the USDA's Target Center at (202) 720–2000 (voice and TDD). USDA is an equal opportunity provider and employer.

Signed this 20th day of July, 2010 in Washington, DC.

Dave White,

Chief, Natural Resources Conservation Service.

[FR Doc. 2010–18452 Filed 7–27–10; 8:45 am]

BILLING CODE 3410–16–P

COMMISSION ON CIVIL RIGHTS

Agenda and Notice of Public Meeting of the District of Columbia Advisory Committee

Notice is hereby given, pursuant to the provisions of the rules and regulations of the U.S. Commission on Civil Rights and the Federal Advisory Committee Act, that planning and briefing meetings of the District of Columbia Advisory Committee will convene at 10 a.m. on Thursday, September 16, 2010, at the U.S. Commission on Civil Rights, 624 Ninth Street, NW., Conference Room 540, Washington, DC 20425. The purpose of the briefing meeting is for the Committee to gather information on Affirmatively Furthering Fair Housing in the District. The purpose of the planning meeting is to discuss the Committee's next steps.

Members of the public are entitled to submit written comments; the comments must be received in the regional office by Friday, October 15, 2010. The address is the Eastern Regional Office, 624 Ninth Street, NW., Suite 740, Washington, DC 20425. Persons wishing to e-mail their comments, or who desire additional information should contact the Eastern Regional Office at 202–376–7533 or by e-mail to: *ero@usccr.gov.*

Hearing-impaired persons who will attend the meeting and require the services of a sign language interpreter should contact the Regional Office at least ten (10) working days before the scheduled date of the meeting.

Records generated from this meeting may be inspected and reproduced at the Eastern Regional Office, as they become available, both before and after the meeting. Persons interested in the work of this advisory committee are advised to go to the Commission's Web site, *http://www.usccr.gov,* or to contact the Eastern Regional Office at the above e-mail or street address.

The meeting will be conducted pursuant to the rules and regulations of the Commission and FACA.

Dated in Washington, DC, July 23, 2010.

Peter Minarik,

Acting Chief, Regional Programs Coordination Unit.

[FR Doc. 2010–18480 Filed 7–27–10; 8:45 am]

BILLING CODE 6335–01–P

COMMISSION ON CIVIL RIGHTS

Agenda and Notice of Public Meeting of the Louisiana Advisory Committee

Notice is hereby given, pursuant to the provisions of the rules and regulations of the U.S. Commission on Civil Rights (Commission), and the Federal Advisory Committee Act (FACA), that a planning meeting of the Louisiana Advisory Committee to the Commission will convene by conference call at 2 p.m. and adjourn at approximately 3:30 p.m. on Wednesday, August 25, 2010. The purpose of this meeting is to provide SAC orientation and to plan future activities for SAC project.

This meeting is available to the public through the following toll-free call-in number: (866) 364–7584, conference call access code number 90226766. Any interested member of the public may call this number and listen to the meeting. Callers can expect to incur charges for calls they initiate over wireless lines, and the Commission will not refund any incurred charges. Callers will incur no charge for calls they initiate over land-line connections to the toll-free telephone number. Persons with hearing impairments may also follow the proceedings by first calling the Federal Relay Service at 1–800–977–8339 and providing the Service with the conference call number and contact name Farella E. Robinson.

To ensure that the Commission secures an appropriate number of lines for the public, persons are asked to register by contacting Corrine Sanders of the Central Regional Office and TTY/TDD telephone number, by 4 p.m. on August 20, 2010.

Members of the public are entitled to submit written comments. The comments must be received in the regional office by September 9, 2010. The address is U.S. Commission on Civil Rights, 400 State Avenue, Suite 908, Kansas City, Kansas 66101. Comments may be e-mailed to *frobinson@usccr.gov.* Records generated by this meeting may be inspected and reproduced at the Central Regional Office, as they become available, both before and after the meeting. Persons interested in the work of this advisory committee are advised to go to the Commission's Web site, *http://www.usccr.gov,* or to contact the Central Regional Office at the above e-mail or street address.

The meeting will be conducted pursuant to the provisions of the rules and regulations of the Commission and FACA.

Dated in Washington, DC, July 23, 2010.

Peter Minarik,

Acting Chief, Regional Programs Coordination Unit.

[FR Doc. 2010–18481 Filed 7–27–10; 8:45 am]

BILLING CODE 6335–01–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

Availability of Seats for the Stellwagen Bank National Marine Sanctuary Advisory Council

AGENCY: Office of National Marine Sanctuaries (ONMS), National Ocean Service (NOS), National Oceanic and Atmospheric Administration, Department of Commerce (DOC).

ACTION: Notice and request for applications.

SUMMARY: The ONMS is seeking applicants for the following seats on the Stellwagen Bank National Marine Sanctuary Advisory Council: Member and alternate seats for Conservation; alternate seats for Education, Mobile Gear Commercial Fishing, Whalewatching, and At-Large. Applicants are chosen based upon their particular expertise and experience in relation to the seat for which they are applying; community and professional affiliations; philosophy regarding the protection and management of marine resources; and possibly the length of residence in the area affected by the sanctuary. Applicants who are chosen as members should expect to serve two- and three-year terms, pursuant to the Council's Charter. The Council consists also of three state and three Federal non-voting ex-officio se ats.

DATES: Applications are due by 10 September 2010.

ADDRESSES: Application kits may be obtained from *Elizabeth.Stokes@noaa.gov,* Stellwagen Bank National Marine Sanctuary, 175 Edward Foster Road, Scituate, MA 02066. Telephone 781–545–8026, ext. 201. Completed applications should be sent to the same address or e-mail, or faxed to 781–545–8036.

FOR FURTHER INFORMATION CONTACT: *Nathalie.Ward@noaa.gov,* External

Affairs Coordinator, telephone: 781–545–8026, ext. 206.

SUPPLEMENTARY INFORMATION: The Council was established in March 2001 to assure continued public participation in the management of the Sanctuary. The Council's 23 members represent a variety of local user groups, as well as the general public, plus seven local, state and Federal government agencies. Since its establishment, the Council has played a vital role in advising NOAA on critical issues and is currently focused on the sanctuary's final five-year Management Plan.

The Stellwagen Bank National Marine Sanctuary encompasses 842 square miles of ocean, stretching between Cape Ann and Cape Cod. Renowned for its scenic beauty and remarkable productivity, the sanctuary supports a rich diversity of marine life including 22 species of marine mammals, more than 30 species of seabirds, over 60 species of fishes, and hundreds of marine invertebrates and plants.

Authority: 16 U.S.C. 1431, *et seq.*

(Federal Domestic Assistance Catalog Number 11.429 Marine Sanctuary Program)

Dated: July 21, 2010.

Daniel J. Basta,

Director, Office of National Marine Sanctuaries, National Ocean Service, National Oceanic and Atmospheric Administration.

[FR Doc. 2010–18300 Filed 7–27–10; 8:45 am]

BILLING CODE 3510–NK–M

DEPARTMENT OF COMMERCE

Office of the Secretary

National Institute of Standards and Technology

International Trade Administration

National Telecommunications and Information Administration

[Docket No.: 100721305–0305–01]

Cybersecurity, Innovation and the Internet Economy

AGENCY: Office of the Secretary, U.S. Department of Commerce; National Institute of Standards and Technology, U.S. Department of Commerce; International Trade Administration, U.S. Department of Commerce; and National Telecommunications and Information Administration, U.S. Department of Commerce.

ACTION: Notice of inquiry.

SUMMARY: The Department of Commerce's Internet Policy Task Force is conducting a comprehensive review of the nexus between cybersecurity challenges in the commercial sector and innovation in the Internet economy. The Department seeks comments from all stakeholders, including the commercial, academic and civil society sectors, on measures to improve cybersecurity while sustaining innovation. Preserving innovation, as well as private sector and consumer confidence in the security of the Internet economy, are important for promoting economic prosperity and social well-being overall. In particular, the Department seeks to develop an up-to-date understanding of the current public policy and operational challenges affecting cybersecurity, as those challenges may shape the future direction of the Internet and its commercial use, both domestically and globally. After analyzing comments on this Notice, the Department intends to issue a report that will contribute to the Administration's domestic and international policies and activities in advancing both cybersecurity and the Internet economy.

DATES: Comments are due on or before September 13, 2010.

ADDRESSES: Written comments may be submitted by mail to Diane Honeycutt, National Institute of Standards and Technology, 100 Bureau Drive, Stop 8930, Gaithersburg, MD 20899. Submissions may be in any of the following formats: HTML, ASCII, Word, rtf, or pdf. Online submissions in electronic form may be sent to *cybertaskforce@doc.gov.* Paper submissions should include a three and one-half inch computer diskette or compact disc (CD). Diskettes or CDs should be labeled with the name and organizational affiliation of the filer and the name of the word processing program used to create the document. Comments will be posted at *http://www.ntia.doc.gov/internetpolicytaskforce* and *http://csrc.nist.gov.*

FOR FURTHER INFORMATION CONTACT: For questions about this Notice contact: Jon Boyens, International Trade Administration, U.S. Department of Commerce, 1401 Constitution Avenue, NW., Room 2806, Washington, DC 20230, telephone (202) 482–0573, e-mail *Jon.Boyens@trade.gov;* or Alfred Lee, National Telecommunications and Information Administration, U.S. Department of Commerce, 1401 Constitution Avenue, NW., Room 4725, Washington, DC 20230, telephone (202) 482–1880, e-mail *Alee@ntia.doc.gov.* Please direct media inquires to the National Institute of Standards and Technology's Office of Public and Business Affairs at (301) 975–6478.

SUPPLEMENTARY INFORMATION: The Internet has become vitally important to U.S. innovation, prosperity, education, civic activity and cultural life as well as aspects of our national security. A top priority of the Department of Commerce is to ensure that the Internet remains an open and trusted infrastructure, both for commercial entities and individuals. In pursuit of this priority, the Department has created an Internet Policy Task Force whose mission is to identify leading policy challenges and to recommend possible solutions. The Task Force leverages expertise across many bureaus at the Department, including those responsible for cybersecurity standards and best practices, information and communications policy, international trade, intellectual property, business advocacy and export control. This Notice of Inquiry is one in a series of inquiries from the Task Force. Other reviews examine information privacy, global free flow of information on the Internet, and online copyright protection issues. The Task Force may explore additional areas in the future.

The Task Force's cybersecurity work aims to identify public policies and private-sector norms that can: (1) Promote conduct by firms and consumers that collectively will sustain growth in the Internet economy and improve the level of security of the infrastructure and online environment that support it; (2) enhance individual and collaborative efforts by those actors who are in the best position to assist firms and their customers in addressing cybersecurity challenges; (3) improve the ability of firms and consumers to keep pace with ever-evolving cybersecurity risks; and (4) promote individual privacy and civil liberties. Public policies and private-sector practices that promote innovation and enhance cybersecurity will help assure that the Internet remains fertile ground for an expanding range of beneficial commercial and consumer activity.

Internet Growth and Evolving Cybersecurity Challenges: The Internet allows users to gather, store, process, and transfer vast amounts of data, including proprietary and sensitive business, transactional, and personal data. At the same time that businesses and consumers rely more and more on such capabilities, cybersecurity risks continue to plague the Internet economy, and it seems highly unlikely that all risks will ever be completely eliminated.

Sources of cybersecurity risks include individual criminals, organized crime, terrorists, and nation-states. Cyber intrusions and attacks are mounted against commercial and individual users, as well as against government, military, and critical infrastructure networks (*e.g.,* energy, water, sewage, transportation, banking, and financial networks). These intrusions and attacks often seek to steal, manipulate, destroy, or deny access to sensitive data and sometimes attempt to disable or disrupt individual systems.[1] Media outlets regularly report on the activities of those who disseminate viruses, spyware, and other malware, as well as those who spoof e-mail addresses, distribute spam, phish for sensitive personal information, and create botnets.[2] Cyber threats can originate from anywhere in the world. They not only target computers, but also mobile phones and other devices connected to the Internet.

Cybersecurity risks seem to evolve as rapidly as the Internet expands, and those risks are becoming increasingly global in nature. Keeping pace with cybersecurity risks requires all users, even the most sophisticated users, to be aware of the threats and improve upon their security practices on an ongoing basis. Creating incentives to motivate all parties in the Internet economy to make appropriate security investments in response to risks they face requires a careful balance of technical and public policy measures.

The constantly evolving nature of the threats and vulnerabilities not only affects individual firms and their customers, but collectively the threats pose a persistent economic and national security challenge. Computing devices are highly and increasingly interconnected, meaning that security deficiencies in a limited number of systems can be exploited to launch cyber intrusions or attacks on other systems. Put another way, poor cyber "hygiene" on one Internet-connected computer negatively impacts other connected computers.

Given the breadth and importance of this challenge, government and private sector actors have for many years been pursuing a range of mitigation strategies. Currently at the Federal level, the White House's Cybersecurity Coordinator is responsible for setting a national agenda and for coordinating Executive Branch cybersecurity activities. Specific Federal activities in this area include research and training, threat reporting and analysis, information collection and dissemination, consumer awareness, and policy development. In addition, the Director of the Office of Management and Budget (OMB) is responsible for overseeing Federal agency information security policies and practices under the Federal Information Security Management Act of 2002.

The Department of Homeland Security (DHS) is an especially important Federal actor that serves as a focal point for the security of cyberspace. It provides consolidated intrusion detection, incident analysis and cyber response capabilities to protect Federal agencies' external access points, including access to the Internet. While the Department of Defense (DOD) defends military and national security systems, DHS has the lead in securing federal civilian systems. DHS also works with public and private stakeholders to protect critical infrastructure and key resources (CIKR).[3] A number of entities within the Department of Justice, including the Federal Bureau of Investigation, as well as the United States Secret Service in DHS, track and prosecute cyber crimes. The National Science and Technology Council and its Committee on Technology serve as the coordinating organization over the Networking and Information Technology Research and Development (NITRD) program, which is the primary mechanism by which the U.S. Government coordinates its unclassified networking and IT research and development investments, including cybersecurity research and development.[4]

The Department of Commerce has programs that complement and support these and other federal efforts. For example, the Department's National Institute of Standards and Technology (NIST)[5] develops standards and guides for securing non-national security Federal information systems. It defines minimum security requirements for federally held information and for information systems. NIST is also a primary contributor and member of the NITRD program, leading research and development in computer forensics tool testing, seamless mobility, trustworthy information systems, information security automation, combinatorial testing, next generation access control, and Internet infrastructure protection (with DHS funding). NIST also is responsible for the National Software Reference Library, National Vulnerability Database, and Security Content Automation Protocol. NIST identifies methods and metrics for assessing the effectiveness of security requirements; evaluates private sector security policies for potential federal agency use; and provides general cybersecurity technical support and assistance to the private sector and federal agencies. Moreover, over the

[1] *See, e.g., Cyberspace Policy Review: Assuring a Trusted and Resilient Information and Communications Infrastructure,* May 29, 2009, at 1, *http://www.whitehouse.gov/assets/documents/Cyberspace_Policy_Review_final.pdf* (Cyberspace Policy Review), *citing* Director of National Intelligence, *Annual Threat Assessment of the Intelligence Community for the Armed Services Committee, Statement for the Record,* March 10, 2009, at 39.

[2] *See, e.g., id.* at 2 (listing several examples of media reported incidents); *see also* David S. Wall, *Cybercrime, Media and Insecurity: The Shaping of Public Perceptions of Cybercrime,* 22 International Review of Law, Computers and Technology 45 (2008). A botnet, short for robot network, is an aggregation of compromised computers that are taken over via network connections without the knowledge or consent of their owners. Michigan Information Sharing and Analysis Center, *Monthly Cyber Security Tips Newsletter* (September 2007), *http://www.michigan.gov/documents/cybersecurity/CSNewsletter_September2007_207450_7.pdf.*

[3] DHS oversees critical infrastructure protection, operates the United States Computer Emergency Readiness Team (US–CERT), oversees implementation of the Trusted Internet Connection initiative, and takes other actions to help secure both the federal civilian government systems and the private sector. DHS exercises primary responsibility within the executive branch for the operational aspects of Federal agency cybersecurity with respect to the Federal information systems that fall within the Federal Information Security Management Act of 2002 (FISMA). These responsibilities include overseeing the government-wide and agency-specific implementation of and reporting on cybersecurity policies and guidance; overseeing and assisting government-wide and agency-specific efforts to provide adequate, risk-based and cost-effective cybersecurity. Under FISMA, the Director of the Office of Management and Budget (OMB) oversees federal agency information security policies and practices, and OMB has directed all departments and agencies to coordinate and cooperate with DHS as necessary to carry out its FISMA responsibilities. OMB Memorandum M–10–28 Clarifying Cybersecurity Responsibilities and Activities of the Executive Office of the President and the Department of Homeland Security (DHS), *http://www.whitehouse.gov/omb/assets/memoranda_2010/m10-28.pdf.*

[4] In addition, the Federal Communications Commission, an independent regulatory agency, is considering launching a voluntary certification program to encourage communications service providers to implement cybersecurity best practices. *See http://hraunfoss.fcc.gov/edocs_public/attachmatch/FCC-10-63A1.pdf.*

[5] The 1965 Brooks Act gave the National Bureau of Standards (now NIST) responsibilities for federal information technology standards. Public Law 89–306 (Oct. 30, 1965). The Computer Security Act of 1987 reaffirmed the responsibilities of NIST for the security of unclassified, non-military government computer systems. Public Law. 100–235 (Jan. 8, 1988). Under the law, the role of the National Security Agency (NSA) was limited in the civilian security realm to providing technical assistance. The 2002 Cyber Security Research and Development Act authorized funding to NIST for computer and network security research and established status reporting requirements. Public Law 107–305 (Nov. 27, 2002). The 2002 Federal Information Security Management Act provided for development and maintenance by NIST of minimum controls required to protect federal information and information systems. Title III of Public Law 107–347 (Dec. 17, 2002).

past two decades, the Department's National Telecommunications and Information Administration (NTIA), in its role as principal adviser to the President on telecommunications and information policies, has worked closely with other parts of government on broadband deployment, Internet policy development, securing the Internet namespace, and other issues. As an advocate for our nation's businesses, NTIA has played an instrumental role in developing policies that have helped commerce over the Internet flourish.[6]

Through its Internet Policy Task Force, the Department intends to recommend public policies and private-sector norms that can markedly improve the overall cybersecurity posture of private sector infrastructure operators, software and service providers, and users outside the critical infrastructure and key resources realm and of their customers.

Cybersecurity and Commerce: Due to the Department's over-arching responsibility to advance the nation's commercial interests, the Task Force is focused on the cybersecurity challenges facing businesses and consumers that use the Internet.

The nation's e-commerce interests are significant. Growth in online sales and expanding use of the Internet are creating new jobs and contributing directly to our economic recovery. Businesses of all sizes increasingly use the Internet to order and track inventory, sell products and services, store financial and other proprietary information, and interact with their customers. These shifts in business practices and other measures have led to a greatly increased average growth in productivity over the last fifteen years.[7] Over the long term, such growth benefits our global competitiveness.[8]

Taking into account both business-to-consumer and business-to-business transactions, online commerce in 2007 accounted for more than $3 trillion in revenue for U.S. companies.[9] In the business-to-consumer e-commerce space, the United States economy enjoyed an increase in revenue of more than 500 percent between 1999 and 2007.[10] Even during the recent economic downturn, the economic benefits provided by the Internet economy increased. In 2009, online retail sales grew 2.0 percent to reach $134.9 billion,[11] while total retail sales fell 7 percent in that same year. Also in 2009, U.S. mobile commerce sales grew more than 200 percent compared to the previous year, reaching $1.2 billion.[12] Analysts expect this growth to continue in 2010, projecting $2.4 billion in mobile commerce.[13]

Notwithstanding this consistent, impressive growth, companies continue to face significant challenges in their ability to appropriately protect their computer systems, secure their proprietary, personal, and financial information, and safeguard the integrity of business and other transactions that they conduct over the Internet.

Reports of significant, persistent, individual cyber intrusions occur on a regular basis, as do reports of widespread, untargeted cyber incidents. The Cyberspace Policy Review described a coordinated attack in 49 cities on more than 130 automated teller machines in 2008, as well as a single 2007 data breach at one company that resulted in more than 45 million compromised consumer financial accounts.[14] While some cyber intrusions are highly sophisticated, some require relatively little skill or effort. For instance, criminals can use widely available, low cost "crimeware kits" to exploit computer systems and software vulnerabilities in order to launch malware against targeted computer systems.[15]

The financial cost of cyber threats to firms and their customers appears to be significant. Though current fraud losses attributed to cybersecurity data breaches are small in comparison to total annual business fraud losses, they are increasing, rising from 7 percent of total fraud losses in 2007 to 11 percent in 2008. In 2009, the dollar loss from all cases of online crime referred to law enforcement in the United States reached $550 million, more than twice the 2008 level.[16]

Small businesses have just as much reason to focus on cybersecurity as do larger enterprises yet they are less likely to have adequately protected themselves from their risks. According to a National Cybersecurity Alliance poll, 65 percent of small businesses store customer data online, 43 percent store financial records online, 33 percent store credit card information online, and 22 percent have intellectual property and other sensitive corporate content online.[17] The same poll shows that only 14 percent of these firms have anyone solely focused on information technology security; only 53 percent check their computers to ensure that anti-virus, anti-spyware, firewalls, and operating systems are up to date; 20 percent say that they use the minimum threshold of security to protect customer and employee data, but 42 percent believe that their customers are

[6] *See* 47 U.S.C. 902 (b)(2)(D) (providing that NTIA has "[t]he authority to serve as the President's principal adviser on telecommunications policies pertaining to the Nation's economic and technological advancement and to the regulation of the telecommunications industry"); *see also* Federal Communications Commission, *Connecting America: The National Broadband Plan,* at 55 (2010), *http://download.broadband.gov/plan/national-broadband-plan.pdf.* In 1993, the White House formed the Information Infrastructure Task Force (White House Task Force), chaired by the Secretary of Commerce, to develop telecommunications and information policies to promote the development of the Internet. In 1997, the White House Clinton Administration published *A Framework for Global Electronic Commerce.* This was the work of an interagency working group of high level representatives of several cabinet agencies, including the Departments of Treasury, State, Justice and Commerce, as well as the Executive Office of the President, including the Council of Economic Advisors, the National Security Council, the Office of Science and Technology Policy, the Office of the Vice President, and the U.S. Trade Representative. Independent commissions including the Federal Communications Commission and the Federal Trade Commission also contributed to the working group. In several instances, the *Framework* notes NTIA's collaborative efforts, in conjunction with other federal agencies, such as the State Department, Federal Trade Commission, U.S. Trade Representative, to explore opportunities for international cooperation to protect consumers and to prosecute false, deceptive, and fraudulent commercial practices in cyberspace. President William J. Clinton and Vice President Albert Gore, Jr., *A Framework for Global Electronic Commerce* (1997) (pagination not available), *http://clinton4.nara.gov/WH/New/Commerce/*; *see also* Memorandum on Electronic Commerce, 33 Weekly Comp. Pres. Doc 1006 (July 1, 1997).

[7] Executive Office of the President of the United States, *Economic Report of the President* (Feb. 2010), *available at http://www.whitehouse.gov/administration/eop/cea/economic-report-of-the-president.*

[8] The Nation relies increasingly on the Internet not only as a platform for commercial activities, but also as a vehicle for innovation, national competitiveness, and a tool for efficiency, transparency and accountability in government.

[9] U.S. Census Bureau, *E–Stats,* May 28, 2009, *http://www.census.gov/econ/estats/2007/2007reportfinal.pdf,* at 2.

[10] *Id.* More recent data released in May 2010 show that this trend continued in 2008. U.S. Census Bureau, *E–Stats,* May 27, 2010, *http://www.census.gov/econ/estats/2008/2008reportfinal.pdf.*

[11] U.S. Census Bureau, "Quarterly Retail E–Commerce Sales: 4th Quarter 2008," Feb. 16, 2010.

[12] *U.S. M–Commerce Sales to Hit $2.4 Billion This Year, ABI Research Says,* Internet Retailer, Feb. 16, 2010, *http://www.internetretailer.com/2010/02/16/u-s-m-commerce-sales-to-hit-2-4-billion-this-year-abi-researc.*

[13] *Id.*

[14] Cyberspace Policy Review at 2.

[15] *See, e.g.,* Tom Zeller, Jr., *Cyberthieves Silently Copy Your Passwords as You Type,* New York Times, Feb. 27, 2006, *available at http://www.nytimes.com/2006/02/27/technology/27hack.html.*

[16] *See* Internet Crime Complaint Center, *2009 Internet Crime Report, http://www.ic3.gov/media/annualreport/2009_IC3Report.pdf.*

[17] National Cyber Security Alliance, Symantec, and Zogby International; *2009 NCSA/Symantec Small Business Study,* Oct. 2009, *http://www.staysafeonline.org/files/2009SMBStudy/FullSMBStudy2009%20FINAL.pdf,* at 4.

concerned about the IT security of their business. Though many businesses are increasing their cybersecurity budgets, anecdotally, the Task Force has been told that there is a continuous requirement for IT managers to justify their expenditure of company resources on cybersecurity.

Given this state of affairs, the Task Force believes that public policies affecting cybersecurity on the Internet, as well as private sector norms (both good and bad), require a fresh look. The Task Force recognizes the valuable roles, responsibilities, and capabilities of the private sector in creating tools and strategies to mitigate cyber risks associated with the Internet. More broadly, over the past two decades, the nation has benefitted greatly from industry-led, Internet-driven innovation and growth, with those benefits reflected throughout the entire economy. That said, the persistence of the cybersecurity challenges compels the Department to seek a better understanding of both how those challenges are affecting U.S. businesses and citizens, as well as useful steps that can enhance the security of e-commerce. Small, medium, and large businesses, and consumers, will continue to increase their reliance on the Internet. As that reliance grows, the level of cybersecurity must increase as well.

Contribution of This NOI to the Internet Policy Task Force: Responses to this Notice will assist the Department's Internet Policy Task Force in preparing a report on cybersecurity, innovation and the Internet economy. The primary purposes of the report will be to identify and evaluate cybersecurity challenges facing commercial actors and consumers outside the critical infrastructure and key resources sectors to analyze various approaches to meet those challenges. The Department would also like to know how it can improve its execution of core cybersecurity responsibilities, including those supporting CIKR sectors and their customers. The Task Force's report may include options and recommendations for changes in public policy, as well as recommendations for voluntary steps that will enhance the commercial sector's and consumers' cybersecurity preparedness. The Task Force is hopeful that the dialogue launched here and the responses to this inquiry will contribute to Administration-wide policy positions and global cybersecurity strategy.

Request for Comment

The primary focus of this inquiry, as reflected above and in the questions listed below, is on enhancing the cybersecurity practices of commercial actors, consumers, and citizens outside the CIKR sectors. Activities involving government systems, other critical infrastructures and key resources receive attention from the Department of Homeland Security and other agencies. As such, they are not the main subject of this inquiry. The questions below are intended to help frame the issues and should not be construed as a limitation on comments that parties may submit. Comments containing references, studies, research, and other empirical data that are not widely published should include copies of the referenced materials. Comments will be posted at *http://www.ntia.doc.gov/internetpolicytaskforce* and *http://csrc.nist.gov.*

1. Quantifying the Economic Impact

Prior to releasing this NOI, the Task Force conducted listening sessions with a wide range of stakeholders in order to understand the issues that have the greatest bearing on cybersecurity preparedness and continued growth of the Internet economy. During those conversations, the Task Force heard that while cybersecurity threats continue to pose challenges for Internet users and services providers, it appears difficult to assess the macro- and microeconomic impact of cybersecurity incidents with current tools. It is hard to manage that which one cannot measure.

Losses related to Internet fraud (*e.g.,* payment fraud, identity theft, credit card fraud) are collected and reported to various government and private entities. However, data that describe the economic impact of cybersecurity incidents more fully and completely, either at the firm or sector level, are not readily available. Not only are losses difficult to quantify with today's tools, but it appears to be difficult to assess in economic terms the return on investments achieved via security measures. Measures of business and consumer investment in security-related activities lack a common reporting entity or information aggregating mechanism.

The availability of authoritative, aggregated data on cybersecurity investments and losses from cyber incidents might yield a quantitative picture of the economic impact of cyber intrusions and attacks. Such data would enable industry and the government to evaluate the severity of cybersecurity threats and emerging trends and to make informed decisions about the trade-offs of different cybersecurity strategies and investment options.

We seek comment on the following questions: How should a data gathering and analysis system (or systems) be fashioned to facilitate the collection of well-defined, consistent metrics to measure the financial impact of cybersecurity incidents and investments in cybersecurity protection? What would be the implementation challenges? Are there adequate incentives for businesses to provide information about security breaches, data security losses, and cybersecurity investments? It would be beneficial from a national perspective to have a greater understanding of the financial costs and benefits of different cybersecurity practices. Does the private sector, however, lack incentives to share information at the firm level? What are reasonable means to acquire the data necessary for greater understanding? At what level of granularity should data be collected and analyzed? What would be the appropriate entity to perform collection and analysis of the data? Aside from assessing the known costs of cyber intrusions and attacks and of cybersecurity measures, what other data would be helpful to better understand the question of whether at the firm, sector and national levels enough is being done to adequately protect the nation's information and communications systems? Can the opportunity costs associated with inadequate security be estimated in some way?

2. Raising Awareness

At the highest level of abstraction, the nation has pursued for the past several years a two-prong strategy for dealing with cybersecurity issues, namely, the continual development of cyber-protection technology and techniques, paired with the sharing of information about those capabilities, about new threats and vulnerabilities, and about data breaches (where required by law). Based on the Task Force's examination to date, these strategies will remain important. The dynamic nature of the cyber risk environment demands continuous innovation in cyber-protection capability. Ongoing improvements in education and other forms of awareness-raising are also necessary, given the fact that a significant proportion of Internet economy participants do not take adequate advantage of readily available cyber-protection tools.

In response to the President's Cyberspace Policy Review, the U.S. Government is stepping up its investment in education and awareness-raising. For example, NIST has assumed overall coordination responsibility for a new National Initiative for

Cybersecurity Education (NICE).[18] NICE has four tracks, each delegated to particular federal agencies. The tracks include: (1) National Cybersecurity Awareness led by the DHS; (2) K–12 and university-level Cybersecurity Education led by the Department of Education and the White House's Office of Science and Technology Policy; (3) the creation of a Federal Cybersecurity Workforce Structure led by the Office of Personnel Management; and (4) the creation of a Cybersecurity Workforce Training effort led by the DOD, DHS, and the Office of the Director of National Intelligence. The Department also recognizes that across the private sector, there are many initiatives—some nationally led, others locally led, some including public-private partnerships—aimed at improving cybersecurity awareness among businesses, consumers, and students.

We seek comment on the efficacy of existing educational efforts, as well as the steps that might be taken to improve them. Are there data that demonstrate that certain educational programs qualify as best practices? What have those who are delivering cybersecurity education learned from their experiences? Which educational plans are succeeding or failing, and have providers of such educational efforts attempted to measure return-on-investment? What additional role, if any, should the government play in cybersecurity education and awareness efforts? What programs, beyond continuing education for IT professionals, workplace training for users, or curriculum development for K–12 or post-secondary institutions, should be developed? Does the private sector require government assistance in developing the kinds of materials and programs that would be useful in this area? Who should be the target audiences?

Given the dynamic nature of cyber threats, it is important for even the most sophisticated commercial entities to be vigilant. One of the best ways to improve defensive capabilities is for good actors to share important information with each other and with appropriate authorities. Yet in our listening sessions, we heard comments that questioned whether enough is being done on this front. Security breach legislation has gone into effect in many states.[19] Nonetheless, our current perception is that for many reasons firms that have experienced cyber intrusions or attacks either do not know with whom to share that information or are reluctant to share.

In the immediate aftermath of a recent, high-profile cyber incident, we heard a variation on this theme. Reportedly, even the most sophisticated small and medium-sized firms are daunted by how complicated it can be to share information on the incidents they have suffered. A successful, targeted intrusion might involve exploitation of a technology vulnerability, loss of customer information, theft of intellectual property or other digital assets, and loss of financial information. Such an exploit might be executed and addressed in a matter of minutes or hours, yet reporting the incident and the losses to the proper officials could consume numerous man-hours, with business owners unsure whether the expenditure of that amount of time yields any benefit to the business.

We seek comment on whether there is adequate awareness of information sharing programs. Are existing information sharing mechanisms adequately-resourced but under-utilized? If so, what deters their use? How can the state of affairs be improved? Are there parts of the business community that do not know the governmental points-of-contact, US–CERT, to report, share information on, and seek guidance regarding cybersecurity incidents? If there are parts of the business community that are unaware of available resources, which parts are they and what steps might help to raise their awareness? Even among that who are aware of the resources and mechanisms available for information sharing and assistance, is there a reluctance to use them? If so, why? Does the government adequately assist businesses in the throes or in the aftermath of a cyber incident? Should the government create a cybersecurity service center to assist the business community in implementing protection measures, sharing information about cyber threats reported by businesses and other sources, and dealing with cybersecurity incidents that occur? What other steps can be taken to improve situational awareness across the business sector?

3. Web Site and Component Security

Increasingly, malware and other malicious content are able to infect computers and other user access devices (*e.g.,* smart phones) in a manner that compromises the integrity of commercial and personal information. Such exploits are often launched through interactive Web sites that end users access online and through the use of external devices (*e.g.,* portable USB drives, digital picture frames). While computer training and consumer education programs can reduce the amount of malware spread through these means by instructing users in safer online practices, there may be other mechanisms or systems that could prove effective in reducing such cyber risks.

In Department of Commerce listening sessions, stakeholders identified improved Web site and component security as another area where modest technology investments might generate large improvements in the level of cybersecurity across the Internet. Should the government alone, the private sector, or the government and private sector collaboratively explore whether third-party verification of Web site and component security is or can prove effective in reducing the proliferation of malware? If so, what measures should be considered? What would be the implementation challenges in deploying such measures?

4. Authentication/Identity (ID) Management

In our listening sessions, several stakeholders urged the Task Force to promote more widespread uptake of state-of-the-art authentication and ID management systems to reduce the incidents of successful cyber intrusions and attacks. Effective authentication and authorization systems establish a user's right to access resources. Many users currently rely on simple password systems for authentication. More sophisticated systems require multiple factors in the authentication process, for example, something the user knows, plus something that the user possesses (*e.g.,* a physical credential or token).[20]

[18] National Initiative for Cybersecurity Education (NICE), *Relationship to President's Education Agenda* (April 19, 2010), *http://www.whitehouse.gov/sites/default/files/rss_viewer/cybersecurity_niceeducation.pdf; see also* Commerce Secretary Gary Locke Announces NIST to Lead National Initiative for Cybersecurity Education, (April 29, 2010), *http://www.commerce.gov/news/press-releases/2010/04/29/commerce-secretary-gary-locke-announces-nist-lead-national-initiative.*

[19] *See, e.g.,* California Database Breach Act, California Civil Code §§ 1798.80–1798.82 (enacted in 2002).

[20] Usability, expense, and support issues are significant considerations in selection of authentication and authorization controls. Most of these systems identify the user. Where the identity of the user is important to a system's access policy, issuance and maintenance of credentials depends on an underlying identity management system. Effective identity management systems establish one party's identity to another party's satisfaction, increasing consumer trust in the use of the Internet, while balancing the security and privacy concerns of all users involved. It is worthwhile to remember that "users" are not a homogeneous group. They consist of individuals, and small, medium, and large enterprises, both public and private. The

The Department seeks comment on the effectiveness of current identity management systems in addressing cybersecurity risks.

On June 25, 2010, the White House released the *National Strategy for Trusted Identities in Cyberspace* for public comment. This strategy promotes a set of options for enhancing on-line security and privacy so that individuals and organizations use trusted, interoperable identity solution as in a manner that promotes confidence, privacy, choice, and innovation to experience efficient and secure access to on line services.[21]

Beyond the measures recommended in the *National Strategy for Trusted Identities in Cyberspace,* what, if any, federal government support is needed to improve authentication/identity management controls, mechanisms, and supporting infrastructures? Do the authentication and/or identity management controls employed by commercial organizations or business sectors, in general, provide adequate assurance? If not, what improvements are needed? What specific controls and mechanisms should be implemented? What role should authentication and identity management controls play in a comprehensive set of cybersecurity measures available to commercial organizations? Are the basic infrastructures that underlie the recommended controls and mechanisms already in place? What, if any, new tools or technologies for authentication or identify management are available or are being developed that may address these needs?

How can the expense associated with improved authentication/identity management controls and mechanisms be justified financially? How can the U.S. Government best support improvement of authentication/identity management controls, mechanisms, and supporting infrastructures? Is there a continuing need for limited revelation identity systems, or even anonymous identity processes and credentials? If so, what would be the potential benefits of wide-scale adoption of limited revelation identity systems or anonymous credentialing from a cybersecurity perspective? What would be the drawbacks?

How might government procurement activities best promote development of a market for more effective authentication tools for use by government agencies and commercial entities? Could a private marketplace for "identity brokers" (*i.e.,* organizations that can be trusted to establish identity databases and issue identity credentials adequate for authorizing financial transactions and accessing private sector components of critical infrastructures) fulfill this need effectively? What would be some of the issues or potential impacts of establishing standards and best practices for private sector identity brokers? Should the government establish a program to support the development of technical standards, metrology, test beds, and conformance criteria to take into account user concerns such as how to: (1) Improve interoperability; (2) strengthen authentication methods; (3) improve privacy protection through authentication and security protocols; and (4) improve the usability of identity management systems? What are the privacy issues raised by identity management systems and how should those issues be addressed? Are there particular privacy and civil liberties questions raised by government involvement in identity management system design and/or operations? What other considerations should factor into government's efforts in this area?

5. Global Engagement

Cybersecurity issues are global. Companies want to design, manufacture, and test their products to make them available for sale in a global marketplace. Many in industry have described fear about the potential for balkanization of the global marketplace due to a proliferation of mandated, sometimes unique cybersecurity standards and conformity assessment requirements among nations—leading to a diverse patchwork of national requirements that can inhibit trade. Such unique national standards and conformity assessment requirements illustrate one way in which some foreign governments seem to be deviating from international norms by using security standards as a de facto entry barrier to protect domestic interests from foreign competition.

We request comment on what other cybersecurity-related problems U.S. businesses may be experiencing when attempting to do business in foreign countries. Please specify discrete areas of concern, such as foreign governments requiring access to product source code. Do U.S. businesses confront unfair competition when competing against nationally controlled companies? If so, in which countries? How can the U.S. Government better encourage the use of internationally accepted cybersecurity standards and practices outside of the United States? Are there more effective ways for the U.S. Government to engage countries that deviate from international norms (*i.e.,* bilaterally, multilaterally, through technical dialogues, at an overarching political level, all of these or through other mechanisms)? Would a set of internationally accepted "cybersecurity principles" in the area of standards and conformity assessment procedures be useful? If so, what role should the Department of Commerce play in promoting such internationally accepted principles?

6. Product Assurance

As noted above, many cybersecurity issues are global, but product assurance is one global issue that warrants particular attention. In the course of conversations with hardware and software developers, the Task Force has heard repeatedly that current domestic and international government product assurance efforts for many products can contribute to costly time-to-market delays, as well as unnecessarily expensive products. Several companies felt that the current U.S. Common Criteria assurance scheme is incompatible with industry product development and maintenance schedules and practices, and that the security assurance derived from many national assurance requirements and evaluation schemes is highly questionable.[22] Additionally, participation in international mutual recognition schemes is, reportedly, so limited that some in industry see themselves as expending very significant resources to satisfy a range of varying security requirements and processes among nations in order to compete in a global market. Industry members have expressed a desire for assistance in improving mutual recognition in the product assurance realm.

We seek comment on the following matters. Do current U.S. Government

diversity of the characteristics among these various categories of users means that each group will make selections among various security solutions based on different criteria that address their unique needs and economic drivers. Privacy considerations also significantly complicate identification based on personally identifiable information. For many purposes, identification needs to simply associate the user's request for access or service with an institutional authorization by the entity that is providing the access or service. By contrast, more sensitive transactions (*e.g.,* online banking or exchange of electronic health records) may require authentication of more of an individual's identifying characteristics. Various audit and enforcement functions benefit from identification of the access with a specific person, but this is not necessary for all use cases.

[21] *National Strategy for Secure Identities in Cyberspace,* at 1 (June 25, 2010), available at *http://www.dhs.gov/xlibrary/assets/ns_tic.pdf.*

[22] More information about the US Common Criteria assurance scheme is available at *http://www.commoncriteriaportal.org/theccra.html.*

product assurance requirements inhibit production of timely security components and/or security-enhanced IT products and systems? Do current assurance processes inhibit innovation? If so, what would be the best way to improve the current U.S. product assurance scheme? What, if any, changes need to be made with respect to international product assurance institutions, standards, and processes (*e.g.,* the Common Criteria Recognition Arrangement)? Should the Common Criteria Recognition Arrangement, the basis for international mutual recognition of cybersecurity product assurance, be expanded to include some of those countries which increasingly stray from international norms? Can useful U.S. Government or international product assurance guidelines be crafted for the current real-world software development environment? To what extent can a security oriented software assurance "tool" be useful in software validation? What elements would be necessary to develop an effective industry-government dialogue to clarify the product assurance goals and challenges, and identify workable solutions?

7. Research and Development

The U.S. Government has a continuing interest in cybersecurity research and development and has funded research on various aspects of security in computing, networking, and data processing for decades. Together with research and development programs at NIST, DOD, and several other agencies, the current unclassified Federal funding in Cyber Security and Information Assurance Research and Development is approximately $350 million per year. One of the goals of the Comprehensive National Cybersecurity Initiative (CNCI) initiated in January 2008 is to develop "leap-ahead" technologies that would achieve orders-of-magnitude improvements in cybersecurity. Based on this directive, in 2009, the agencies of the NITRD Program identified three initial research and development themes to exemplify and motivate future federal cybersecurity game-change research activities.[23] In addition to eliminating redundancies in federally funded cybersecurity research, identifying research gaps, and prioritizing research and development efforts, the Federal government has actively sought to create incentives for private industry and academic institutions to increase their research and development efforts.

The following questions should be considered from the perspective of the Department of Commerce. How can the federal government best promote additional commercial and academic research and development in cybersecurity technology? What particular research and development areas do not receive sufficient attention in the private sector? What cybersecurity disciplines most need research and development resources (*e.g.,* performance metrics, availability, status monitoring, usability, and cost effectiveness)? How effective would a federal government-sponsored "grand challenge program" be at drawing attention to and promoting work on specific technical problems?

8. An Incentives Framework for Evolving Cyber-Risk Options and Cybersecurity Best Practices

Outside the CIKR sectors, U.S. businesses and consumers generally have resorted to their own devices and evolved their own practices for dealing (or not dealing) with cyber risks. In other words, across large segments of the economy, the level of cybersecurity relies upon the private sector's development, dissemination and adoption of best practices. As Internet usage has grown domestically and abroad, U.S. companies have been faced with a range of Internet-related issues. Based on feedback the Task Force received, the adoption of industry best practices is uneven.

According to some stakeholders, smaller and medium sized businesses may lack the specialized knowledge and resources necessary to meet cybersecurity challenges. Some stakeholders also suggested that the fundamental challenge may be a misalignment of incentives. Still others argued for greater leadership from industry and/or government in developing improved standards for securing cyberspace in a manner that will promote greater economic benefits from an expanding Internet economy. These assertions suggest several questions:

Are existing incentives adequate to address the current risk environment? Do particular business segments lack sufficient incentives to make cybersecurity investments? If so, why? What would be the best way to encourage businesses to make appropriate investments in cybersecurity? Are there public policies or private sector initiatives in the United States or other countries that have successfully increased incentives to make such security investments? Are there disincentives that inhibit cybersecurity investments by firms? If so, what should be done to eliminate them?

Are there examples of cybersecurity best practices that have been (or can be) sufficiently tailored to meet the diverse needs of commercial actors outside the CIKR sectors? Are those best practices well known and understood? Should a set, or sets, of best practices be developed to guide commercial organizations' investment decisions? What role, if any, should the U.S. Government play in their development?

Are minimum performance standards for cybersecurity necessary to protect individual and collective security interests? If so, how should those minimum standards be determined and what could be done to promote their adoption? Would a collaborative government-private sector partnership be appropriate here? What are the merits of providing legal safe-harbors to those individuals and commercial entities that meet a specified minimum security level? By contrast, what would be the merits or implications of enhancing existing frameworks that hold entities accountable for failure to exercise reasonable care and that results in a loss due to inadequate security measures? Should an entity be required to implement a cybersecurity plan or meet a set of minimum security standards prior to receiving government financial guarantees or assistance? Would it be beneficial to utilize government procurement policies to stimulate cybersecurity research, development, and investment generally? How do national security requirements affect the commercial sector's adoption of cybersecurity protection measures?

In addition, companies traditionally carry insurance protection to mitigate various business, natural disaster, and political risks. The growth of the Internet has begun to create a demand for new insurance products that specifically address the risk of Internet connectivity.[24] While there is growth in the adoption of cyber insurance, a compelling economic case for large scale underwriting of cyber risk insurance, apparently, has not been made. As noted above, metrics for establishing the basis for underwriting appear inadequate.

[23] For more information, please visit *http://cybersecurity.nitrd.gov.*

[24] The market for cyber insurance was estimated to be $350 million in 2005, from a negligible amount almost a decade earlier. George Mason University School of Law, Critical Infrastructure Protection Program, *The CIP Report,* at 2 (Sept. 2007), *http://cip.gmu.edu/archive/cip_report_6.3.pdf.*

What role could/should public policy play, if any, in the development of a cyber-risk measurement framework that would be useful in developing insurance products? In the face of growing risk from the increasing volume of cyber threats and vulnerabilities, what data can be made available to companies to support decisions regarding protection through the purchase of insurance products or investing more in cybersecurity protection controls? If companies were able to predictably limit financial risk through specific cyber-insurance coverage at a reliably predictable cost, how would this affect investment in cyber-security programs and infrastructure?

To what extent might insurance providers create incentives or requirements for such investment? In the absence of empirical data to quantify losses from certain types of cyber incidents, what criteria could be used to most accurately and effectively determine premium costs? What, if any, quantitative relationship can be established between investment in security controls and the cost of insurance?

Dated: July 22, 2010.

Gary Locke,

Secretary of Commerce.

Patrick Gallagher,

Director, National Institute of Standards and Technology.

Francisco J. Sánchez,

Under Secretary of Commerce for International Trade, International Trade Administration.

Lawrence E. Strickling,

Assistant Secretary for Communications and Information, National Telecommunications and Information Administration.

[FR Doc. 2010–18507 Filed 7–27–10; 8:45 am]

BILLING CODE 3510–13–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

RIN 0648–XX57

Fisheries of the Northeast Region; South Atlantic Region

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

ACTION: Notification of determination of overfishing or an overfished condition.

SUMMARY: This action serves as a notice that NMFS, on behalf of the Secretary of Commerce (Secretary), has determined that in the Northeast Region, wolffish is in an overfished condition. In the South Atlantic Region, red grouper is subject to overfishing and is in an overfished condition.

NMFS notifies the appropriate fishery management council (Council) whenever it determines that; overfishing is occurring, a stock is in an overfished condition, or a stock is approaching an overfished condition. If a Council has been notified that a stock is in an overfished condition the Council must, within 2 years, prepare and implement an FMP amendment or proposed regulations to rebuild the affected stock.

FOR FURTHER INFORMATION CONTACT: Mark Nelson, (301) 713–2341.

SUPPLEMENTARY INFORMATION: Pursuant to sections 304(e)(2) and (e)(7) of the Magnuson-Stevens Fishery Conservation and Management Act (Magnuson-Stevens Act), 16 U.S.C. 1854(e)(2) and (e)(7), and implementing regulations at 50 CFR 600.310(e)(2), NMFS, on behalf of the Secretary, notifies Councils whenever it determines; a stock or stock complex is approaching an overfished condition, a stock or stock complex is overfished, or existing action taken to prevent previously identified overfishing or rebuilding a previously identified overfished stock or stock complex has not resulted in adequate progress. NMFS also notifies Councils when it determines a stock or stock complex is subject to overfishing.

For a fishery determined to be overfished or approaching an overfished condition, NMFS also requests that the appropriate Council, or the Secretary, for fisheries under section 302(a)(3) of the Magnuson-Stevens Act, take action to end or prevent overfishing in the fishery and to implement conservation and management measures to rebuild overfished stocks. Councils (or the Secretary) receiving notification that a fishery is overfished must, within 2 years of notification, implement a rebuilding plan, through an FMP Amendment or proposed regulations, which ends overfishing immediately and provides for rebuilding the fishery in accordance with 16 U.S.C. 1854(e)(3)-(4) as implemented by 50 CFR 600.310(j)(2)(ii). Councils receiving a notice that a fishery is approaching an overfished condition must prepare and implement, within two years, an FMP amendment or proposed regulations to prevent overfishing from occurring. When developing rebuilding plans Councils (or the Secretary), in addition to rebuilding the fishery within the shortest time possible in accordance with 16 U.S.C. 1854(e)(4) and 50 CFR 600.310(j)(2)(ii), must ensure that such actions address the requirements to amend the FMP for each affected stock or stock complex to establish a mechanism for specifying and actually specify Annual Catch Limits (ACLs) and Accountability Measures (AMs) to prevent overfishing in accordance with 16 U.S.C. 1853(a)(15) and 50 CFR 600.310(j)(2)(i).

In January 2009, the Northeast Data Poor Stocks Working Group concluded that Atlantic wolffish was in an overfished condition but could not determine whether overfishing was occurring. The New England Fishery Management Council was alerted of this condition on February 6, 2009. However, at that time Atlantic wolffish was not managed under any FMP. Effective with Amendment 16 to the NE Multispecies FMP, in May 2010, wolffish was added as a fishery management unit species. Therefore, this gives public notice that wolffish is has been determined to be in an overfished condition and the overfishing status is unknown.

On July 9, 2010, NMFS informed the South Atlantic Fishery Management Council that based on the 2010 assessment of southern Atlantic coast stock of red grouper, that the stock is currently undergoing overfishing and that the stock is in an overfished condition. Prior to this assessment the previous determination was that overfishing was occurring but the overfished status was unknown.

As noted above, within 2 years of notification of an overfished determination, the respective Council (or the Secretary) must adopt and implement a rebuilding plan, through an FMP Amendment or proposed implementing regulations, which ends overfishing immediately and provides for rebuilding of the stock. In addition, for the fisheries experiencing overfishing, the responsible Councils must propose, and NMFS must adopt, effective ACLs and AMs to end overfishing.

Dated: July 22, 2010.

Emily H. Menashes,

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

[FR Doc. 2010–18536 Filed 7–27–10; 8:45 am]

BILLING CODE 3510–22–S

DEPARTMENT OF COMMERCE

Foreign-Trade Zones Board

[Order No. 1699]

Grant of Authority for Subzone Status; Yankee Candle Corporation (Candles and Gift Sets); Whately and South Deerfield, MA

Pursuant to its authority under the Foreign-Trade Zones Act of June 18, 1934, as amended (19 U.S.C. 81a–81u), the Foreign-Trade Zones Board (the Board) adopts the following Order:

Whereas, the Foreign-Trade Zones Act provides for "* * * the establishment * * * of foreign-trade zones in ports of entry of the United States, to expedite and encourage foreign commerce, and for other purposes," and authorizes the Foreign-Trade Zones Board to grant to qualified corporations the privilege of establishing foreign-trade zones in or adjacent to U.S. Customs and Border Protection ports of entry;

Whereas, the Board's regulations (15 CFR part 400) provide for the establishment of special-purpose subzones when existing zone facilities cannot serve the specific use involved, and when the activity results in a significant public benefit and is in the public interest;

Whereas, the Holyoke Economic Development and Industrial Corporation, grantee of Foreign-Trade Zone 201, has made application to the Board for authority to establish a special-purpose subzone at the candle and gift set manufacturing and distribution facilities of Yankee Candle Corporation, located in Whately and South Deerfield, Massachusetts, (FTZ Docket 2–2010, filed 1–13–2010);

Whereas, notice inviting public comment has been given in the **Federal Register** (75 FR 3705–3706, 1–22–2010) and the application has been processed pursuant to the FTZ Act and the Board's regulations; and,

Whereas, the Board adopts the findings and recommendations of the examiner's report, and finds that the requirements of the FTZ Act and Board's regulations are satisfied, and that the proposal is in the public interest;

Now, therefore, the Board hereby grants authority for subzone status for activity related to the manufacturing and distribution of candles and gift sets at the facilities of Yankee Candle Corporation, located in Whately and South Deerfield, Massachusetts (Subzone 201C), as described in the application and **Federal Register** notice, subject to the FTZ Act and the Board's regulations, including Section 400.28.

Signed at Washington, DC, July 20, 2010.

Ronald K. Lorentzen,

Deputy Assistant Secretary for Import Administration, Alternate Chairman, Foreign-Trade Zones Board.

Andrew McGilvray,

Executive Secretary.

[FR Doc. 2010–18534 Filed 7–27–10; 8:45 am]

BILLING CODE P

DEPARTMENT OF COMMERCE

International Trade Administration

Initiation of Antidumping and Countervailing Duty Administrative Reviews and Requests for Revocations in Part

AGENCY: Import Administration, International Trade Administration, Department of Commerce.

SUMMARY: The Department of Commerce ("the Department") has received requests to conduct administrative reviews of various antidumping duty orders and findings with June anniversary dates. In accordance with the Department's regulations, we are initiating those administrative reviews. The Department received requests to revoke three antidumping duty orders in part.

DATES: *Effective Date:* July 28, 2010.

FOR FURTHER INFORMATION CONTACT: Sheila E. Forbes, Office of AD/CVD Operations, Customs Unit, Import Administration, International Trade Administration, U.S. Department of Commerce, 14th Street and Constitution Avenue, NW., Washington, DC 20230, telephone: (202) 482–4697.

SUPPLEMENTARY INFORMATION:

Background

The Department has received timely requests, in accordance with 19 CFR 351.213(b), for administrative reviews of various antidumping duty orders and findings with June anniversary dates. The Department also received requests to revoke in part the antidumping duty orders on Certain Polyester Staple Fiber from the People's Republic of China ("PRC") with respect to two exporters, Polyethylene Terephthalate Film, Sheet, and Strip ("PET Film") from South Korea with respect to one exporter, and Folding Metal Tables and Chairs from the PRC with respect to one exporter.

In the notice we published on June 30, 2010 (75 FR 37759), initiating the 2009/10 administrative reviews of the antidumping duty orders on ball bearings and parts thereof from various countries, we inadvertently referred to the case numbers U.S. Customs and Border Protection ("CBP") uses in its application of the orders to entries of subject merchandise. Parties wishing to make submissions concerning the respective country-specific reviews should use, instead, the following case numbers in all such submissions to the Department: France A–427–801; Germany A–428–801; Italy A–475–801; Japan A–588–804; United Kingdom A–412–801.

Notice of No Sales

Under 19 CFR 351.213(d)(3), the Department may rescind a review where there are no exports, sales, or entries of subject merchandise during the respective period of review ("POR") listed below. If a producer or exporter named in this initiation notice had no exports, sales, or entries during the POR, it must notify the Department within 60 days of publication of this notice in the **Federal Register**. The Department will consider rescinding the review only if the producer or exporter, as appropriate, submits a properly filed and timely statement certifying that it had no exports, sales, or entries of subject merchandise during the POR. All submissions must be made in accordance with 19 CFR 351.303 and are subject to verification in accordance with section 782(i) of the Tariff Act of 1930, as amended ("the Act"). Six copies of the submission should be submitted to the Assistant Secretary for Import Administration, International Trade Administration, Room 1870, U.S. Department of Commerce, 14th Street and Constitution Avenue, NW., Washington, DC 20230. Further, in accordance with 19 CFR 351.303(f)(1)(i), a copy of each request must be served on every party on the Department's service list.

Respondent Selection

In the event the Department limits the number of respondents for individual examination for administrative reviews, the Department intends to select respondents based on CBP data for U.S. imports during the POR. We intend to release the CBP data under Administrative Protective Order ("APO") to all parties having an APO within five days of publication of this initiation notice and to make our decision regarding respondent selection within 20 days of publication of this **Federal Register** notice. The Department invites comments regarding the CBP data and respondent selection within 10 calendar days of publication of this **Federal Register** notice.

Separate Rates

In proceedings involving non-market economy ("NME") countries, the Department begins with a rebuttable

presumption that all companies within the country are subject to government control and, thus, should be assigned a single antidumping duty deposit rate. It is the Department's policy to assign all exporters of merchandise subject to an administrative review in an NME country this single rate unless an exporter can demonstrate that it is sufficiently independent so as to be entitled to a separate rate.

To establish whether a firm is sufficiently independent from government control of its export activities to be entitled to a separate rate, the Department analyzes each entity exporting the subject merchandise under a test arising from the *Final Determination of Sales at Less Than Fair Value: Sparklers from the People's Republic of China,* 56 FR 20588 (May 6, 1991), as amplified by *Final Determination of Sales at Less Than Fair Value: Silicon Carbide from the People's Republic of China,* 59 FR 22585 (May 2, 1994). In accordance with the separate-rates criteria, the Department assigns separate rates to companies in NME cases only if respondents can demonstrate the absence of both *de jure* and *de facto* government control over export activities.

All firms listed below that wish to qualify for separate-rate status in the administrative reviews involving NME countries must complete, as appropriate, either a separate-rate application or certification, as described below. For these administrative reviews, in order to demonstrate separate-rate eligibility, the Department requires entities for whom a review was requested, that were assigned a separate rate in the most recent segment of this proceeding in which they participated, to certify that they continue to meet the criteria for obtaining a separate rate. The Separate Rate Certification form will be available on the Department's Web site at *http://www.trade.gov/ia* on the date of publication of this **Federal Register**. In responding to the certification, please follow the "Instructions for Filing the Certification" in the Separate Rate Certification. Separate Rate Certifications are due to the Department no later than 60 calendar days of publication of this **Federal Register** notice. The deadline and requirement for submitting a Certification applies equally to NME-owned firms, wholly foreign-owned firms, and foreign sellers who purchase and export subject merchandise to the United States.

Entities that currently do not have a separate rate from a completed segment of the proceeding [1] should timely file a Separate Rate Application to demonstrate eligibility for a separate rate in this proceeding. In addition, companies that received a separate rate in a completed segment of the proceeding that have subsequently made changes, including, but not limited to, changes to corporate structure, acquisitions of new companies or facilities, or changes to their official company name,[2] should timely file a Separate Rate Application to demonstrate eligibility for a separate rate in this proceeding. The Separate Rate Application will be available on the Department's Web site at *http://www.trade.gov/ia* on the date of publication of this **Federal Register** notice. In responding to the Separate Rate Status Application, refer to the instructions contained in the application. Separate Rate Status Applications are due to the Department no later than 60 calendar days of publication of this **Federal Register** notice. The deadline and requirement for submitting a Separate Rate Status Application applies equally to NME-owned firms, wholly foreign-owned firms, and foreign sellers that purchase and export subject merchandise to the United States.

For exporters and producers who submit a separate-rate status application or certification and subsequently are selected as mandatory respondents, these exporters and producers will no longer be eligible for separate-rate status unless they respond to all parts of the questionnaire as mandatory respondents.

Initiation of Reviews

In accordance with section 19 CFR 351.221(c)(1)(i), we are initiating administrative reviews of the following antidumping and countervailing duty orders and findings. We intend to issue the final results of these reviews not later than June 30, 2011.

	Period to be reviewed
Antidumping Duty Proceedings	
Japan:	
Certain Large Diameter Carbon and Alloy Seamless, Standard, Line, and Pressure Pipe, A–588–850	6/1/09–5/31/10
JFE Steel Corporation	
Nippon Steel Corporation	
NKK Tubes	
Sumitomo Metal Industries, Ltd.	
South Korea:	
Polyethylene Terephthalate Film, Sheet, and Strip, A–580–807	6/1/09–5/31/10
Kolon Industries, Inc.	
The People's Republic of China:	
Certain Polyester Staple Fiber,[3] A–570–905	6/1/09–5/31/10
Far Eastern Industries, Ltd. (Shanghai) and Far Eastern Polychem Industries	
Cixi Sansheng Chemical Fiber Co., Ltd.	
Cixi Santai Chemical Fiber Co., Ltd.	
Cixi Waysun Chemical Fiber Co., Ltd.	
Hangzhou Sanxin Paper Co., Ltd.	
Nantong Luolai Chemical Fiber Co., Ltd.	
Nan Yang Textiles Co., Ltd.	
Ningbo Dafa Chemical Fiber Co., Ltd.	

[1] Such entities include entities that have not participated in the proceeding, entities that were preliminarily granted a separate rate in any currently incomplete segment of the proceedings (*e.g.,* an ongoing administrative review, new shipper review, *etc.*) and entities that lost their separate rate in the most recently complete segment of the proceeding in which they participated.

[2] Only changes to the official company name, rather than trade names, need to be addressed via a Separate Rate Application. Information regarding new trade names may be submitted via a Separate Rate Application.

	Period to be reviewed
Zhaoqing Tifo New Fiber Co., Ltd.	
Zhejiang Waysun Chemical Fiber Co., Ltd.	
Huvis Sichuan Chemical Fiber Corporation	
Chlorinated Isocyanurates,[4] A–570–898	6/1/09–5/31/10
Arch Chemicals (China) Co., Ltd.	
Hebei Jiheng Chemical Co. Ltd.	
Juancheng Kangtai Chemical Co. Ltd.	
Zhucheng Taisheng Chemical Co., Ltd.	
Folding Metal Tables and Chairs,[5] A–570–868	6/1/09–5/31/10
New-Tec Integration Co., Ltd.	
New-Tec Integration (Xiamen) Co., Ltd.	
Feili Furniture Development Ltd. Quanzhou City	
Feili Group (Fujian) Co., Ltd.	
Lifetime Hong Kong Ltd.	
Non-Frozen Apple Juice Concentrate,[6] A–570–855	6/1/09—5/31/10
Sanmenxia Luck Fruit Industry Co., Ltd.	
Qin'an Great Wall Fruit Juice Beverage Co., Ltd.	
Silicon Metal,[7] A–570–806	6/1/09–5/31/10
Shanghai Jinneng International Trade Co., Ltd.	
Jiangxi Gangyuan Silicon Industry Company, Ltd.	
Zhejiang Kaihua Yuantong Silicon Industry Co., Ltd.	
Tapered Roller Bearings and Parts Thereof, Finished and Unfinished,[8] A–570–601	6/1/09—5/31/10
Zhejiang Sihe Machine Co., Ltd	
Xinchang Kaiyuan Automotive Bearing Co., Ltd.	
Peer Bearing Company—Changshan	
Tianshui Hailin Import and Export Corporation	

Countervailing Duty Proceeding

None.

Suspension Agreements

None.

During any administrative review covering all or part of a period falling between the first and second or third and fourth anniversary of the publication of an antidumping duty order under 19 CFR 351.211 or a determination under 19 CFR 351.218(f)(4) to continue an order or suspended investigation (after sunset review), the Secretary, if requested by a domestic interested party within 30 days of the date of publication of the notice of initiation of the review, will determine, consistent with *FAG Italia* v. *United States,* 291 F.3d 806 (Fed. Cir. 2002), as appropriate, whether antidumping duties have been absorbed by an exporter or producer subject to the review if the subject merchandise is sold in the United States through an importer that is affiliated with such exporter or producer. The request must include the name(s) of the exporter or producer for which the inquiry is requested.

For the first administrative review of any order, there will be no assessment of antidumping or countervailing duties on entries of subject merchandise entered, or withdrawn from warehouse, for consumption during the relevant provisional-measures "gap" period, of the order, if such a gap period is applicable to the POR.

Interested parties must submit applications for disclosure under administrative protective orders in accordance with 19 CFR 351.305. On January 22, 2008, the Department published *Antidumping and Countervailing Duty Proceedings: Documents Submission Procedures; APO Procedures,* 73 FR 3634 (January 22, 2008). Those procedures apply to administrative reviews included in this notice of initiation. Parties wishing to participate in any of these administrative reviews should ensure that they meet the requirements of these procedures (*e.g.,* the filing of separate letters of appearance as discussed at 19 CFR 351.103(d)).

These initiations and this notice are in accordance with section 751(a) of the Act (19 U.S.C. 1675(a)), and 19 CFR 351.221(c)(1)(i).

Dated: July 21, 2010.

Edward C. Yang,

Acting Deputy Assistant Secretary for Antidumping and Countervailing Duty Operations.

[FR Doc. 2010–18535 Filed 7–27–10; 8:45 am]

BILLING CODE 3510–DS–P

[3] If one of the above-named companies does not qualify for a separate rate, all other exporters of Certain Polyester Staple Fiber from the PRC who have not qualified for a separate rate are deemed to be covered by this review as part of the single PRC entity of which the named exporters are a part.

[4] If one of the above-named companies does not qualify for a separate rate, all other exporters of Chlorinated Isocyanurates from the PRC who have not qualified for a separate rate are deemed to be covered by this review as part of the single PRC entity of which the named exporters are a part.

[5] If one of the above-named companies does not qualify for a separate rate, all other exporters of Folding Metal Tables and Chairs from the PRC who have not qualified for a separate rate are deemed to be covered by this review as part of the single PRC entity of which the named exporters are a part.

[6] If one of the above-named companies does not qualify for a separate rate, all other exporters of Non-Frozen Apple Juice Concentrate from the PRC who have not qualified for a separate rate are deemed to be covered by this review as part of the single PRC entity of which the named exporters are a part.

[7] If one of the above-named companies does not qualify for a separate rate, all other exporters of Silicon Metal from the PRC who have not qualified for a separate rate are deemed to be covered by this review as part of the single PRC entity of which the named exporters are a part.

[8] If one of the above-named companies does not qualify for a separate rate, all other exporters of Tapered Roller Bearings and Part Thereof, Finished and Unfinished from the PRC who have not qualified for a separate rate are deemed to be covered by this review as part of the single PRC entity of which the named exporters are a part.

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

RIN: 0648–XX90

Mid-Atlantic Fishery Management Council (MAFMC); Public Meetings

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

ACTION: Notice of public meetings.

SUMMARY: The Mid-Atlantic Fishery Management Council (Council) and its Research Set-Aside Committee (RSA),

its Ecosystems and Ocean Planning Committee, its Squid, Mackerel, and Butterfish (SMB) Committee, and its Executive Committee will hold public meetings.

DATES: The meetings will be held Monday, August 16, 2010 through Thursday, August 19, 2010. See **SUPPLEMENTARY INFORMATION** for specific dates and times of meetings.

ADDRESSES: The meetings will be held at the Holiday Inn, Historic District, 400 Arch Street, Philadelphia, PA 19106; telephone: (215) 923–8660.

Council address: Mid-Atlantic Fishery Management Council, 800 N. State St., Suite 201, Dover, DE 19901–3910; telephone: (302) 674–2331.

FOR FURTHER INFORMATION CONTACT: Dr. Christopher Moore, Executive Director, Mid-Atlantic Fishery Management Council; telephone: (302) 674–2331 ext. 255.

SUPPLEMENTARY INFORMATION:

Monday, August 16, 2010

12:30 p.m. to 2 p.m. - The RSA Committee will meet.

2 p.m. to 3:30 p.m. - The Ecosystems and Ocean Planning Committee will meet.

3:30 p.m. to 5 p.m. - The Squid, Mackerel, and Butterfish Committee will meet.

Tuesday, August 17, 2010

8 a.m. - The Council will convene.

8 a.m. to 8:15 a.m. - New and reappointed Council members will be sworn into office.

8:15 a.m. to 4:30 p.m. - The Council will discuss the Omnibus ACL/AM Amendment (Annual Catch Limits / Accountability Measures).

4:30 p.m. to 5:30 p.m. - The Executive Committee will meet.

Wednesday, August 18, 2010

8 a.m. - The Council will convene.

8 a.m. to 5 p.m. - The Council will finalize scup, black sea bass, summer flounder, and bluefish management measures for 2011 in conjunction with the Atlantic States Marine Fisheries Commission's (ASMFC) Summer Flounder, Scup, Black Sea Bass, and Bluefish Boards.

5 p.m. to 5:30 p.m. - The Council will receive a presentation by the National Policy Advisor for Recreational Fisheries, Office of the Assistant Administrator NOAA Fisheries.

Thursday, August 19, 2010

8 a.m. - The Council will convene.

8 a.m. to 8:30 a.m. - The Council will receive a report on the 50th Stock Assessment Review Committee.

8:30 a.m. to 9 a.m. - The Council will receive a Marine Recreational Information Program (MRIP) update.

9 a.m. to 10 a.m. - The Council will receive a presentation on the General Counsel's Enforcement and Litigation Group regarding purposes, practices, and policies.

10 a.m. to 10:45 a.m. - The Council will receive a presentation on the Final Recommendations on the Interagency Ocean Policy Task Force.

10:45 a.m. to 1:30 p.m. - The Council will convene to conduct its regular Business Session, receive Council Liaison Reports, Organizational Reports, Executive Director Reports, receive a report on the status of MAFMC's FMPs, Committee Reports, and any continuing and/or new business.

Agenda items by day for the Council's Committees and the Council itself are:

On Monday, August 16 - The RSA Committee will the review their 2012 research priorities list and their draft mission statement. The Ecosystems and Ocean Planning Committee will receive a presentation on activities of the Northeast Fishery Science Center's (NEFSC) Ecosystems Branch by Dr. Michael Fogerty. The SMB Committee will review Amendment 14 scoping comments and refine its goals and receive an update on butterfish cap control mechanism affecting the Loligo fishery from the Northeast Regional Office (NERO) officials.

On Tuesday, August 17 - new and reappointed Council members will be sworn into office. The Council will review and discuss management alternatives to address ABCs, ACLs, and AMs for all FMP species and approve and adopt the Omnibus Amendment for Secretarial submission. The Executive Committee will review the Ricks E Savage Award criteria and nomination process, excessive share project update, Scientific and Statistical Committee (SSC) membership, and Visioning Project update.

On Wednesday, August 18 - The Council in conjunction with the Atlantic States Marine Fisheries Commission's (ASMFC) Summer Flounder, Scup, and Black Sea Bass Board will review the Scientific and Statistical Committee (SSC) and the associated Monitoring Committee's specification recommendations for 2011 and adopt 2011 commercial and recreational harvest levels and commercial management measures for scup, black sea bass, and summer flounder. The Council in conjunction with the ASMFC's Bluefish Board will review the SSC and the Bluefish Monitoring Committees' specification recommendations regarding the 2011 harvest levels and associated management measures and adopt recommendations for harvest levels and associated management measures for 2011. The Council will receive a presentation by Russell Dunn, National Policy Advisor for Recreational Fisheries, Office of the Assistant Administrator NOAA Fisheries.

On Thursday, August 19 - the Council will receive a report by Dr. James Weinberg (NMFS NEFSC) on the 50th Stock Assessment Review Committee. The Council will receive an update on the MRIP provided by Gordon Colvin. The Council will receive a presentation by Mitch MacDonald on Office of General Counsel's Enforcement and Litigation Group regarding purposes, practices, and policies. The Council will receive a presentation by Samuel Rauch on the final recommendations of the Interagency Ocean Policy Task Force. The Council will hold its regular Business Session to approve the June 2010 minutes and address any outstanding actions from the June 2010 meeting, receive Liaison Reports, Organizational Reports, the Executive Director's Report, an update on the status of the Council's FMPs, Committee Reports, and any continuing and new business to include addressing a request for initiation of an Anadromous FMP.

Special Accommodations

These meetings are physically accessible to people with disabilities. Requests for sign language interpretation or other auxiliary aid should be directed to M. Jan Saunders, (302) 526–5251), at least 5 days prior to the meeting date.

Dated: July 23, 2010.

Tracey L. Thompson,

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

[FR Doc. 2010–18489 Filed 7–27–10; 8:45 am]

BILLING CODE 3510–22–S

DEPARTMENT OF COMMERCE

Bureau of Industry and Security

Materials Technical Advisory Committee; Notice of Partially Closed Meeting

The Materials Technical Advisory Committee will meet on August 12, 2010, 10 a.m., Herbert C. Hoover Building, Room 3884, 14th Street between Constitution & Pennsylvania Avenues, NW., Washington, DC. The Committee advises the Office of the Assistant Secretary for Export Administration with respect to technical questions that affect the level of export

controls applicable to materials and related technology.

Agenda

Open Session

1. Opening Remarks and Introduction.

2. Remarks from the Bureau of Industry and Security Management.

3. Report on Composite Working Group and Export Control Classification Number (ECCN) Review Subgroup.

4. Report on Regime-Based Activities.

5. Public Comments and New Business.

Closed Session

6. Discussion of matters determined to be exempt from the provisions relating to public meetings found in 5 U.S.C. app. 2 §§ 10(a)(1) and 10(a)(3).

The open session will be accessible via teleconference to 20 participants on a first come, first serve basis. To join the conference, submit inquiries to Ms. Yvette Springer at *Yspringer@bis.doc.gov* no later than August 5, 2010.

A limited number of seats will be available during the public session of the meeting. Reservations are not accepted. To the extent time permits, members of the public may present oral statements to the Committee. Written statements may be submitted at any time before or after the meeting. However, to facilitate distribution of public presentation materials to Committee members, the materials should be forwarded prior to the meeting to Ms. Springer via e-mail.

The Assistant Secretary for Administration, with the concurrence of the delegate of the General Counsel, formally determined on December 18, 2009, pursuant to Section 10(d) of the Federal Advisory Committee Act, as amended, that the portion of the meeting dealing with matters the premature disclosure of which would likely frustrate the implementation of a proposed agency action as described in 5 U.S.C. 552b(c)(9)(B) shall be exempt from the provisions relating to public meetings found in 5 U.S.C. app. 2 § § 10(a)(1) and 10(a)(3). The remaining portions of the meeting will be open to the public.

For more information, call Yvette Springer at (202) 482–2813.

Dated: July 22, 2010.

Yvette Springer,

Committee Liaison Officer.

[FR Doc. 2010–18549 Filed 7–27–10; 8:45 am]

BILLING CODE 3510–JT–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

RIN: 0648–XX88

Fisheries of the South Atlantic; South Atlantic Fishery Management Council; Public Meeting

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

ACTION: Notice of a public meeting.

SUMMARY: The South Atlantic Fishery Management Council will hold a meeting of its Golden Crab Advisory Panel in North Charleston, SC. See **SUPPLEMENTARY INFORMATION**.

DATES: The meeting will take place August 18, 2010, from 8:30 a.m. until 5 p.m.

ADDRESSES: The meeting will be held at the South Atlantic Fishery Management Council office, 4055 Faber Place Drive, Suite 201, North Charleston, SC; telephone: (843) 571–4366 or toll free: (866) SAFMC–10.

FOR FURTHER INFORMATION CONTACT: Kim Iverson, Public Information Officer, South Atlantic Fishery Management Council, 4055 Faber Place Drive, Suite 201, N. Charleston, SC 29405; telephone: (843) 571–4366 or toll free: (866) SAFMC–10; fax: (843) 769–4520; email: *kim.iverson@safmc.net*.

SUPPLEMENTARY INFORMATION: The Golden Crab Advisory Panel will receive an update on the draft catch share amendment to the Golden Crab Fishery Management Plan, review Annual Catch Limits and Overfishing Level values for the commercial golden crab fishery in the South Atlantic Economic Exclusive Zone (EEZ) and provide recommendations to the Council.

Although non-emergency issues not contained in this agenda may come before this group for discussion, in accordance with the Magnuson-Stevens Fishery Conservation and Management Act (Magnuson-Stevens Act), those issues may not be the subject of formal action during this meeting. Actions will be restricted to those issues specifically identified in this notice and any issues arising after publication of this notice that require emergency action under Section 305(c) of the Magnuson-Stevens Act, provided the public has been notified of the Council's intent to take final action to address the emergency.

Special Accommodations

The meeting is physically accessible to people with disabilities. Requests for auxiliary aids should be directed to the Council office (see **ADDRESSES**) 3 days prior to the meeting.

NOTE: The times and sequence specified in this agenda are subject to change.

Dated: July 23, 2010.

Tracey L. Thompson,

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

[FR Doc. 2010–18456 Filed 7–27–10; 8:45 am]

BILLING CODE 3510–22–S

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

RIN: 0648–XX89

North Pacific 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 North Pacific Fishery Management Council (Council) and its advisory committees will hold public meetings, August 16–19, 2010.

DATES: The Council will begin its plenary session at 8 a.m. on Wednesday, August 18 continuing through Thursday, August 19, 2010. The Council's Advisory Panel (AP) will begin at 8 a.m., Tuesday, August 17 and continue through Wednesday, August 18, 2010. The Scientific and Statistical Committee (SSC) will begin at 8 a.m. on Monday, August 16 and continue through Tuesday, August 17, 2010. All meetings are open to the public, except executive sessions.

ADDRESSES: The meetings will be held at the Hotel Captain Cook, 939 West 5th Avenue, Anchorage, AK.

Council address: North Pacific Fishery Management Council, 605 W. 4th Avenue, Suite 306, Anchorage, AK 99501–2252.

FOR FURTHER INFORMATION CONTACT: David Witherell, Council staff, telephone: (907) 271–2809.

SUPPLEMENTARY INFORMATION: Council Plenary Session: The agenda for the Council and its Advisory Committees is to review the Draft Steller Sea Lion Biological Opinion. The Council may take action as appropriate on any of the issues identified.

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 these groups 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 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: July 23, 2010.

Tracey L. Thompson,

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

[FR Doc. 2010–18457 Filed 7–27–10; 8:45 am]

BILLING CODE 3510–22–S

DEPARTMENT OF COMMERCE

International Trade Administration

(A–533–840)

Certain Frozen Warmwater Shrimp from India: Preliminary Results of Antidumping Duty Changed Circumstances Review

AGENCY: Import Administration, International Trade Administration, Department of Commerce.

EFFECTIVE DATE: July 28, 2010.

SUMMARY: The Department of Commerce (the Department) is conducting a changed circumstances review of the antidumping duty order on certain frozen warmwater shrimp (shrimp) from India pursuant to section 751(b) of the Tariff Act of 1930, as amended (the Act), and 19 CFR 351.216 and 351.221(c)(3). We preliminarily determine that Srikanth International (Srikanth) is the successor–in-interest to NGR Aqua International (NGR) for purposes of determining antidumping liability. Interested parties are invited to comment on these preliminary results.

FOR FURTHER INFORMATION CONTACT: Blaine Wiltse; AD/CVD Operations, Office 2, Import Administration, International Trade Administration, U.S. Department of Commerce, 14th Street and Constitution Avenue NW, Washington, DC 20230; telephone: (202) 482–6345.

SUPPLEMENTARY INFORMATION:

Background

On February 3, 2010, Srikanth requested that the Department conduct an expedited changed circumstances review under 19 CFR 351.221(c)(3)(iii) to determine whether it is the successor–in-interest to NGR for purposes of determining antidumping liability. On April 1, 2010, the Department initiated a changed circumstances review but did not expedite the review, as requested by Srikanth, because questions remained regarding the completeness of the factual statements forming the basis of Srikanth's changed circumstances review request. *See Certain Frozen Warmwater Shrimp From India: Initiation of Antidumping Duty Changed Circumstances Review*, 75 FR 16436 (Apr. 1, 2010) (*Initiation Notice*). On April 19 and June 3, 2010, we requested further information and documentation from Srikanth to substantiate its claim to be the successor–in-interest to NGR. Srikanth submitted this information on May 6 and June 17, 2010, respectively.

Scope of the Order

The scope of this order includes certain frozen warmwater shrimp and prawns, whether wild–caught (ocean harvested) or farm–raised (produced by aquaculture), head–on or head–off, shell–on or peeled, tail–on or tail–off,[1] deveined or not deveined, cooked or raw, or otherwise processed in frozen form.

The frozen warmwater shrimp and prawn products included in the scope of this order, regardless of definitions in the Harmonized Tariff Schedule of the United States (HTSUS), are products which are processed from warmwater shrimp and prawns through freezing and which are sold in any count size. The products described above may be processed from any species of warmwater shrimp and prawns. Warmwater shrimp and prawns are generally classified in, but are not limited to, the *Penaeidae* family. Some examples of the farmed and wild–caught warmwater species include, but are not limited to, whiteleg shrimp (*Penaeus vannemei*), banana prawn (*Penaeus merguiensis*), fleshy prawn (*Penaeus chinensis*), giant river prawn (*Macrobrachium rosenbergii*), giant tiger prawn (*Penaeus monodon*), redspotted shrimp (*Penaeus brasiliensis*), southern brown shrimp (*Penaeus subtilis*), southern pink shrimp (*Penaeus notialis*), southern rough shrimp (*Trachypenaeus curvirostris*), southern white shrimp (*Penaeus schmitti*), blue shrimp (*Penaeus stylirostris*), western white shrimp (*Penaeus occidentalis*), and Indian white prawn (*Penaeus indicus*).

Frozen shrimp and prawns that are packed with marinade, spices or sauce are included in the scope of this order. In addition, food preparations, which are not "prepared meals," that contain more than 20 percent by weight of shrimp or prawn are also included in the scope of this order.

Excluded from the scope are: 1) breaded shrimp and prawns (HTSUS subheading 1605.20.10.20); 2) shrimp and prawns generally classified in the *Pandalidae* family and commonly referred to as coldwater shrimp, in any state of processing; 3) fresh shrimp and prawns whether shell–on or peeled (HTSUS subheadings 0306.23.00.20 and 0306.23.00.40); 4) shrimp and prawns in prepared meals (HTSUS subheading 1605.20.05.10); 5) dried shrimp and prawns; 6) canned warmwater shrimp and prawns (HTSUS subheading 1605.20.10.40); 7) certain dusted shrimp; and 8) certain battered shrimp. Dusted shrimp is a shrimp–based product: 1) that is produced from fresh (or thawed–from-frozen) and peeled shrimp; 2) to which a "dusting" layer of rice or wheat flour of at least 95 percent purity has been applied; 3) with the entire surface of the shrimp flesh thoroughly and evenly coated with the flour; 4) with the non–shrimp content of the end product constituting between four and 10 percent of the product's total weight after being dusted, but prior to being frozen; and 5) that is subjected to IQF freezing immediately after application of the dusting layer. Battered shrimp is a shrimp–based product that, when dusted in accordance with the definition of dusting above, is coated with a wet viscous layer containing egg and/or milk, and par–fried.

The products covered by this order are currently classified under the following HTSUS subheadings: 0306.13.00.03, 0306.13.00.06, 0306.13.00.09, 0306.13.00.12, 0306.13.00.15, 0306.13.00.18, 0306.13.00.21, 0306.13.00.24, 0306.13.00.27, 0306.13.00.40, 1605.20.10.10, and 1605.20.10.30. These HTSUS subheadings are provided for convenience and for customs purposes only and are not dispositive, but rather the written description of the scope of this order is dispositive.

[1] "Tails" in this context means the tail fan, which includes the telson and the uropods.

Successor–in-Interest Determination

Pursuant to section 751(b)(1) of the Act and 19 CFR 351.216, the Department will conduct a changed circumstances review upon receipt of information concerning, or request from an interested party for review of, an antidumping duty order which shows changed circumstances sufficient to warrant review of the order. In this case, we found that the information submitted by Srikanth provided evidence of changed circumstances sufficient to warrant a review. *See Initiation Notice*, 75 FR at 16437. Thus, in accordance with section 751(b) of the Act, we initiated a changed circumstances review to determine whether Srikanth is the successor–in-interest to NGR. *Id.*

In making a successor–in–interest determination, the Department typically examines several factors including, but not limited to: 1) management; 2) production facilities; 3) supplier relationships; and 4) customer base. *See, e.g., Pressure Sensitive Plastic Tape from Italy: Preliminary Results of Antidumping Duty Changed Circumstances Review*, 75 FR 8925 (Feb. 26, 2010), unchanged in *Pressure Sensitive Plastic Tape From Italy: Final Results of Antidumping Duty Changed Circumstances Review*, 75 FR 27706 (May 18, 2010); *Brake Rotors From the People's Republic of China: Final Results of Changed Circumstances Antidumping Duty Administrative Review*, 70 FR 69941 (Nov. 18, 2005) (*Brake Rotors*), citing *Brass Sheet and Strip from Canada; Final Results of Antidumping Duty Administrative Review*, 57 FR 20460 (May 13, 1992). While no single factor or combination of these factors will necessarily be dispositive, the Department will generally consider the new company to be the successor to the previous company if its resulting operation is not materially dissimilar to that of its predecessor. *See, e.g., Brake Rotors*. Thus, if the record demonstrates that, with respect to the production and sale of the subject merchandise, the new company's operations are not materially dissimilar to the former company, the Department will generally accord the new company the same antidumping duty treatment as its predecessor. *Id.*

Preliminary Results of Changed Circumstances Review

In its request for a changed circumstances review, Srikanth explained that, in March 2009, it purchased the seafood processing and packing plant, including all buildings and equipment, previously owned by NGR. Srikanth submitted documentation to demonstrate its March 2009 purchase of NGR (*see* Srikanth's February 3, 2010, submission at Exhibit 7). Srikanth also provided information regarding whether there were any changes in management, production, suppliers, and customers that occurred after Srikanth acquired NGR. The information provided by Srikanth indicated that, except for one transfer of duties in management and the loss of one customer, the company's business operations otherwise had not been affected by the acquisition (*see* Srikanth's May 6, 2010, and June 17, 2010, responses). Therefore, we preliminarily find that, based on the totality of the facts and circumstances, there have been no material changes in Srikanth's operations that would cause us to question whether Srikanth is the successor–in-interest to NGR. Specifically, we preliminarily find that Srikanth is the successor–in-interest to NGR because the changes in management and customers that took place after Srikanth's purchase of NGR were not so significant as to materially alter the production or business operations of the company. For more detailed discussion of the Department's analysis and decision, see Memorandum to James Maeder, Director, Office 2, AD/CVD Operations, from Blaine Wiltse, Analyst, Office 2, AD/CVD Operations, entitled, "Changed Circumstances Review of the Antidumping Duty Order on Certain Frozen Warmwater Shrimp from India; Successor–In-Interest Determination for NGR Aqua International and Srikanth International," dated July 20, 2010.

In conclusion, as a result of this determination, we preliminarily find that Srikanth should receive the rate previously assigned to NGR in the most recently completed review of the antidumping duty order on shrimp from India. *See Certain Frozen Warmwater Shrimp from India: Final Results of Antidumping Duty Administrative Review, Partial Rescission of Review, and Notice of Revocation of Order in Part*, 75 FR 41813, 41816 (Jul. 19, 2010). If the above preliminary results are affirmed in the Department's final results, we will instruct U.S. Customs and Border Protection (CBP) to liquidate all previously unliquidated entries of the subject merchandise produced and exported by Srikanth entered, or withdrawn from warehouse, for consumption on or after the date of publication of the final results of this changed circumstances review at the rate previously assigned to NGR. Additionally, upon the adoption of these preliminary results in the Department's final results, we will instruct CBP to assign NGR's cash deposit rate to Srikanth.

Public Comment

Interested parties are invited to comment on these preliminary results. Written comments may be submitted no later than 14 days after the date of publication of these preliminary results. Rebuttals to written comments, limited to issues raised in such comments, may be filed no later than 21 days after the date of publication of this notice. All written comments shall be submitted in accordance with 19 CFR 351.303. Any interested party may request a hearing within 14 days of publication of this notice. Any hearing, if requested, will be held no later than 30 days after the date of publication of this notice, or the first workday thereafter. Persons interested in attending the hearing, if one is requested, should contact the Department for the date and time of hearing. In accordance with 19 CFR 351.216(e), the Department will issue the final results of this antidumping duty changed circumstances review no later than 270 days after the date on which this review was initiated, or within 45 days if all parties agree to our preliminary results.

During the course of this antidumping duty changed circumstances review, cash deposit requirements for the subject merchandise produced and exported by Srikanth will continue to be the all–others rate established in the investigation (*i.e.*, 10.17 percent). *See Notice of Amended Final Determination of Sales at Less Than Fair Value and Antidumping Duty Order: Certain Frozen Warmwater Shrimp from India*, 70 FR 5147, 5148 (Feb. 1, 2005). The cash deposit rate requirement for Srikanth will be altered, if warranted, pursuant to the final results of this review.

We are issuing and publishing these preliminary results and notice in accordance with sections 751(b)(1) and 777(i)(1) and (2) of the Act and 19 CFR 351.216 and 351.221(c)(3).

Dated: July 21, 2010.

Ronald K. Lorentzen,

Deputy Assistant Secretary for Import Administration.

[FR Doc. 2010–18533 Filed 7–27–10; 8:45 am]

BILLING CODE 3510–DS–S

DEPARTMENT OF DEFENSE

Office of the Secretary

Federal Advisory Committee; Department of Defense Wage Committee

AGENCY: Department of Defense (DoD).

ACTION: Notice of closed meeting.

SUMMARY: Pursuant to the provisions of section 10 of Public Law 92–463, the Federal Advisory Committee Act, notice is hereby given that a closed meeting of the Department of Defense Wage Committee will be held on August 24, 2010, in Rosslyn, VA.

DATES: The meeting will be held on Tuesday, August 24, 2010, at 10 a.m.

ADDRESSES: The meeting will be held at 1400 Key Boulevard, Level A, Room A101, Rosslyn, VA 22209.

FOR FURTHER INFORMATION CONTACT: Additional information concerning the meeting may be obtained by writing to the Chairman, Department of Defense Wage Committee, 4000 Defense Pentagon, Washington, DC 20301–4000.

SUPPLEMENTARY INFORMATION: Under the provisions of section 10(d) of Public Law 92–463, the Department of Defense has determined that the meetings meet the criteria to close meetings to the public because the matters to be considered are related to internal rules and practices of the Department of Defense and the detailed wage data to be considered were obtained from officials of private establishments with a guarantee that the data will be held in confidence.

However, members of the public who may wish to do so are invited to submit material in writing to the chairman (*see* **FOR FURTHER INFORMATION CONTACT**) concerning matters believed to be deserving of the Committee's attention.

Dated: July 22, 2010.

Mitchell S. Bryman,

Alternate OSD Federal Register Liaison Officer, Department of Defense.

[FR Doc. 2010–18427 Filed 7–27–10; 8:45 am]

BILLING CODE 5001–06–P

DEPARTMENT OF DEFENSE

Defense Representative Guam, Commonwealth of the Northern Mariana Islands, Federated States of Micronesia and Republic of Palau; Notice of Availability of Record of Decision for the Mariana Islands Range Complex

AGENCY: Department of Defense Representative Guam, Commonwealth of the Northern Mariana Islands, Federated States of Micronesia and Republic of Palau.

ACTION: Notice.

SUMMARY: After carefully weighing the operational and environmental consequences of the Proposed Action, the Department of Defense (DoD) Representative Guam, Commonwealth of the Northern Mariana Islands (CNMI), Federated States of Micronesia and Republic of Palau (DoD REP), announces his decision to support and conduct current, emerging, and future military training and Research, Development, Test, and Evaluation (RDT&E) activities in the Mariana Islands Range Complex (MIRC), while enhancing training resources through investment in the MIRC. These training and RDT&E activities are conducted by the Department of the Navy (DoN), the United States Marine Corps, the United States Air Force, Guam National Guard, the United States Coast Guard and other users based and deployed in the Western Pacific. The DoN is the Executive Agent for management of the MIRC.

The proposed action does not involve extensive changes to MIRC facilities, operations, training, or RDT&E capacities. Rather, the proposed action would result in relatively small-scale but critical enhancements to the MIRC that are necessary if the Military Services are to maintain a state of military readiness commensurate with their national defense mission. In its decision, the DoD REP considered applicable laws, regulations and executive orders, including an analysis of the effects of its actions outside the U.S. or its territories under Executive Order (EO) 12114, "Environmental Effects Abroad of Major Federal Actions".

The proposed action will be accomplished as set out in Alternative 1, described in the Final Environmental Impact Statement/Overseas Environmental Impact Statement (EIS/OEIS) as the preferred alternative. Implementation of the preferred alternative could begin immediately.

SUPPLEMENTARY INFORMATION: The Record of Decision (ROD) has been distributed to all those individuals who requested a copy of the Final EIS/OEIS and agencies and organizations that received a copy of the Final EIS/OEIS. The complete text of the ROD is available for public viewing on the project Web site at *http://www.MarianasRangeComplexEIS.com*, along with copies of the Final EIS/OEIS and supporting documents. Single copies of the ROD will be made available upon request by contacting: Mariana Islands Range Complex Environmental Impact Statement/Overseas Environmental Impact Statement (EIS/OEIS), Project Manager, Code EV21, Naval Facilities Engineering Command, Pacific, 258 Makalapa Drive, Suite 100, Pearl Harbor, HI 96869–3134, telephone number 808–472–1402.

D.J. Werner,

Lieutenant Commander, Judge Advocate General's Corps, U.S. Navy, Federal Register Liaison Officer.

[FR Doc. 2010–18455 Filed 7–27–10; 8:45 am]

BILLING CODE 3810–FF–P

DEPARTMENT OF EDUCATION

Notice of Proposed Extension of Project Period and Waiver for the State and Federal Policy Forum for Program Improvement Center (CFDA No. 84.326F)

AGENCY: Office of Special Education Programs, Office of Special Education and Rehabilitative Services, Department of Education.

ACTION: Notice of proposed extension of project period and waiver for the State and Federal Policy Forum for Program Improvement Center (CFDA No. 84.326F).

SUMMARY: The Secretary proposes to waive the requirements in the Education Department General Administrative Regulations (EDGAR), in 34 CFR 75.250 and 75.261(a) and (c), respectively, that generally prohibit project periods exceeding five years and extensions of project periods involving the obligation of additional Federal funds. This extension of project period and waiver would enable the currently funded State and Federal Policy Forum for Program Improvement Center to receive funding from October 1, 2010 through September 30, 2011.

DATES: We must receive your comments on or before August 12, 2010.

ADDRESSES: Address all comments about this proposed extension of project period and waiver to Patricia Gonzalez, U.S. Department of Education, 400 Maryland Avenue, SW., Room 4057, Potomac Center Plaza, Washington, DC 20202–2600. Telephone: (202) 245–7355.

If you prefer to send your comments by e-mail, use the following address: *patricia.gonzalez@ed.gov.* You must include the phrase "proposed extension of project period and waiver" in the subject line of your message.

FOR FURTHER INFORMATION CONTACT: Patricia Gonzalez at the address listed in the **ADDRESSES** section of this notice.

Telephone: (202) 245–7355. If you use a telecommunications device for the deaf (TDD), call the Federal Relay Service (FRS), toll-free, at 1–800–877–8339.

Individuals with disabilities can obtain this document in an accessible format (*e.g.,* braille, large print, audiotape, or computer diskette) on request to the contact person listed in this section:

Invitation To Comment

We invite you to submit comments regarding this proposed extension of project period and waiver.

During and after the comment period, you may inspect all public comments about this proposed extension of project period and waiver in room 4082, Potomac Center Plaza, 550 12th Street, SW., Washington, DC, between the hours of 8:30 a.m. and 4:00 p.m., Eastern time, Monday through Friday of each week except Federal holidays.

Assistance to Individuals With Disabilities in Reviewing the Rulemaking Record

On request, we will supply an appropriate accommodation or auxiliary aid to an individual with a disability who needs assistance to review the comments or other documents in the public rulemaking record for this proposed extension of project period and waiver. If you want to schedule an appointment for this type of accommodation or auxiliary aid, please contact the person listed under **FOR FURTHER INFORMATION CONTACT**.

Background

On March 3, 2005, the Department published a notice in the **Federal Register** (70 FR 10374), inviting applications for new awards for fiscal year (FY) 2005 under the Technical Assistance and Dissemination to Improve Services and Results for Children with Disabilities (TA&D) program, authorized under section 663 of the Individuals with Disabilities Education Act (IDEA), to support a State and Federal Policy Forum for Program Improvement Center (Project Forum). Based on that notice, the Department made one award for a period of 60 months to the National Association of State Directors of Special Education to carry out Project Forum. The purpose of Project Forum is to provide States, local educational agencies (LEAs) and Federal decision makers responsible for the implementation of the Individuals with Disabilities Education Act (IDEA) with access to valid statistics, research findings, policy analyses, and current information on trends in the provision of special education and related services and early intervention services. Specifically, Project Forum assists States and LEAs with the process of planning systemic changes that will promote improved early intervention, education, and transitional results for children with disabilities. Project Forum also provides the Office of Special Education Programs (OSEP) with a mechanism and resources for analyzing policies and emerging issues that are of significant national concern.

Project Forum's current project period is scheduled to end on September 30, 2010. We do not believe it would be in the public interest to hold new competitions under the TA&D program until the Department has considered changes being made to the Elementary and Secondary Education Act (ESEA) during the process of reauthorizing that Act and the Department has developed a coordinated strategy for the provision of technical assistance that is designed to help States, LEAs, and schools effectively implement key provisions of the ESEA and IDEA and improve educational results for all students. We also have concluded that it would be contrary to the public interest to have a lapse in the provision of technical assistance provided under the TA&D program pending the reauthorization of ESEA. For these reasons, the Secretary proposes to waive the requirements in 34 CFR 75.250, which prohibit project periods exceeding five years, and the requirements in 34 CFR 75.261(a) and (c), which limit the extension of a project period if the extension involves the obligation of additional Federal funds, and issue a continuation award in the amount of $450,000 to the National Association of State Directors of Special Education (H326F050001) for an additional twelve-month period.

Waiving these regulations and issuing this continuation award would ensure that continued technical assistance is available to assist Federal decision makers, States, and LEAs with systemic changes that will promote improved early intervention, education, and transitional results for children with disabilities, as the Department works on reauthorization of the ESEA and designs IDEA technical assistance competitions that are coordinated and aligned with the Department's technical assistance priorities.

During the next fiscal year, Project Forum would conduct the following activities:

(a) Identify, through contact with experts, research reviews, regular communication with State and local policy officials, and other types of needs assessments, the information that programs need to improve, both at the national, State, and local levels;

(b) Collect, organize, synthesize, interpret, and integrate information needed for program improvement using a variety of methods and formats such as surveys, interviews, brief case examinations, and meetings among special education administrators, outside experts, representatives of students with disabilities and their families, and others;

(c) Analyze emerging policy or program issues regarding the administration of special education, early intervention, and related services at the Federal, State, and local levels, and review, plan, and provide leadership in recommending multi-level actions that respond to emerging issues;

(d) Communicate, collaborate, and form partnerships as appropriate and as directed by OSEP, with technical assistance providers at the national and regional levels, including those that are part of the OSEP-supported special education technical assistance and dissemination network;

(e) Communicate regularly with OSEP to provide and receive information that may assist OSEP in improving its efficiency and effectiveness in administering IDEA;

(f) As a result of the activities associated with paragraphs (a) through (e), at a minimum—

(1) Complete three in-depth policy analyses;

(2) Prepare ten policy syntheses; and

(3) Convene one policy forum and write a proceedings document;

(g) Disseminate documents noted under paragraph (f) to a wide audience, including State and local directors of special education; and

(h) Maintain the project Web site.

Regulatory Flexibility Act Certification

The Secretary certifies that the proposed extension of project period and waiver would not have a significant economic impact on a substantial number of small entities. The only entity that would be affected is Project Forum.

Paperwork Reduction Act of 1995

This proposed extension of project period and waiver does not contain any information collection requirements.

Intergovernmental Review

This program is subject to the requirements of Executive Order 12372 and the regulations in 34 CFR part 79. One of the objectives of the Executive order is to foster an intergovernmental partnership and a strengthened federalism. The Executive order relies

on processes developed by State and local governments for coordination and review of proposed Federal financial assistance. This document provides early notification of our specific plans and actions for this program.

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: July 22, 2010.

Alexa Posny,

Assistant Secretary for Special Education and Rehabilitative Services.

[FR Doc. 2010–18525 Filed 7–27–10; 8:45 am]

BILLING CODE 4000–01–P

DEPARTMENT OF EDUCATION

[CFDA No. 84.326J]

Notice of Proposed Extension of Project Period and Waiver for the National Secondary Transition Technical Assistance Center

AGENCY: Office of Special Education Programs, Office of Special Education and Rehabilitative Services, Department of Education.

ACTION: Notice of proposed extension of project period and waiver for the National Secondary Transition Technical Assistance Center (CFDA No. 84.326J).

SUMMARY: The Secretary proposes to waive the requirements in the Education Department General Administrative Regulations (EDGAR), in 34 CFR 75.250 and 75.261(a) and (c), respectively, that generally prohibit project periods exceeding five years and extensions of project periods involving the obligation of additional Federal funds. This extension of project period and waiver would enable the currently funded National Secondary Transition Technical Assistance Center to receive funding from October 1, 2010 through September 30, 2011.

DATES: We must receive your comments on or before August 12, 2010.

ADDRESSES: Address all comments about this proposed extension of project period and waiver to Michael Slade, U.S. Department of Education, 400 Maryland Avenue, SW., Room 4083, Potomac Center Plaza, Washington, DC 20202–2600. *Telephone:* (202) 245–7527.

If you prefer to send your comments by e-mail, use the following address: *michael.slade@ed.gov.* You must include the phrase "proposed extension of project period and waiver" in the subject line of your message.

FOR FURTHER INFORMATION CONTACT: Michael Slade at the address listed in the **ADDRESSES** section of this notice. *Telephone:* (202) 245–7527. If you use a telecommunications device for the deaf (TDD), call the Federal Relay Service (FRS), toll-free, at 1–800–877–8339.

Individuals with disabilities can obtain this document in an accessible format (*e.g.,* braille, large print, audiotape, or computer diskette) on request to the contact person listed in this section.

SUPPLEMENTARY INFORMATION:

Invitation To Comment

We invite you to submit comments regarding this proposed extension of project period and waiver.

During and after the comment period, you may inspect all public comments about this proposed extension of project period and waiver in Room 4083, Potomac Center Plaza, 550 12th Street, SW., Washington, DC, between the hours of 8:30 a.m. and 4:00 p.m., Eastern time, Monday through Friday of each week except Federal holidays.

Assistance to Individuals With Disabilities in Reviewing the Rulemaking Record:

On request, we will supply an appropriate accommodation or auxiliary aid to an individual with a disability who needs assistance to review the comments or other documents in the public rulemaking record for this proposed extension of project period and waiver. If you want to schedule an appointment for this type of accommodation or auxiliary aid, please contact the person listed under **FOR FURTHER INFORMATION CONTACT**.

Background

On March 8, 2005, the Department published a notice in the **Federal Register** (70 FR 11214), inviting applications for new awards for fiscal year (FY) 2005 under the Technical Assistance and Dissemination to Improve Services and Results for Children with Disabilities (TA&D) program, authorized under section 663 of the Individuals with Disabilities Education Act (IDEA), to support a Secondary Transition Technical Assistance Center. Based on that notice, the Department made one award for a period of 60 months to the University of North Carolina at Charlotte to carry out the National Secondary Transition Technical Assistance Center (NSTTAC). Currently, the Office of Special Education Programs (OSEP) funds NSTTAC to support the improvement of transition planning, services, and outcomes for youth with disabilities by disseminating information and providing technical assistance (TA) on evidence-based practices with an emphasis on building and sustaining State-level infrastructures of support and building district-level demonstrations of effective transition methods. NSTTAC has demonstrated significant progress in disseminating information on evidence-based practices and providing TA to States and local educational agencies (LEAs) to advance implementation of effective transition planning and services.

NSTTAC's current project period is scheduled to end on December 31, 2010. We do not believe it would be in the public interest to hold new competitions under the TA&D program until the Department has considered changes being made to the Elementary and Secondary Education Act (ESEA) during the process of reauthorizing that Act and the Department has developed a coordinated strategy for the provision of technical assistance that is designed to help States, LEAs, and schools effectively implement key provisions of the ESEA and IDEA and improve educational results for all students. We also have concluded that it would be contrary to the public interest to have a lapse in the provision of technical assistance provided under the TA&D program pending the reauthorization of the ESEA. For these reasons, the Secretary proposes to waive the requirements in 34 CFR 75.250, which prohibit project periods exceeding five years, and the requirements in 34 CFR 75.261(a) and (c), which limit the extension of a project period if the extension involves the obligation of additional Federal funds, and issue a continuation award in the amount of $1,100,000 to the University of North Carolina at Charlotte (H326J050004) for an additional twelve-month period.

Waiving these regulations and issuing this continuation award would ensure that continued technical assistance is available to assist States and LEAs with effective transition planning and services, as the Department works on reauthorization of the ESEA and designs TA&D competitions that are coordinated

and aligned with the Department's technical assistance priorities.

During the next fiscal year, NSTTAC would continue, update, and expand its work to (1) identify evidence-based practices that provide a foundation for States to improve transition planning and services that enhance post-school outcomes; (2) disseminate information to State personnel, practitioners, researchers, parents, and students regarding effective transition planning and services that improve post-school outcomes; (3) build the capacity of States and LEAs to implement effective transition planning and services that improve post-school outcomes; and (4) assist State educational agencies with collecting data on IDEA Part B State Performance Plan/Annual Performance Report Indicator 13, which assesses States' implementation of comprehensive transition planning and services, and using these data to guide improvement activities.

Regulatory Flexibility Act Certification

The Secretary certifies that the proposed extension of project period and waiver would not have a significant economic impact on a substantial number of small entities. The only entity that would be affected is NSTTAC.

Paperwork Reduction Act of 1995

This proposed extension of project period and waiver does not contain any information collection requirements.

Intergovernmental Review

This program is subject to the requirements of Executive Order 12372 and the regulations in 34 CFR part 79. One of the objectives of the Executive order is to foster an intergovernmental partnership and a strengthened federalism. The Executive order relies on processes developed by State and local governments for coordination and review of proposed Federal financial assistance. This document provides early notification of our specific plans and actions for this program.

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.

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Dated: July 22, 2010.

Alexa Posny,

Assistant Secretary for Special Education and Rehabilitative Services.

[FR Doc. 2010–18520 Filed 7–27–10; 8:45 am]

BILLING CODE 4000–01–P

DEPARTMENT OF EDUCATION

[CFDA No. 84.326G]

Notice of Proposed Extension of Project Period and Waiver for the National Center on Educational Outcomes at the University of Minnesota

AGENCY: Office of Special Education Programs, Office of Special Education and Rehabilitative Services, Department of Education.

ACTION: Notice of proposed extension of project period and waiver for the National Center on Educational Outcomes at the University of Minnesota (CFDA No. 84.326G).

SUMMARY: The Secretary proposes to waive the requirements in the Education Department General Administrative Regulations (EDGAR), in 34 CFR 75.250 and 75.261(a) and (c), respectively, that generally prohibit project periods exceeding five years and extensions of project periods involving the obligation of additional Federal funds. This extension of project period and waiver would enable the currently funded National Center on Educational Outcomes at the University of Minnesota to receive funding from October 1, 2010 through September 30, 2011.

DATES: We must receive your comments on or before August 12, 2010.

ADDRESSES: Address all comments about this proposed extension of project period and waiver to David Malouf, U.S. Department of Education, 400 Maryland Avenue, SW., Room 4114, Potomac Center Plaza, Washington, DC 20202–2600. *Telephone:* (202) 245–6253.

If you prefer to send your comments by e-mail, use the following address: *david.malouf@ed.gov.* You must include the phrase "proposed extension of project period and waiver" in the subject line of your message.

FOR FURTHER INFORMATION CONTACT: David Malouf at the address listed in the **ADDRESSES** section of this notice. *Telephone:* (202) 245–6253. If you use a telecommunications device for the deaf (TDD), call the Federal Relay Service (FRS), toll-free, at 1–800–877–8339.

Individuals with disabilities can obtain this document in an accessible format (*e.g.,* braille, large print, audiotape, or computer diskette) on request to the contact person listed in this section.

SUPPLEMENTARY INFORMATION:

Invitation To Comment

We invite you to submit comments regarding this proposed extension of project period and waiver.

During and after the comment period, you may inspect all public comments about this proposed extension of project period and waiver in room 4114, Potomac Center Plaza, 550 12th Street, SW., Washington, DC, between the hours of 8:30 a.m. and 4:00 p.m., Eastern time, Monday through Friday of each week except Federal holidays.

Assistance to Individuals With Disabilities in Reviewing the Rulemaking Record:

On request, we will supply an appropriate accommodation or auxiliary aid to an individual with a disability who needs assistance to review the comments or other documents in the public rulemaking record for this proposed extension of project period and waiver. If you want to schedule an appointment for this type of accommodation or auxiliary aid, please contact the person listed under **FOR FURTHER INFORMATION CONTACT**.

Background

On August 8, 2005, the Department published a notice in the **Federal Register** (70 FR 45712), inviting applications for new awards for fiscal year (FY) 2005 under the Technical Assistance and Dissemination to Improve Services and Results for Children with Disabilities program (TA&D), authorized under section 663 of the Individuals with Disabilities Act (IDEA), to support a National Technical Assistance Center on Assessment for Children with Disabilities. Based on that notice, the Department made one award for a period of 60 months to the University of Minnesota, National Center on Educational Outcomes (NCEO). Under this award, the Office of Special Education Programs (OSEP) funds NCEO to address national, State, and local assessment issues related to students with disabilities. NCEO also assists OSEP with analyzing State assessment data submitted in the State Performance Plan/Annual Performance Reports (SPP/APR) required under the IDEA.

NCEO's current project period is scheduled to end on September 30, 2010. We do not believe it would be in the public interest to hold new

competitions under the TA&D program until the Department has considered changes being made to the Elementary and Secondary Education Act (ESEA) during the process of reauthorizing that Act and the Department has developed a coordinated strategy for the provision of technical assistance that is designed to help States, local educational agencies (LEAs), and schools effectively implement key provisions of the ESEA and IDEA and improve educational results for all students. We also have concluded that it would be contrary to the public interest to have a lapse in the provision of technical assistance provided under the TA&D program pending the reauthorization of ESEA. For these reasons, the Secretary proposes to waive the requirements in 34 CFR 75.250, which prohibit project periods exceeding five years, and the requirements in 34 CFR 75.261(a) and (c), which limit the extension of a project period if the extension involves the obligation of additional Federal funds, and issue a continuation award in the amount of $1,000,000 to the University of Minnesota (H326G050007) for an additional twelve-month period.

Waiving these regulations and issuing this continuation award would ensure that continued technical assistance is available to assist States with developing and implementing appropriate assessments of students with disabilities, as well as emerging issues related to the inclusion of children with disabilities in assessments, as the Department works on reauthorization of the ESEA and designs IDEA technical assistance competitions that are coordinated and aligned with the Department's technical assistance priorities.

During the next fiscal year, NCEO would (1) provide, upon request, technical assistance to States regarding the inclusion of students with disabilities as they develop new academic assessments, including assessments that consortia of States may develop under the Race to the Top Assessment Program, and assessments associated with other Federal laws (*e.g.,* the ESEA and IDEA); (2) develop and implement national and regional activities to ensure that students with disabilities are included in and benefit from emerging approaches to assessment (*e.g.,* supporting communities of practice and convening national forums); (3) continue, update, and expand analyses of State SPP/APR assessment data; (4) collect, analyze, synthesize, and disseminate relevant information related to the assessment of students with disabilities, as appropriate; and (5) serve as a national resource for policymakers, administrators, teachers, advocates, and parents on the assessment of students with disabilities.

Regulatory Flexibility Act Certification

The Secretary certifies that the proposed extension of project period and waiver would not have a significant economic impact on a substantial number of small entities. The only entity that would be affected is NCEO.

Paperwork Reduction Act of 1995

This proposed extension of project period and waiver does not contain any information collection requirements.

Intergovernmental Review

This program is subject to the requirements of Executive Order 12372 and the regulations in 34 CFR part 79. One of the objectives of the Executive order is to foster an intergovernmental partnership and a strengthened federalism. The Executive order relies on processes developed by State and local governments for coordination and review of proposed Federal financial assistance. This document provides early notification of our specific plans and actions for this program.

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: July 22, 2010.

Alexa Posny,

Assistant Secretary for Special Education and Rehabilitative Services.

[FR Doc. 2010–18524 Filed 7–27–10; 8:45 am]

BILLING CODE 4000–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

Notice of Commissioner and Staff Attendance at North American Electric Reliability Corporation Meetings

July 21, 2010.

The Federal Energy Regulatory Commission hereby gives notice that members of the Commission and/or Commission staff may attend the following meetings:

North American Electric Reliability Corporation, Member Representatives Committee and Board of Trustees Meetings. Toronto Marriott Eaton Centre, 525 Bay Street, Toronto, Ontario MSG 2L2, Canada. August 4 (1 p.m.–5 p.m.) and 5 (8 a.m.–1 p.m.), 2010.

Further information regarding these meetings may be found at: *http://www.nerc.com/calendar.php.*

The discussions at the meetings, which are open to the public, may address matters at issue in the following Commission proceedings:

Docket No. RC08–4, North American Electric Reliability Corporation
Docket No. RC08–5, North American Electric Reliability Corporation
Docket No. RC09–3, North American Electric Reliability Corporation
Docket No. RR08–4, North American Electric Reliability Corporation
Docket No. RR09–6, North American Electric Reliability Corporation
Docket No. RR09–7, North American Electric Reliability Corporation
Docket No. RR10–1, North American Electric Reliability Corporation
Docket No. RR10–7, North American Electric Reliability Corporation
Docket No. RR10–9, North American Electric Reliability Corporation
Docket No. RR10–10, North American Electric Reliability Corporation
Docket No. RR10–11, North American Electric Reliability Corporation
Docket No. RR10–12, North American Electric Reliability Corporation
Docket No. RD09–5, North American Electric Reliability Corporation
Docket No. RD09–7, North American Electric Reliability Corporation
Docket No. RD09–8, North American Electric Reliability Corporation
Docket No. RD09–11, North American Electric Reliability Corporation
Docket No. RD10–2, North American Electric Reliability Corporation
Docket No. RD10–4, North American Electric Reliability Corporation
Docket No. RD10–5, North American Electric Reliability Corporation
Docket No. RD10–6, North American Electric Reliability Corporation
Docket No. RD10–8, North American Electric Reliability Corporation
Docket No. RD10–10, North American Electric Reliability Corporation
Docket No. RD10–11, North American Electric Reliability Corporation
Docket No. RD10–12, North American Electric Reliability Corporation

For further information, please contact John Carlson, 202–502–6288, or *john.carlson@ferc.gov.*

Kimberly D. Bose,

Secretary.

[FR Doc. 2010–18431 Filed 7–27–10; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Project No. 405–097]

Exelon Generation Company, LLC; Notice of Dispute Resolution Process Schedule, Panel Meeting and Technical Conference

July 21, 2010.

On February 25, 2010, the state of Maryland Department of the Environment (Maryland DOE) filed a Notice to initiate formal study dispute resolution process pursuant to 18 CFR 5.14. Maryland DOE disputed the Commission's study determinations on the following studies: (1) Seasonal and diurnal water quality in Conowingo Pond and below Conowingo dam (study 3.1); (2) downstream fish passage effectiveness study (study 3.2); (3) hydrologic study of the lower Susquehanna River (study 3.11); and (4) characterization of downstream aquatic communities (study 3.18).

On March 5, 2010, Commission staff denied Maryland DOE's request for formal study dispute resolution. In response, Maryland DOE filed a request for rehearing on the matter on March 19, 2010, and on May 20, 2010, the Commission granted Maryland DOE formal dispute resolution pending filing of an explanation of how the requested studies apply to its consideration of Clean Water Act section 401 certification. Maryland DOE filed its explanation on June 3, 2010, and requested that two panels be established, each with a different representative for Maryland DOE. On June 18, 2010, Commission staff directed Maryland DOE to designate a single panelist as its representative for all disputed studies. Maryland DOE designated Mr. Jim Uphoff as its single panelist on June 23, 2010.

The schedule for the dispute resolution process is as follows:

Pre-filing milestone	Date
Notice of Dispute Resolution Process Schedule, Panel Meeting, and Technical Conference	Weds, 7/21/2010.
Dispute Resolution Panel Convenes	Tues, 8/10/2010.
Applicant Comments on Study Dispute	Mon, 8/16/2010.
Dispute Resolution Panel Technical Conference	Tues, 8/31/2010.
Dispute Resolution Panel Findings	Thurs, 9/9/2010.
Director's Study Dispute Determination	Weds, 9/29/2010.

As noted above, the Panel will hold a technical conference on the disputed studies on Tuesday, August 31, 2010. Details will be supplied in a future notice.

For more information, please contact Stephen Bowler, the Dispute Panel Chair, at *stephen.bowler@ferc.gov* or 202–502–6861.

Kimberly D. Bose,

Secretary.

[FR Doc. 2010–18432 Filed 7–27–10; 8:45 am]

BILLING CODE 6717–01–P

ENVIRONMENTAL PROTECTION AGENCY

[EPA–HQ–OECA–2010–0375; FRL–9181–6]

Agency Information Collection Activities; Submission to OMB for Review and Approval; Comment Request; NESHAP for Petroleum Refineries, Catalytic Cracking, Reforming and Sulfur Units (Renewal); EPA ICR Number 1844.04, OMB Control Number 2060–0554

AGENCY: Environmental Protection Agency.

ACTION: Notice.

SUMMARY: In compliance with the Paperwork Reduction Act (44 U.S.C. 3501 *et seq.*), this document announces that an Information Collection Request (ICR) has been forwarded to the Office of Management and Budget (OMB) for review and approval. This is a request to renew an existing approved collection. The ICR which is abstracted below describes the nature of the collection and the estimated burden and cost.

DATES: Additional comments may be submitted on or before August 27, 2010.

ADDRESSES: Submit your comments, referencing docket ID number EPA–HQ–OECA–2010–0375, to (1) EPA online using *http://www.regulations.gov* (our preferred method), or by e-mail to *docket.oeca@epa.gov,* or by mail to: EPA Docket Center (EPA/DC), Environmental Protection Agency, Enforcement and Compliance Docket and Information Center, mail code 28221T, 1200 Pennsylvania Avenue, NW., Washington, DC 20460, and (2) OMB at: Office of Information and Regulatory Affairs, Office of Management and Budget (OMB), Attention: Desk Officer for EPA, 725 17th Street, NW., Washington, DC 20503.

FOR FURTHER INFORMATION CONTACT: Robert Marshall, Jr., Compliance Assessment and Media Programs Division (Mail Code 2223A), Office of Compliance, Environmental Protection Agency, 1200 Pennsylvania Avenue, NW., Washington, DC 20460; telephone number: (202) 564–7021; fax number: (202) 564–0050; e-mail address: *marshall.robert@epa.gov.*

SUPPLEMENTARY INFORMATION: EPA has submitted the following ICR to OMB for review and approval according to the procedures prescribed in 5 CFR 1320.12. On October 6, 2006 (75 FR 30813), EPA sought comments on this ICR pursuant to 5 CFR 1320.8(d). EPA received no comments. Any additional comments on this ICR should be submitted to EPA and OMB within 30 days of this notice.

EPA has established a public docket for this ICR under docket ID number EPA–HQ–OECA–2010–0375, which is available for public viewing online at *http://www.regulations.gov,* or in person viewing at the Enforcement and Compliance Docket and Information Center in the EPA Docket Center (EPA/DC), EPA West, Room 3334, 1301 Constitution Avenue, 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 Reading Room is (202) 566–1744, and the telephone number for the Enforcement and Compliance Docket and Information Center is (202) 566–1752.

Use EPA's electronic docket and comment system at *http://www.regulations.gov,* to submit or view public comments, access the index listing of the contents of the docket, and to access those documents in the docket that are available electronically. Once in the system, select "docket search," then key in the docket ID number identified above. Please note that EPA's policy is that public comments, whether submitted electronically or in paper, will be made available for public viewing at *http://www.regulations.gov,* as EPA receives them and without change, unless the comment contains copyrighted material, Confidential Business Information (CBI) or other information whose public disclosure is restricted by statute. For further information about the electronic docket, go to *http://www.regulations.gov.*

Title: NESHAP for Petroleum Refineries, Catalytic Cracking, Reforming and Sulfur Units (Renewal).

ICR Numbers: EPA ICR Number 1844.04, OMB Control Number 2060–0554.

ICR Status: This ICR is scheduled to expire on October 31, 2010. Under OMB regulations, the Agency may continue to conduct or sponsor the collection of information while this submission is pending at OMB. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. The OMB control numbers for EPA's regulations in title 40 of the CFR, after appearing in the **Federal Register** when approved, are listed in 40 CFR part 9, and displayed either by publication in the **Federal Register** or by other appropriate means, such as on the related collection instrument or form, if applicable. The display of OMB control numbers in certain EPA regulations is consolidated in 40 CFR part 9.

Abstract: The National Emission Standards for Hazardous Air Pollutants (NESHAP) for Petroleum Refineries, Catalytic Cracking, Reforming and Sulfur Units (40 CFR part 63, subpart UUU) were proposed on September 11, 1998, promulgated on April 11, 2002, and amended on February 09, 2005.

In general, all NESHAP standards require initial notifications, performance tests, and periodic reports. Owners or operators are also required to maintain records of the occurrence and duration of any startup, shutdown, or malfunction in the operation of an affected facility, or any period during which the monitoring system is inoperative. These notifications, reports, and records are essential in determining compliance, and are required of all sources subject to NESHAP. Specifically, data is being collected on performance of the continuous monitoring systems for gasoline vapor and related hazardous air pollutants (HAPs), any excess emissions, and any operating parameter exceedances.

Any owner or operator subject to the provisions of this part shall maintain a file of these measurements, and retain the file for at least five years following the date of such measurements, maintenance reports, and records. All reports are sent to the delegated state or local authority. In the event that there is no such delegated authority, the reports are sent directly to the United States Environmental Protection Agency (EPA) regional office.

Burden Statement: The annual public reporting and recordkeeping burden for this collection of information is estimated to average 42 (rounded) hours per response. Burden means the total time, effort, or financial resources expended by persons to generate, maintain, retain, or disclose or provide information to or for a Federal agency. This includes the time needed to review instructions; develop, acquire, install, and utilize technology and systems for the purposes of collecting, validating, and verifying information, processing and maintaining information, and disclosing and providing information; adjust the existing ways to comply with any previously applicable instructions and requirements which have subsequently changed; train personnel to be able to respond to a collection of information; search data sources; complete and review the collection of information; and transmit or otherwise disclose the information.

Respondents/Affected Entities: Owners or operators of petroleum refineries.

Estimated Number of Respondents: 132.

Frequency of Response: Initially and semiannually.

Estimated Total Annual Hour Burden: 11,040 hours.

Estimated Total Annual Cost: $8,814,941, which includes $983,339 of annualized labor costs, no annualized capital/startup costs, and $7,831,602 in annualized operating and maintenance (O&M) costs.

Changes in the Estimates: There is no change in the labor hours or cost to the respondents in this ICR compared to the previous ICR. This is due to two considerations: (1) The regulations have not changed over the past three years and are not anticipated to change over the next three years; and (2) the growth rate for the respondents is very low, negative, or non-existent. Therefore, the labor hours and cost figures in the previous ICR reflect the current burden to the respondents and are reiterated in this ICR. However, there is a correction of a previous error in the calculation of the O&M costs from $6,850,602 to $7,831,602.

Dated: July 22, 2010.

John Moses,

Director, Collection Strategies Division.

[FR Doc. 2010–18559 Filed 7–27–10; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

[EPA–HQ–OAR–2010–0258; FRL–9181–9]

Agency Information Collection Activities; Submission to OMB for Review and Approval; Comment Request; Recordkeeping and Reporting Requirements Regarding the Sulfur Content of Motor Vehicle Gasoline Under the Tier 2 Rule (Renewal), EPA ICR Number 1907.05, OMB Control Number 2060–0437

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: In compliance with the Paperwork Reduction Act (44 U.S.C. 3501 *et seq.*), this document announces that an Information Collection Request (ICR) has been forwarded to the Office of Management and Budget (OMB) for review and approval. This is a request for a renewal of an existing approved collection. This ICR describes the nature of the information collection and its estimated burden and cost.

DATES: Additional comments may be submitted on or before August 27, 2010.

ADDRESSES: Submit your comments, referencing docket ID number EPA–HQ–OAR–2010–0258, to (1) EPA online using *http://www.regulations.gov* (our preferred method), by e-mail to *a-and-r-docket@epa.gov,* or by mail to: EPA Docket Center, Environmental Protection Agency, Air and Radiation Docket and Information Center, Mail Code 28221T, 1200 Pennsylvania Ave., NW., Washington, DC 20460, and (2) OMB by mail to: Office of Information and Regulatory Affairs, Office of Management and Budget (OMB), *Attention:* Desk Officer for EPA, 725 17th Street, NW., Washington, DC 20503.

FOR FURTHER INFORMATION CONTACT: Geanetta Heard, Office of Transportation and Air Quality, Mail Code 6406J, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington,

DC 20460; *telephone number:* 202–343–9017; *fax number:* 202–343–2801; *e-mail address: heard.geanetta@epa.gov.*

SUPPLEMENTARY INFORMATION: EPA has submitted the following ICR to OMB for review and approval according to the procedures prescribed in 5 CFR 1320.12. On April 2, 2010 (75 FR 16786), EPA sought comments on this ICR pursuant to 5 CFR 1320.8(d). EPA received no comments. Any additional comments on this ICR should be submitted to EPA and OMB within 30 days of this notice.

EPA has established a public docket for this ICR under Docket ID No. EPA–HQ–OAR–2010–0258, which is available for online viewing at *http://www.regulations.gov* or in person viewing at the Air and Radiation Docket and Information Center in the EPA Docket Center (EPA/DC), 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 Reading Room is (202) 566–1744, and the telephone number for the Office of Air and Radiation Docket is (202) 566–1742.

Use EPA's electronic docket and comment system at *http://www.regulations.gov* to submit or view public comments, access the index listing of the contents of the docket, and to access those documents in the docket that are available electronically. Once in the system, select "docket search," then key in the docket ID number identified above. Please note that EPA's policy is that public comments, whether submitted electronically or in paper, will be made available for public viewing at *http://www.regulations.gov* as EPA receives them and without change, unless the comment contains copyrighted material, confidential business information (CBI), or other information whose public disclosure is restricted by statute. For further information about the electronic docket, go to *http://www.regulations.gov.*

Title: Recordkeeping and Reporting Requirements Regarding the Sulfur Content of Motor Vehicle Gasoline under the Tier 2 Rule (Renewal).

ICR Numbers: EPA ICR No. 1907.05, OMB Control Number 2060–0437.

ICR Status: This ICR is scheduled to expire on July 31, 2010. Under OMB regulations, the Agency may continue to conduct or sponsor the collection of information while this submission is pending at OMB. An Agency may not conduct or sponsor, and a person is not required to respond to, a collection of information, unless it displays a currently valid OMB control number. The OMB control numbers for EPA's regulations in title 40 of the CFR, after appearing in the Federal Register when approved, are listed in 40 CFR part 9 and are displayed either by publication in the Federal Register or by other appropriate means, such as on the related collection instrument or form, if applicable. The display of OMB control numbers in certain EPA regulations is consolidated in 40 CFR part 9.

Abstract: With this ICR renewal, EPA is seeking permission to continue recordkeeping and reporting requirements for refiners and importers as they relate to gasoline sulfur content of motor vehicles under Section 211(e)(1) of the Clean Air Act and 40 CFR part 80, subpart H, and to provide a compliance option whereby a refiner or importer may demonstrate compliance with the gasoline sulfur control requirement via test results. These provisions, which have been in effect since 2006, are designed to grant compliance flexibility.

Burden Statement: The annual public reporting and recordkeeping burden for this collection of information is estimated to average 1 hour per response. Burden means the total time, effort, or financial resources expended by persons to generate, maintain, retain, or disclose or provide information to or for a Federal agency. This includes the time needed to review instructions; develop, acquire, install, and utilize technology and systems for the purposes of collecting, validating, and verifying information, processing and maintaining information, and disclosing and providing information; adjust the existing ways to comply with any previously applicable instructions and requirements which have subsequently changed; train personnel to be able to respond to a collection of information; search data sources; complete and review the collection of information; and transmit or otherwise disclose the information.

Respondents/Affected Entities: Gasoline Refiners, Importers, Gasoline Terminals, Pipelines, Truckers and Users of Research and Development Gasoline.

Estimated Number of Respondents: 1,380.

Frequency of Response: On occasion, monthly and annually.

Estimated Total Annual Hour Burden: 38,498.

Estimated Total Annual Cost: $2,569,634 in labor costs. There are no annualized capital or O&M costs.

Changes in the Estimates: The annual burdens and cost estimates for gasoline refiners and importers decreased slightly to account for the expiration of the requirements for refineries of geographic phase-in area gasoline. The total hourly burden decreased 75 hours, the total cost decreased by $4,320 and the total number of responses decreased by 60.

Dated: July 22, 2010.

John Moses,

Director, Collection Strategies Division.

[FR Doc. 2010–18554 Filed 7–27–10; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

[EPA–HQ–OECA–2010–0341; FRL–9181–5]

Agency Information Collection Activities; Submission to OMB for Review and Approval; Comment Request; NESHAP for Automobile and Light-Duty Truck Surface Coating (Renewal), EPA ICR Number 2045.04, OMB Control Number 2060–0550

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: In compliance with the Paperwork Reduction Act (44 U.S.C. 3501 *et seq.*), this document announces that an Information Collection Request (ICR) has been forwarded to the Office of Management and Budget (OMB) for review and approval. This is a request to renew an existing approved collection. The ICR which is abstracted below describes the nature of the collection and the estimated burden and cost.

DATES: Additional comments may be submitted on or before August 27, 2010.

ADDRESSES: Submit your comments, referencing docket ID number EPA–HQ–OECA–2010–0341 to (1) EPA online using *http://www.regulations.gov* (our preferred method), or by e-mail to *docket.oeca@epa.gov,* or by mail to: EPA Docket Center (EPA/DC), Environmental Protection Agency, Enforcement and Compliance Docket and Information Center, mail code 28221T, 1200 Pennsylvania Avenue, NW., Washington, DC 20460, and (2) OMB at: Office of Information and Regulatory Affairs, Office of Management and Budget (OMB), *Attention:* Desk Officer for EPA, 725 17th Street, NW., Washington, DC 20503.

FOR FURTHER INFORMATION CONTACT: Learia Williams, Compliance Assessment and Media Programs Division, Office of Compliance, Mail Code 2223A, Environmental Protection Agency, 1200 Pennsylvania Avenue, NW., Washington, DC 20460; *telephone*

number: (202) 564–4113; *fax number:* (202) 564–0050; *e-mail address: williams.learia@epa.gov.*

SUPPLEMENTARY INFORMATION: EPA has submitted the following ICR to OMB for review and approval according to the procedures prescribed in 5 CFR 1320.12. On June 2, 2010 (75 *FR* 30813), EPA sought comments on this ICR pursuant to 5 CFR 1320.8(d). EPA received no comments. Any additional comments on this ICR should be submitted to EPA and OMB within 30 days of this notice.

EPA has established a public docket for this ICR under docket ID number EPA–HQ–OECA–2010–0341, which is available for public viewing online at *http://www.regulations.gov,* in person viewing at the Enforcement and Compliance Docket in the EPA Docket Center (EPA/DC), EPA West, Room 3334, 1301 Constitution Avenue, 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 Reading Room is (202) 566–1744, and the telephone number for the Enforcement and Compliance Docket is (202) 566–1752.

Use EPA's electronic docket and comment system at *http://www.regulations.gov,* to submit or view public comments, access the index listing of the contents of the docket, and to access those documents in the docket that are available electronically. Once in the system, select "docket search," then key in the docket ID number identified above. Please note that EPA's policy is that public comments, whether submitted electronically or in paper will be made available for public viewing at *http://www.regulations.gov,* as EPA receives them and without change, unless the comment contains copyrighted material, Confidential Business Information (CBI), or other information whose public disclosure is restricted by statute. For further information about the electronic docket, go to *http://www.regulations.gov.*

Title: NESHAP for Automobile and Light-duty Truck Surface Coating (Renewal).

ICR Numbers: EPA ICR Number 2045.04, OMB Control Number 2060–0550.

ICR Status: This ICR is scheduled to expire on October 31, 2010. Under OMB regulations, the Agency may continue to conduct or sponsor the collection of information while this submission is pending at OMB. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. The OMB control numbers for EPA's regulations in title 40 of the CFR, after appearing in the **Federal Register** when approved, are listed in 40 CFR part 9, and displayed either by publication in the **Federal Register** or by other appropriate means, such as on the related collection instrument or form, if applicable. The display of OMB control numbers in certain EPA regulations is consolidated in 40 CFR part 9.

Abstract: The National Emission Standards for Hazardous Air Pollutants (NESHAP) for Automobile and Light-duty Truck Surface Coating (40 CFR Part 63, Subpart IIII) were proposed on December 24, 2002, and promulgated on April 26, 2004. These standards apply to facilities in automobile and light-duty truck surface coating operations that are major sources of hazardous air pollutants (HAP). Owners or operators of the affected facilities described must make initial reports when a source becomes subject to the standard, conduct and report on a performance test, demonstrate and report on continuous monitor performance, and maintain records of the occurrence and duration of any startup, shutdown, or malfunction in the operation of an affected facility. In general, all NESHAP requires initial notifications, performance tests, and periodic reports.

These notifications, reports, and records are essential in determining compliance, and in general, are required of all sources subject to NESHAP. Semiannual reports of excess emissions are also required.

Any owner or operator subject to the provisions of this part shall maintain a file of these measurements, and retain the records for at least five years following the date of such measurements, maintenance reports, and records. Performance tests reports are required as this is the Agency's record of a source's initial capability to comply with the emission standard, and serve as a record of the operating conditions under which compliance was achieved.

All reports are sent to the delegated state or local authority. In the event that there is no such delegated authority, the reports are sent directly to the EPA regional office. This information is being collected to assure compliance with 40 CFR part 63, subpart IIII, as authorized in sections 112 and 114(a) of the Clean Air Act. The required information consists of emissions data and other information that have been determined to be private.

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB Control Number. The OMB Control Number for EPA regulations listed in 40 CFR part 9 and 48 CFR chapter 15, are identified on the form and/or instrument, if applicable.

Burden Statement: The annual public reporting and recordkeeping burden for this collection of information is estimated to average 91 hours per response. Burden means the total time, effort, or financial resources expended by persons to generate, maintain, retain, or disclose, and provide information to or for a Federal agency. This includes the time needed to review instructions; develop, acquire, install, and utilize technology and systems for the purposes of collecting, validating, and verifying information, processing and maintaining information, and disclosing and providing information. All existing ways will have to adjust to comply with any previously applicable instructions and requirements that have subsequently changed; train personnel to be able to respond to a collection of information; search data sources; complete and review the collection of information; and transmit or otherwise disclose the information.

Respondents/Affected Entities: Automobile and light-duty truck surface coating facilities.

Estimated Number of Respondents: 65.

Frequency of Response: Initially, semiannually, and occasionally.

Estimated Total Annual Hour Burden: 25,190.

Estimated Total Annual Cost: $2,321,787 which includes $2,243,787 in labor costs, no capital/startup costs, and $78,000 in operation and maintenance (O&M) costs.

Changes in the Estimates: There is no change in the labor hours or cost in this ICR compared to the previous ICR. This is due to two considerations: (1) The regulations have not changed over the past three years and are not anticipated to change over the next three years; and (2) the growth rate for the industry is very low, negative or non-existent. Therefore, there is no significant change in the overall burden.

Since there are no changes in the regulatory requirements and there is no significant industry growth, the labor hours and cost figures in the previous ICR are used in this ICR, and there is no change in burden to industry.

Dated: July 22, 2010.

John Moses,

Director, Collection Strategies Division.

[FR Doc. 2010–18556 Filed 7–27–10; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

[EPA–HQ–OPP–2010–0535; FRL–8835–2]

Cancellation of Pesticides for Non-Payment of Year 2010 Registration Maintenance Fees

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: Since the amendments of October 1988, the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) have required payment of an annual maintenance fee to keep pesticide registrations in effect. The fee due last January 15, 2010, has gone unpaid for 337 registrations. Section 4(i)(5)(G) of FIFRA provides that the EPA Administrator may cancel these registrations by order and without a hearing; orders to cancel all 337 of these registrations have been issued within the past few days.

DATES: A cancellation is effective on the date the cancellation order is signed.

FOR FURTHER INFORMATION CONTACT: John Jamula, Information Technology and Resources Management Division (7502P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001; telephone number: (703) 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. How Can I Get Copies of this Document and Other Related Information?

EPA has established a docket for this action under docket identification (ID) number EPA–HQ–OPP–2010–0535. 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 Office of Pesticide Programs (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.

II. Background

Section 4(i)(5) of FIFRA, as amended in October 1988 (Public Law 100–532), December 1991 (Public Law 102–237), and again in August 1996 (Public Law 104–170), requires that all pesticide registrants pay an annual registration maintenance fee, due by January 15 of each year, to keep their registrations in effect. This requirement applies to all registrations granted under FIFRA section 3 as well as those granted under FIFRA section 24(c) to meet special local needs. Registrations for which the fee is not paid are subject to cancellation by order and without a hearing.

The Food, Agriculture, Conservation, and Trade Act Amendments of 1991, Public Law 102–237, amended FIFRA to allow the EPA Administrator to reduce or waive maintenance fees for minor agricultural use pesticides when she determines that the fee would be likely to cause significant impact on the availability of the pesticide for the use. The Agency has waived the fee for 193 minor agricultural use registrations at the request of the registrants.

In fiscal year 2010, maintenance fees were collected in one billing cycle. The Pesticide Registration Improvement Renewal Act (PRIRA) was passed by Congress in October 2007. PRIRA authorized the Agency to collect 22 million dollars in maintenance fees in fiscal year 2010. In late November, 2009, all holders of either FIFRA section 3 registrations or FIFRA section 24(c) registrations were sent lists of their active registrations, along with forms and instructions for responding. They were asked to identify which of their registrations they wished to maintain in effect, and to calculate and remit the appropriate maintenance fees. Most responses were received by the statutory deadline of January 15. A notice of intent to cancel was sent in February, 2010 to companies who did not respond and to companies who responded, but paid for less than all of their registrations. Since mailing the notices of intent to cancel, EPA has maintained a toll-free inquiry number through which the questions of affected registrants have been answered.

Maintenance fees have been paid for about 16,377 FIFRA section 3 registrations, or about 97% of the registrations on file in December, 2009. Fees have been paid for about 2,301 FIFRA section 24(c) registrations, or about 95% of the total on file in December, 2009. Cancellations for non-payment of the maintenance fee affect about 309 FIFRA section 3 registrations and about 28 FIFRA section 24(c) registrations.

The cancellation orders generally permit registrants to continue to sell and distribute existing stocks of the cancelled products until January 15, 2011, one year after the date on which the fee was due. Existing stocks already in the hands of dealers or users, however, can generally be distributed, sold, or used legally until they are exhausted. Existing stocks are defined as those stocks of a registered pesticide product 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 order.

The exceptions to these general rules are cases where more stringent restrictions on sale, distribution, or use of the products have already been imposed, through special reviews or other Agency actions. These general provisions for disposition of stocks should serve in most cases to cushion the impact of these cancellations while the market adjusts.

III. Listing of Registrations Cancelled for Non-Payment

Table 1 of this unit lists all of the FIFRA section 24(c) registrations, and Table 2 of this unit lists all of the FIFRA section 3 registrations which were cancelled for non-payment of the 2010 maintenance fee. These registrations have been cancelled by order and without hearing. Cancellation orders were sent to affected registrants via certified mail in the past several days. The Agency is unlikely to rescind cancellation of any particular registration unless the cancellation resulted from Agency error.

TABLE 1.—FIFRA SECTION 24(C) REGISTRATIONS CANCELLED FOR NON-PAYMENT OF 2010 MAINTENANCE FEE

SLN No.	Product Name
001677 CA–00–0011	Oxy-15
079709 CA–09–0009	Methyl Bromide 100
059623 CA–77–0445	Gowan Malathion 8
036029 CA–79–0145	Wilco “gopher Getter” Restricted Use Bait 1.80%

TABLE 1.—FIFRA SECTION 24(C) REGISTRATIONS CANCELLED FOR NON-PAYMENT OF 2010 MAINTENANCE FEE—Continued

SLN No.	Product Name
068722 CA–94–0028	Roundup Export Herbicide
067858 FL–03–0012	Dylox 80 Turf and Ornamental Insecticide
035253 FL–88–0013	Soluble 97 Oil-455
054555 GA–03–0006	Dormex
002749 ID–05–0004	Sprout Nip Briquette
002749 ME–00–0004	CIPC 98a
000655 MN–03–0014	Prentox Synpren-Fish Toxicant
002749 MN–05–0007	Sprout Nip Briquette
082597 MS–09–0016	Prothor WP
002749 ND–05–0009	Sprout Nip Briquette
056576 NE–08–0003	Copper Sulfate Crystals
039924 NJ–02–0001	Universal Chemicals Sodium Hypochlorite
056228 NV–01–0006	Compound Drc-1339 98% Concentrate-Livestock Nest & Fodder Depredations
036029 NV–07–0008	Wilco Gopher Getter Restricted Use Bait
060217 OR–03–0023	Sprout Nip Emulsifiable Concentrate
002749 OR–06–0022	Spud NIC-3 EC
000655 PA–86–0009	Prentox Vapon 4e
072642 PR–04–0007	Elector
056228 TN–02–0001	Compound Drc-1339 Concentrate-Feedlots
056228 TN–02–0002	Compound Drc-1339 Concentrate-Staging Areas

TABLE 1.—FIFRA SECTION 24(C) REGISTRATIONS CANCELLED FOR NON-PAYMENT OF 2010 MAINTENANCE FEE—Continued

SLN No.	Product Name
084127 WA–07–0018	Ethoywrap
066158 WA–92–0026	Di-Syston 8
002749 WI–07–0003	Sprout Nip Briquette

TABLE 2.—SECTION 3 REGISTRATIONS CANCELLED FOR 2010 NON-PAYMENT OF MAINTENANCE FEE

Registration No.	Product Name
000052–00063	West Sanikleen
000211–00063	Pro-Tech Disinfectant Cleaner
000278–00045	Cuprogen Swimming Pool Algaecide
000278–00063	Miami Liquid Chlorinating Disinfectant & Germicide
000303–00091	Hi-Tor Germicidal Detergent
000421–00434	#25 Quaternary Ammonium Cleaner-Disinfectant
000475–00337	Swish
000655–00013	Prentox Pyrethrum Powder 0.9%
000655–00133	Prentox Pyrethrum Powder 1.3%
000655–00322	Prentox Pyrethrum 1%
000655–00347	Prentox Pyronyl Dry Concentrate
000655–00479	Prentox Pco Pyrethrum Powder 0.9%
000655–00503	Co-Rax Concentrate Rp
000655–00787	Prentox Resmethrin Ec3
000675–00021	Amphyl Disinfectant Deodorant Detergent
000675–00026	Quatsyl 256

TABLE 2.—SECTION 3 REGISTRATIONS CANCELLED FOR 2010 NON-PAYMENT OF MAINTENANCE FEE—Continued

Registration No.	Product Name
000675–00033	Vani-Sol Disinfectant Washroom Cleaner
000675–00034	Vani-Sol Per Diem
000675–00035	Vani Sol Bulk Disinfectant Washroom Cleaner
000675–00057	Formula GP
000777–00027	Lysol Brand Disinfectant Aerosol Foam Deodorizing Cleaner
000777–00029	Lysol Liquid Disinfectant Toilet Bowl Cleaner
000777–00051	Lysol Brand Disinfectant Bathroom Cleaner for Basin Tub & Tile
000777–00058	Lysol Brand Scouring Cream
000777–00060	Lysol Brand Pine Action
000777–00063	Lysol Brand Disinfectant Cling Thick Liquid Toilet Bowl Cleaner
000777–00064	Lysol Brand Laundry Sanitizer (No Phosphate)
000777–00065	Lysol Brand Disinfectant Foam Power Heavy Duty Bathroom Cleaner
000777–00067	Lysol Brand Bathroom Touch-Ups Disinfectant Cleaning Wipes
000777–00069	Extra Care Laundry Detergent
000777–00072	Biosol
000777–00073	Lysol Brand Disinfectant Trigger Spray
000777–00075	Barrage Pine Action Cleaner
000777–00076	QU-SOL Brand Disinfectant

TABLE 2.—SECTION 3 REGISTRATIONS CANCELLED FOR 2010 NON-PAYMENT OF MAINTENANCE FEE—Continued

Registration No.	Product Name
000777–00077	Lysol Brand Disinfectant Basin, Tub, & Tile Cleaner Pre-Moistened Wipe
000777–00078	Lysol Brand Disinfectant Multi-Purpose Cleaner
000777–00079	Lysol Brand Disinfectant Pine Scent Basin Tub & Tile Cleaner
000777–00086	Lysol Brand Hard Water Stain Cleaner
000777–00095	Rb102 (crisp Linen Lysol Disinfectant Pump)
000777–00096	Biosol
001124–00077	Franklin Sani-Turge 256
001124–00102	Franklin AQ+
001278–00005	Triangle Brand Copper Sulfate Instant Powder
001278–00008	Triangle Brand Copper Sulfate Crystal
001459–00044	Bullen Vegetation Killer
001459–00055	Vegetation Killer
001459–00101	Ready-To-Use Bathroom Cleaner and Disinfectant
001475–00146	ENOZ Skat!
001543–00011	Absorbine Supershield
001543–00013	Absorbine Ultrashield Brand Residual Insecticide & Repellent Towelette
001677–00019	Mikro-Chlor
001677–00096	Q-Quat II
001677–00109	Nomold
001677–00111	Ecolab Pyrethrin Spray
001677–00112	Entrol
001677–00130	Solid Sani-Glide

TABLE 2.—SECTION 3 REGISTRATIONS CANCELLED FOR 2010 NON-PAYMENT OF MAINTENANCE FEE—Continued

Registration No.	Product Name
001677–00148	Quorum Clear/claro
001677–00157	Solid Choice Plus
001677–00159	TX-8848
001677–00190	Coolingcare 2915
001677–00203	Oxysept LDI
001677–00210	Midland 655
001677–00217	Ld Base Concentrate
001677–00218	SD-2
001677–00220	Sanova GPD Concentrate
001677–00221	Dairyglide AM
001677–00222	Sanova 335
001719–00024	BLP Jack Tar Marine Finishes Vinyl Anti-Fouling 473-73
001719–00034	Jack Tar Vinyl Antifouling Blue 473-33
001719–00038	ZIN-TOX 202 Water Based Wood Preservative
001769–00373	Danco Concentrate
001965–00055	Vancide Th
002230–00016	Xtra
002800–00058	Humco Copper Sulfate Crystals
002915–00065	Industrial Insect Spray III
003095–00067	Pic Roach Control Paste
003095–00071	Pic Ant Killer Gel
004170–00036	Forest 5
004170–00056	Scorch Plus Rtu Vegetation Killer
004170–00058	Scorch Plus 1021
004482–00013	Guard All Pine Odor Disinfectant Cleaner
004482–00019	Mintrol
004987–00005	Young's Rabon 7.76 Oral Larvicide Premix

TABLE 2.—SECTION 3 REGISTRATIONS CANCELLED FOR 2010 NON-PAYMENT OF MAINTENANCE FEE—Continued

Registration No.	Product Name
005389–00009	Kay Quaternary Sanitizer
005389–00021	Chlorsan
005602–00209	Hub States CIK
007056–00020	Chem Spray Bug Ban Insect Repellent Spray
007056–00099	CSA Household Flying Insect Killer #1
007056–00162	CSA WB Total Release Fogger #1
007056–00180	CSA Aerosol Insecticide Formula Seven
007056–00185	IQ Multipurpose House &Garden Spray
007424–00001	Jasco Green Termin-8 Wood Preservative
007537–00002	Hobby's Ready To Use Rat and Mouse Bait
007779–00022	Houghton Wb-207
008155–00008	Husky Creme Cleanser
008155–00009	High Fragrance Husky 802 *h/f Disinfectant Cleaner
008383–00004	Sporicidin Brand Disinfectant Spray
008709–00009	Pond Care Dimilin
008730–00061	Disrupt Ofm
008730–00063	Hercon Disrupt CM-Xtra
008730–00064	Hercon Disrupt DFTM
008730–00066	Hercon Disrupt Micro-Flake Ofm
008730–00067	Disrupt Micro-Flake Wpsb
009152–00019	Shur-San
009608–00005	Termite Prufe Ready To Use
009630–00011	M-Gard W510

TABLE 2.—SECTION 3 REGISTRATIONS CANCELLED FOR 2010 NON-PAYMENT OF MAINTENANCE FEE—Continued

Registration No.	Product Name
010190–00013	Penetize
011011–00002	Esbro-Chlor
012455–00039	Quintox Rat and Mouse Bait
012455–00057	Quintox Mouse Seed
012455–00077	Warfarin Rat and Mouse Bait Ready To Use Place Pacs
012455–00109	Hawk All-Weather Bait Chunx AG
012455–00110	Hawk Rodenticide AG
012455–00111	Jaguar Rodenticide AG
012455–00112	Hawk All-Weather Rodent Block AG
012455–00113	Jaguar All Weather Bait Chunx AG
012455–00114	Hawk Rodenticide Rtu Place Pac AG
012455–00115	Jaguar Rodenticide Place Pacs AG
015142–00001	Fly-Curb Insecticide Spray for Horses
025026–00006	Insectaway Multi-Purpose Insecticide II
030573–00002	Pyrellin E.C.
032977–00001	Sterisol Germicide
033161–00019	F-50 Fogging Compound
033658–00025	Napropamide 80 MUP
034052–00003	Sani Clean One-Step
034052–00011	Bear-Cat 20 Plus
034688–00082	Aquatreat DNM-80
034688–00083	Aquatreat Dcd
036404–00001	Nissin Niclon-70-Granular
036404–00002	Calcium Hypochlorite Granular ≥star-Chlon≥
036638–00032	Nomate LRX MEC

TABLE 2.—SECTION 3 REGISTRATIONS CANCELLED FOR 2010 NON-PAYMENT OF MAINTENANCE FEE—Continued

Registration No.	Product Name
038083–00001	Myris-100
039272–00011	Wepak Pine Disinfectant
039444–00008	Micropur Mfl
039578–00001	Finacide
039578–00002	Finacide IPC
039578–00003	Finacide Lq
039924–20001	Universal Chemicals Sodium Hypochlorite
042177–00022	Olympic Universal Chlorinator Cartridge
042964–00005	A-33
042964–00014	Omega
042964–00016	Aquinoc
042964–00025	A-33 Dry
042964–00030	A-428-N
044392–00001	MBC 115
044616–00022	Temephos Technical
045220–00009	Diatom Dust Insect Powder
045458–00019	Maintain Pool Pro Concentrated Stabilized Pool Chlorinating Sticks
046579–00010	Resmethrin Ulv 3-9 Multipurpose Spray
046579–00011	Resmethrin 5-1.5 Contact and Space Spray
046579–00012	Resmethrin ULV 3 Multipurpose Spray
047550–00001	Elite Flea and Tick Shampoo
048668–00013	Ppp Flea &Tick Mousse II
049403–00002	Nipacide Bcp
049403–00003	Nipacide BCP Solution
049403–00019	Nipacide Pcmc
049403–00021	Nipacide OPP

TABLE 2.—SECTION 3 REGISTRATIONS CANCELLED FOR 2010 NON-PAYMENT OF MAINTENANCE FEE—Continued

Registration No.	Product Name
049403–00024	Nipacide CI
049403–00035	Nipacide C40
050404–00011	Cic Residual Insecticide No.2
052287–00013	Weed-Free One Eleven
053575–00023	Isomate-Lptb Pheromone
053575–00027	Isomate-Gbm Plus
053842–00005	Coastal 781
055392–00004	Rabon Mineral Block for Cattle and Horses
058300–00017	Sanicide Pro-2
058618–00001	Chlorine Liquefied Gas Under Pressure
059807–00009	Marathon II
059807–00010	Sextant 50 Wp Fungicide
059825–00004	CX 1078
061181–00001	Multi-Wash
061181–00002	Multi-Wash Mini
062401–00006	Nordico Kitchen Cleaning and Disinfectant Wipes
062575–00010	Global Technical Suffa
062575–00013	Gilmectin 2.0% EC
063838–00007	Bcdmh Granules
064864–00059	Shield DPA 31%
064898–00004	Rout
065009–00001	Sodium Hypochlorite
065864–00002	Safe-T Green 18 Turf Fungicide/nematicide
066551–00006	Buzz Away Insect Repellent Towelettes
066887–00005	LA Chemchlor (manufacturing Use Only)
068186–00002	E-Rase Ready-To-Use

TABLE 2.—SECTION 3 REGISTRATIONS CANCELLED FOR 2010 NON-PAYMENT OF MAINTENANCE FEE—Continued

Registration No.	Product Name
068329–00001	Alpha 133
069191–20001	Synchlor 12.5% Sodium Hypochlorite Solution
069361–00014	Triclopyr Technical
069361–00015	Triclopyr 3 Herbicide
069361–00016	Triclopyr Butoxy Ethyl Ester
069361–00024	Relief Herbicide
069361–00025	Eliminator Herbicide
069834–00012	Messenger
069834–00013	Messenger Seed Treatment
070126–00001	Organic Resources Multipurpose Insecticide
070191–00001	Organica Neem Oil Insecticidal Soap Concentrate
070191–00002	Organica Ready-To-Use K+neem Insecticidal Soap
070252–00009	Nations Ag Technical Mefenoxam
070252–00010	Mefenoxam 2E
070252–00011	Mefenoxam 2l
070404–00010	Hygate 4000
070728–00001	Promote Tm Prochek Gp99.5 L
070799–00007	State Formula 400 Parch
070845–00001	Environ 4h2o
070909–00004	The Dragonfly Carbon Dioxide Canister
071272–00001	Technical Silver
071645–00003	Zinc Oxide
071771–00004	Messenger Seed Treatment
071986–00001	XT-2000 Orange Oil
072112–00007	Prokoz 008
072112–00008	Prokoz 009
072112–00009	Prokoz 010

TABLE 2.—SECTION 3 REGISTRATIONS CANCELLED FOR 2010 NON-PAYMENT OF MAINTENANCE FEE—Continued

Registration No.	Product Name
072112–00010	Prokoz 011
072315–00002	Sodium Hypochlorite-5
072315–00003	Sodium Hypochlorite 7
072500–00010	Kaput-D Wax Blocks with Diphacinone
072639–00001	LT Biosyn, Inc. Technical 3-Indolebutyric Acid
072639–00003	Lt Biosyn 6-Benzylaminopurine Technical
072639–00004	Kinetin Technical
072639–00005	LT Biosyn Technical Gibberellic Acid (GA3)
072639–00006	Gibberellin A4+7 Technical
072642–00006	Elector Loose Mineral Mix
072680–00001	Vine-X
072852–00001	Electrolite 25
072852–00002	Electrolite 31
072898–00002	Virosoft CP4
072947–00001	Egisprene Insect Growth Regulator
073073–00001	Klor-San
073637–00003	Sutan + 6.7-E Selective Herbicide
073637–00004	Sutan Technical
073825–00001	Ecozap Wasp & Hornet Insecticide
073825–00002	Ecozap Crawling and Flying Insecticide
073873–00003	Anti-Growth
073912–00002	ANTX 75
073912–00003	Roach X Paste
074412–00001	Trident 51
074530–00005	Glyphosate Pro Herbicide
074530–00012	Helosate Aq

TABLE 2.—SECTION 3 REGISTRATIONS CANCELLED FOR 2010 NON-PAYMENT OF MAINTENANCE FEE—Continued

Registration No.	Product Name
074530–00013	Helosate Ex Herbicide
074530–00027	Helm Propanil4
074530–00031	Kendo EC Insecticide
074530–00035	Kendo Insecticide
074621–00003	Bug Stomper Spray &Wipe for Horses
074627–00005	Zeocide Ag
075512–00002	Ebiox Trukleen Spray
075512–00003	Ebiox Trukleen Concentrate
075801–00007	Envirotech WP
075801–00008	Stump Guard
075832–00001	Fprl Acc 50 Wood Preservative
079755–00003	F10SC Veterinary Disinfectant
081038–00001	Skeet-Daddle Fogging Insecticide
081206–00001	Oculus Microcyn Sanitizer
082052–00005	Greenmatch Burndown Herbicide
082133–00001	Bkl Laminate
082493–00001	Glyphosate Technical
082493–00002	Glygran Wdg
082542–00006	Ethofumesate 43 Sc Herbicide
082542–00007	Oxyfluoren Technical
082542–00010	Metsulfuron-Methyl 60df
082542–00013	Oxyfluorfen 4 SC Herbicide
082542–00017	Imidacloprid 75% Wdg Insecticide
082542–00018	Imidacloprid 75% Wdg Termiticide
082542–00021	Technical Metsulfuron-Methyl

TABLE 2.—SECTION 3 REGISTRATIONS CANCELLED FOR 2010 NON-PAYMENT OF MAINTENANCE FEE—Continued

Registration No.	Product Name
082633–00009	Sharda Nicosulfuron Technical Herbicide
082706–00001	Agro-Guard Z
082723–00001	Big 6 Plus
082757–00006	TCS Growstar Atrazine 1.38% + Fertilizer
082971–00001	Bluewater
083028–00006	NCA Biotech, Inc. GA3 4%
083028–00009	Rootgro
083028–00011	Nca Goldengro R
083028–00012	Nca Megagro L
083028–00014	NCA GA3 20%
083070–00003	Enforce 1.47% Fl
083070–00006	Imidacloprid 2 Flowable Mup
083070–00007	Enforce 0.2g
083103–00005	Hdh Vinegar 20
083222–00016	Tebucure 3.6F Fungicide
083424–00001	Moth-Be-Gone Moth Balls 1
083424–00003	Moth Avoid Mosture Absorbing Moth Ball Sachet
083487–00001	Uncle Albert's Super Smart Ant Bait
083529–00010	Nicosulfuron 75 WDG
083529–00017	Nicosh 4sc
083857–00002	X-Mold!
083884–00005	Mitin FF High Conc.
083918–00001	Genchlor 150
083918–00002	Genchlor 100
083918–00003	Genchlor 60
083979–00004	Rotam MEP 4.2%
083979–00005	Rotam Bifen 7.9%
084127–00001	Ethoywrap

TABLE 2.—SECTION 3 REGISTRATIONS CANCELLED FOR 2010 NON-PAYMENT OF MAINTENANCE FEE—Continued

Registration No.	Product Name
084224–00001	Eckroat Gopher Getter Bait
084229–00004	Technical Abamectin
084557–00001	TPTH Technical Fungicide
084684–00001	Canopy
084708–00001	Green Dragon Roach Kill
084836–00001	Regatta 80wp Agricultural Herbicide
084836–00002	Regatta 80wp Ornamental Herbicide
084836–00003	Regatta 75wg Agricultural Herbicide
084836–00004	Regatta 75wg Ornamental Herbicide
084836–00005	Regatta 2g Ornamental Herbicide
084836–00006	Regatta Ornamental Herbicide
084836–00007	Regatta 10g Herbicide
084930–00008	Arc-Nico 75 WG
084930–00012	Arc-Lamcy
085131–00001	Tribenuron Methyl Technical
085131–00002	Thilfensulfuron-Methyl Technical
085607–00002	Reddick Bro-Mean C-2r
085607–00003	Reddick Bro-Mean C-33
085607–00004	Reddick Bro-Mean C-O
085719–00001	Super-Chlor

IV. 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 until January 15, 2011, one year after the date on which the fee was due.

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 order. 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.

V. Docket

Complete lists of registrations cancelled for non-payment of the maintenance fee will also be available for reference during normal business hours in the OPP Regulatory Public Docket, Rm. S–4400, One Potomac Yard (South Bldg.), 2777 S. Crystal Dr., Arlington, VA. Product-specific status inquiries may be made by calling toll-free, 1–800–444–7255.

List of Subjects

Environmental protection, Administrative practice and procedure, Pesticides and pests.

Dated: July 15, 2010.

Steven Bradbury,

Director, Office of Pesticide Programs.

[FR Doc. 2010–18092 Filed 7–27–10; 8:45 am]

BILLING CODE 6560–50–S

ENVIRONMENTAL PROTECTION AGENCY

[ER–FRL–8991–7]

Environmental Impacts Statements; Notice of Availability

Responsible Agency: Office of Federal Activities, General Information (202) 564–1399 or *http://www.epa.gov/compliance/nepa/.*

Weekly Receipt of Environmental Impact Statements

Filed 07/23/2010 through 07/23/2010. Pursuant to 40 CFR 1506.9.

Notice: In accordance with Section 309(a) of the Clean Air Act, EPA is required to make its comments on EISs issued by other Federal agencies public. Historically, EPA has met this mandate by publishing weekly notices of availability of EPA comments, which

includes a brief summary of EPA's comment letters, in the **Federal Register**. Since February 2008, EPA has been including its comment letters on EISs on its Web site at: *http://www.epa.gov/compliance/nepa/eisdata.html.* Including the entire EIS comment letters on the Web site satisfies the Section 309(a) requirement to make EPA's comments on EISs available to the public. Accordingly, on March 31, 2010, EPA discontinued the publication of the notice of availability of EPA comments in the **Federal Register**.

EIS No. 20100271, Final EIS, USN, GU, Guam and Commonwealth of the Northern Mariana Islands (CNMI) Military Relocation, Proposed Relocating Marines from Okinawa, Visiting Aircraft Carrier Berthing, and Army Air and Missile Defense Task Force, Implementation, GU, Wait Period Ends: 08/26/2010, Contact: Kyle Fujimoto, 808–472–1442.

EIS No. 20100272, Final EIS, BLM, CA, Imperial Valley Solar Project, (Formerly Known as Stirling Energy Systems (SES) Solar 2 Project), Construct and Operate, Electric-Generating Facility, Imperial Valley, Imperial County, CA, Wait Period Ends: 08/26/2010, Contact: Jim Stobaugh, 775–861–6478.

Dated: July 23, 2010.

Ken Mittleholtz,

Deputy Director, NEPA Compliance Division, Office of Federal Activities.

[FR Doc. 2010–18550 Filed 7–27–10; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

[EPA–HQ–OPP–2010–0474; FRL–8830–5]

Petition For Rulemaking to Establish Procedures For The Creation and Amendment of Endangered Species Protection Bulletins; Notice of Availability

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: EPA is announcing the availability of a January 19, 2010 petition from Dow AgroSciences LLC ("DAS"), Makhteshim Agan of North America, Inc. ("MANA"), and Cheminova, Inc. USA ("Cheminova") requesting EPA promulgate a rule for creating and amending Endangered Species Protection Bulletins ("County Bulletins") intended to provide additional label directions as part of the Agency's Endangered Species Protection Program (ESPP). DAS, MANA, and Cheminova state that appropriate, clear, and equitable procedures for creating and amending County Bulletins must be established. They further claim that the current process used to develop and implement County Bulletins is ad hoc, and that EPA has no established procedures for input by the agricultural or forestry communities, or to assure the pesticide registrant's ability to review, comment upon and/or challenge proposed language in County Bulletins that would be referenced on its label.

DATES: Comments must be received on or before September 27, 2010.

ADDRESSES: Submit your comments, identified by docket identification (ID) number EPA–HQ–OPP–2010–0474, 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–2010–0474. 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: Catherine Eiden, Pesticide Re-evaluation Division, Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001; telephone number: (703) 305–7887; fax number: (703) 308–8005; e-mail address: *eiden.catherine@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.

II. What Action is the Agency Taking?

EPA is announcing availability of a petition from Dow AgroSciences LLC ("DAS"), Makhteshim Agan of North America, Inc. ("MANA"), and Cheminova, Inc. USA ("Cheminova") under docket ID number EPA–HQ–2010–0474.

List of Subjects

Environmental Protection, Endangered Species Protection Bulletins, Endangered Species, Pesticides.

Dated: July 20, 2010.

Stephen A. Owens,

Assistant Administrator, Office of Chemical Safety and Pollution Prevention.

[FR Doc. 2010–18381 Filed 7–27–10; 8:45 am]

BILLING CODE 6560–50–S

ENVIRONMENTAL PROTECTION AGENCY

[EPA–HQ–OPP–2009–0901; FRL–8836–9]

Product Cancellation Order for Certain Pesticide Registrations

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: This notice announces EPA's order for the cancellations, voluntarily requested by the registrants and accepted by the Agency, of the products listed in Table 1, pursuant to section 6(f)(1) of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), as amended. This cancellation order follows a December 30, 2009 **Federal Register** Notice of Receipt of Requests from the registrants listed in Table 2 to voluntarily cancel these product registrations. In the December 30, 2009 notice, EPA indicated that it would issue an order implementing the cancellations unless the Agency received substantive comments within the 180–day comment period that would merit its further review of these requests or unless the registrants withdrew their requests. The Agency did not receive any comments on the notice. The registrants did not withdraw their requests. Accordingly, EPA hereby issues in this notice a cancellation order granting the requested cancellations. Any distribution, sale, or use of the products subject to this cancellation order is permitted only in accordance with the terms of this order, including any existing stocks provisions.

DATES: The cancellations are effective July 28, 2010.

FOR FURTHER INFORMATION CONTACT: Barbara Briscoe, Pesticide Re-evaluation Division (7508P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001; telephone number: (703) 308–8177; fax number: (703) 308–8090; e-mail address: *briscoe.barbara@epa.gov*.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this Action Apply to Me?

This action is directed to the public in general and may be of interest to a wide range of stakeholders including environmental, human health, and agricultural advocates; the chemical industry; pesticide users; and members of the public interested in the sale, distribution, or use of pesticides. Since others also may 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. How Can I Get Copies of this Document and Other Related Information?

EPA has established a docket for this action under docket identification (ID) number EPA–HQ–OPP–2009–0901. 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 Office of Pesticide Programs (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.

II. What Action is the Agency Taking?

This notice announces the cancellation, as requested by registrants, of 17 products registered under FIFRA section 3. These registrations are listed in sequence by registration number in Table 1.

TABLE 1. —PRODUCT CANCELLATIONS

EPA Registration Number	Product Name	Chemical Name
002382-00054	Otomite-Pesticidal	Piperonyl butoxide, Pyrethrins
002382-00092	Pet-Guard Gel Forte	Piperonyl butoxide, Butoxypolypropylene glycol
002382-00126	Duocide L.A.	Permethrin, MGK 264, Pyrethrins
002382-00158	Knockout Flea and Tick Carpet Spray #1	Permethrin, Piperonyl butoxide, Pyriproxyfen
042697-00034	Safer Brand Entire Insect Killer Concentrate	Pyrethrins, Potassium laurate
067517-00004	Insecticide Mist	Pyrethrins, Piperonyl butoxide
067517-00012	Dairy Spray	Pyrethrins, Piperonyl butoxide
067517-00041	Rose and Flower Spray	Pyrethrins, Piperonyl butoxide
067517-00042	Tomato and Vegetable Spray	Pyrethrins, Piperonyl butoxide
067517-00043	Fly-A-Rest AQ	Pyrethrins, Piperonyl butoxide
067517-00045	Hard Hitter Aerosol	Permethrin
067517-00049	Dog and Cat Spray Or Dip	Pyrethrins, Piperonyl butoxide
067517-00051	Flea And Tick Spray	Pyrethrins, Permethrin
067517-00056	Flea And Insect Carpet Dust	Pyrethrins, Piperonyl butoxide
067517-00057	Cat And Dog Pyrethrin Powder	Pyrethrins, Piperonyl butoxide
067517-00061	Permethrin 10% W.B. Multi-Purpose Concentrate	Permethrin
067517-00080	Permethrin 10% Oil Base Concentrate	Permethrin

Table 2 includes the names and addresses of record for all registrants of the products in Table 1, in sequence by EPA company number. This number corresponds to the first part of the EPA registration numbers of the products listed in Table 1.

TABLE 2. —REGISTRANTS OF CANCELLED PRODUCTS

EPA Company Number	Company Name and Address
002382	Virbac AH, Inc. 1445 Ross Avenue, Suite 3800 Dallas, TX 75202
042697	Safer, Inc. 69 North Locust St., P.O. Box 327 Lititz, PA 17543
067517	PM Resources, Inc. P.O. Box 162059 Fort Worth, TX 76161

III. Summary of Public Comments Received and Agency Response to Comments

During the public comment period provided, EPA received no comments in response to the December 30, 2009 **Federal Register** notice announcing the Agency's receipt of the requests for voluntary cancellations of products listed in Table 1.

IV. Cancellation Order

Pursuant to FIFRA section 6(f), EPA hereby approves the requested cancellations of the registrations identified in Table 1. Accordingly, the Agency hereby orders that the product registrations identified in Table 1 are canceled. The effective date of the cancellations that are subject of this notice is July 28, 2010. Any distribution, sale, or use of existing stocks of the products identified in Table 1 in a manner inconsistent with any of the provisions for disposition of existing stocks set forth in Unit VI. will be a violation of FIFRA.

V. What is the Agency's Authority for Taking this Action?

Section 6(f)(1) of FIFRA provides that a registrant of a pesticide product may at any time request that any of its pesticide registrations be canceled or amended to terminate one or more uses. FIFRA further provides that, before acting on the request, EPA must publish a notice of receipt of any such request in the **Federal Register**. Thereafter, following the public comment period, the EPA Administrator may approve such a request. The notice of receipt for this action was published for comment in the **Federal Register** issue of December 30, 2009 (74 FR 69090) (FRL–8804–6). The comment period closed on June 28, 2010.

VI. Provisions for Disposition of Existing Stocks

Existing stocks are those stocks of registered pesticide products which are currently in the United States and which were packaged, labeled, and released for shipment prior to the effective date of the cancellation action. The existing stocks provisions for the products subject to this order are as follows.

The registrants may continue to sell and distribute existing stocks of products listed in Table 1 until July 28, 2011, which is 1 year after the publication of the Cancellation Order in the **Federal Register**. Thereafter, the registrants are prohibited from selling or distributing products listed in Table 1, except for export in accordance with FIFRA section 17, or proper disposal. Persons other than the registrants may sell, distribute, or use existing stocks of products listed in Table 1 until existing stocks are exhausted, provided that such

sale, distribution, or use is consistent with the terms of the previously approved labeling on, or that accompanied, the canceled products.

List of Subjects

Environmental protection, Pesticides and pests.

Dated: July 21, 2010.

Richard P. Keigwin, Jr.,

Director, Pesticide Re-evaluation Division, Office of Pesticide Programs.

[FR Doc. 2010–18375 Filed 7–27–10; 8:45 am]

BILLING CODE 6560–50–S

ENVIRONMENTAL PROTECTION AGENCY

[EPA–HQ–OPPT–2009–0867; FRL–8813–4]

Proposed Acute Exposure Guideline Levels for Hazardous Substances; Notice of Availability

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: The National Advisory Committee for Acute Exposure Guideline Levels for Hazardous Substances (NAC/AEGL Committee) is developing AEGLs on an ongoing basis to provide Federal, State, and local agencies with information on short-term exposures to hazardous substances. This notice provides a list of 13 proposed AEGLs that are available for public review and comment. Comments are welcome on both the proposed AEGLs and their Technical Support Documents placed in the docket.

DATES: Comments must be received on or before August 27, 2010.

ADDRESSES: Submit your comments, identified by docket identification (ID) number EPA–HQ–OPPT–2009–0867, by one of the following methods:

• *Federal eRulemaking Portal*: *http://www.regulations.gov*. Follow the on-line instructions for submitting comments.

• *Mail*: Document Control Office (7407M), Office of Pollution Prevention and Toxics (OPPT), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001.

• *Hand Delivery*: OPPT Document Control Office (DCO), EPA East, Rm. 6428, 1201 Constitution Ave., NW., Washington, DC. Attention: Docket ID Number EPA–HQ–OPPT–2009–0867. The DCO is open from 8 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The telephone number for the DCO is (202) 564–8930. Such deliveries are only accepted during the DCO's normal hours of operation, and special arrangements should be made for deliveries of boxed information.

Instructions: Direct your comments to docket ID number EPA–HQ–OPPT–2009–0867. 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, will be publicly available only in hard copy. Publicly available docket materials are available electronically at *http://www.regulations.gov*, or, if only available in hard copy, at the OPPT Docket. The OPPT Docket is located in the EPA Docket Center (EPA/DC) at Rm. 3334, EPA West Bldg., 1301 Constitution Ave., NW., Washington, DC. The EPA/DC Public Reading Room hours of operation are 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number of the EPA/DC Public Reading Room is (202) 566–1744, and the telephone number for the OPPT Docket is (202) 566–0280. Docket visitors are required to show photographic identification, pass through a metal detector, and sign the EPA visitor log. All visitor bags are processed through an X-ray machine and subject to search. Visitors will be provided an EPA/DC badge that must be visible at all times in the building and returned upon departure.

FOR FURTHER INFORMATION CONTACT: *For technical information contact*: Paul S. Tobin, Designated Federal Officer (DFO), Office of Pollution Prevention and Toxics (7406M), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001; telephone number: (202) 564–8557; e-mail address: *tobin.paul@epa.gov*.

For general information contact: The TSCA-Hotline, ABVI-Goodwill, 422 South Clinton Ave., Rochester, NY 14620; telephone number: (202) 554–1404; e-mail address: *TSCA-Hotline@epa.gov*.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this Action Apply to Me?

This action is directed to the general public to provide an opportunity for review and comment on proposed AEGLs and their Technical Support Documents. This action may be of particular interest to anyone who may be affected if the AEGLs are adopted by government agencies for emergency planning, prevention, or response programs, such as EPAs Risk Management Program under the Clean Air Act and Amendments Section 112r. It is possible that other Federal agencies besides EPA, as well as State and local agencies and private organizations, may adopt the AEGLs for their programs. As such, 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 DFO 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 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?

EPA's Office of Prevention, Pesticides and Toxic Substances (OPPTS), renamed the Office of Chemical Safety and Pollution Prevention (OCSPP), as of April 22, 2010, provided notice on October 31, 1995 (60 FR 55376) (FRL–4987–3) of the establishment of the NAC/AEGL Committee with the stated charter objective as "the efficient and effective development of AEGLs and the preparation of supplementary qualitative information on the hazardous substances for Federal, State, and local agencies and organizations in the private sector concerned with [chemical] emergency planning, prevention, and response." The NAC/AEGL Committee is a discretionary Federal advisory committee formed with the intent to develop AEGLs for hazardous substances through the combined efforts of stakeholder members from both the public and private sectors in a cost-effective approach that avoids duplication of efforts and provides uniform values, while employing the most scientifically sound methods available.

This action provides notice of availability for public review and comment of proposed AEGLs and underlying supporting documents for 13 hazardous substances. These AEGLs represent the 13th set of exposure levels proposed and published by the NAC/AEGL Committee. These 13 sets of AEGLs cover 261 hazardous substances. Background information on the AEGL Program may be found in these earlier **Federal Register** notices, on regulations.gov, or the AEGL webpage (*http://www.epa.gov/oppt/aegl*).

Following public review and comment, the NAC/AEGL Committee will reconvene to consider relevant comments, data, and information that may have an impact on the NAC/AEGL Committee's position and will again seek consensus for the establishment of Interim AEGLs. Although the Interim AEGLs will be available to Federal, State, and local agencies and to organizations in the private sector as biological reference values, a National Academies subcommittee for AEGLs will serve as a peer review of the Interim AEGLs and as the final arbiter in the resolution of issues regarding the AEGLs, and the data and basic methodology used for setting AEGLs. Following concurrence, Final AEGLs will be published under the auspices of the NAS.

III. List of Hazardous Substances

On behalf of the NAC/AEGL Committee, EPA is providing an opportunity for public comment on the proposed AEGLs for the 13 hazardous substances identified in the table in this unit. Technical Support Documents are available in the docket for this notice. See **ADDRESSES** for docket information.

Chemical Name	CAS Number
Cadmium	7440–43–9
Calcium cyanide	592–01–8
Dimethyl phosphite	868–85–9
Gasoline—automotive	86290–81–5
Mercury vapor	7439–97–6
Perchloryl fluoride	7616–94–6
Perfluoroisobutylene	382–21–8
Phosgene	75–44–5
Phosgene oxime	1794–86–1
Potassium cyanide	151–50–8
Sodium cyanide	143–33–9
Tellurium hexafluoride	7783–80–4
Trimethylphosphite	121–45–9

List of Subjects

Environmental protection, Acute Exposure Guideline Levels, Hazardous substances, Health.

Dated: July 21, 2010.

Stephen A. Owens,

Assistant Administrator, Office of Chemical Safety and Pollution Prevention.

[FR Doc. 2010–18546 Filed 7–27–10; 8:45 am]

BILLING CODE 6560–50–S

ENVIRONMENTAL PROTECTION AGENCY

[FRL–9182–5]

Proposed Administrative Settlement Agreement Under Section 122 of the Comprehensive Environmental Response, Compensation, and Liability Act for the Turnpike Dump No. 5 Site located in Jersey City, Hudson County, NJ

AGENCY: Environmental Protection Agency.

ACTION: Notice of Proposed Administrative Settlement and Opportunity for Public Comment.

SUMMARY: The United States Environmental Protection Agency ("EPA") is proposing to enter into an administrative settlement agreement ("Settlement Agreement") with the City of Jersey City, New Jersey (the "Settling Party") pursuant to Section 122 of the Comprehensive Environmental Response, Compensation, and Liability Act ("CERCLA"), 42 U.S.C. 9622. The Settlement Agreement provides for Settling Party payment of certain response costs incurred by EPA at the Turnpike Dump No. 5 Site ("Site") located in Jersey City, Hudson County, New Jersey.

In accordance with Section 122(i) of CERCLA, 42 U.S.C. 9622(i), this notice is being published to inform the public of the proposed Settlement Agreement and of the opportunity to comment. For thirty (30) days following the date of publication of this notice, EPA will receive written comments relating to the proposed Settlement Agreement. EPA will consider all comments received and may modify or withdraw its consent to the settlement if comments received disclose facts or considerations that indicate that the proposed settlement is inappropriate, improper or inadequate. EPA's response to any comments received will be available for public inspection at EPA Region 2, 290 Broadway, 17th floor, New York, New York 10007–1866.

DATES: Comments must be provided by August 27, 2010.

ADDRESSES: Comments should reference the Turnpike Dump No. 5 Site, EPA Index No. II–CERCLA–02–2010–2015 and should be sent to the U.S. Environmental Protection Agency, Office of Regional Counsel, New Jersey Superfund Branch, 290 Broadway—17th Floor, New York, NY 10007.

SUPPLEMENTARY INFORMATION: A copy of the proposed administrative settlement, as well as background information relating to the settlement, may be obtained from Juan M. Fajardo, Assistant Regional Counsel, New Jersey Superfund Branch, Office of Regional Counsel, U.S. Environmental Protection Agency, 17th Floor, 290 Broadway, New York, New York 10007–1866. *Telephone:* 212–637–3132.

FOR FURTHER INFORMATION CONTACT: Juan M. Fajardo, Assistant Regional Counsel, New Jersey Superfund Branch, Office of Regional Counsel, U.S. Environmental Protection Agency, 17th Floor, 290 Broadway, New York, New York 10007–1866. *Telephone:* 212–637–3132.

Dated: May 19, 2010.

Walter Mugdan,

Director, Emergency and Remedial Response Division.

[FR Doc. 2010–18562 Filed 7–27–10; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

[FRL–9182–4]

Proposed Administrative Settlement Agreement Under Section 122 of the Comprehensive Environmental Response, Compensation, and Liability Act for the Turnpike Dump No. 5 Site Located in Jersey City, Hudson County, NJ

AGENCY: Environmental Protection Agency.

ACTION: Notice of proposed administrative settlement and opportunity for public comment.

SUMMARY: The United States Environmental Protection Agency ("EPA") is proposing to enter into an administrative settlement agreement ("Settlement Agreement") with the Colgate-Palmolive Company (the "Settling Party") pursuant to Section 122 of the Comprehensive Environmental Response, Compensation, and Liability Act ("CERCLA"), 42 U.S.C. 9622. The Settlement Agreement provides for Settling Party payment of certain response costs incurred by EPA at the Turnpike Dump No. 5 Site ("Site") located in Jersey City, Hudson County, New Jersey.

In accordance with Section 122(i) of CERCLA, 42 U.S.C. 9622(i), this notice is being published to inform the public of the proposed Settlement Agreement and of the opportunity to comment. For thirty (30) days following the date of publication of this notice, EPA will receive written comments relating to the proposed Settlement Agreement. EPA will consider all comments received and may modify or withdraw its consent to the settlement if comments received disclose facts or considerations that indicate that the proposed settlement is inappropriate, improper or inadequate. EPA's response to any comments received will be available for public inspection at EPA Region 2, 290 Broadway, 17th floor, New York, New York 10007–1866.

DATES: Comments must be provided by August 27, 2010.

ADDRESSES: Comments should reference the Turnpike Dump No. 5 Site, EPA Index No. II–CERCLA–02–2010–2015 and should be sent to the U.S. Environmental Protection Agency, Office of Regional Counsel, New Jersey Superfund Branch, 290 Broadway—17th Floor, New York, NY 10007.

SUPPLEMENTARY INFORMATION: A copy of the proposed administrative settlement, as well as background information relating to the settlement, may be obtained from Juan M. Fajardo, Assistant Regional Counsel, New Jersey Superfund Branch, Office of Regional Counsel, U.S. Environmental Protection Agency, 17th Floor, 290 Broadway, New York, New York 10007–1866. *Telephone:* 212–637–3132.

FOR FURTHER INFORMATION CONTACT: Juan M. Fajardo, Assistant Regional Counsel, New Jersey Superfund Branch, Office of Regional Counsel, U.S. Environmental Protection Agency, 17th Floor, 290 Broadway, New York, New York 10007–1866. *Telephone:* 212–637–3132.

Dated: May 19, 2010.

Walter Mugdan,

Director, Emergency and Remedial Response Division.

[FR Doc. 2010–18558 Filed 7–27–10; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

EPA–HQ–OPP–2010–0441; FRL–8829–8

Wood Oils and Gums, and *Streptomyces* Strain K61; Registration Review Proposed Decisions; Notice of Availability

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: This notice announces the availability of EPA's proposed registration review decisions for the pesticides listed in the table in Unit II.A. and opens a public comment period on the proposed decisions. Registration review is EPA's periodic review of pesticide registrations to ensure that each pesticide continues to satisfy the statutory standard for registration, that is, that the pesticide can perform its intended function without unreasonable adverse effects on human health or the environment. Through this program, EPA is ensuring that each pesticide's registration is based on current scientific and other knowledge, including its effects on human health and the environment.

DATES: Comments must be received on or before September 27, 2010.

ADDRESSES: Submit your comments, identified by the docket identification (ID) number for the specific pesticide of interest provided in the table in Unit II.A., 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 the docket identification (ID) number for the specific pesticide of interest provided in the table in Unit II.A. 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: *For pesticide specific information, contact*: The Regulatory Action Leader for the pesticide of interest identified in the table in Unit II.A.

For general information on the registration review program, contact: Kevin Costello, Pesticide Re-evaluation Division (7508P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001; telephone number: (703) 305–5026; fax number: (703) 308–8090; e-mail address: *costello.kevin@epa.gov*.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this Action Apply to Me?

This action is directed to the public in general, and may be of interest to a wide range of stakeholders including environmental, human health, farm worker, and agricultural advocates; the chemical industry; pesticide users; and members of the public interested in the sale, distribution, or use of pesticides. Since others also may 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 chemical review manager 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. Background

A. What Action is the Agency Taking?

Pursuant to 40 CFR 155.58, this notice announces the availability of EPA's proposed registration review decision(s) for the pesticide(s) shown in the following table, and opens a 60–day public comment period on the proposed decision(s).

Streptomyces Strain K61 is a naturally occurring soil bacterium and is classified as a microbial pesticide. It is believed to act against disease-causing fungi in at least two ways: By colonizing plant roots to deprive disease organisms of space and nourishment; and by producing several kinds of chemicals that attack the harmful fungi. It is used on lettuce and flowers as a seed treatment, transplant and seedling root dip treatment, cut flower dip treatments, soil drench applications, field side-dress applications, band or in-furrow treatments, soil spray treatments, seedling sprays, and integrated use in tank mixes with chemical fungicides.

The Wood Oils and Gums Registration Review Case no longer contains any other wood oils or gums with active ingredients with registered products except for cedarwood oil. Cedarwood oils are extracted from the Cupressaceae family, which includes true cedars, junipers, and cypresses. In the United States, cedarwood oil is mainly extracted from Juniperus virginiana (Eastern red cedar or Virginia cedar), Juniperus ashei or mexicana (Texas cedar), and Thuja plicata (Western red cedar). Cedar oil is registered for use as repellents and feeding depressants to control moths and fleas and retard the growth of mildew on fabrics.

TABLE — REGISTRATION REVIEW PROPOSED FINAL DECISIONS

Registration Review Case Name and Number	Pesticide Docket ID Number	Chemical Review Manager,Telephone Number, E-mail Address
Streptomyces Strain K61 (6066)	EPA–HQ–OPP–2009–0509	Anna Gross, (703) 305–5614, gross.anna@epa.gov

TABLE — REGISTRATION REVIEW PROPOSED FINAL DECISIONS—Continued

Registration Review Case Name and Number	Pesticide Docket ID Number	Chemical Review Manager,Telephone Number, E-mail Address
Wood Oils and Gums (3150)	EPA–HQ–OPP–2009–0258	Sadaf Shaukat, (703) 347–8670, shaukat.sadaf@epa.gov

The registration review docket for a pesticide includes earlier documents related to the registration review of the case. For example, the review opened with the posting of a Summary Document, containing a Preliminary Work Plan, for public comment. A Final Work Plan was posted to the docket following public comment on the initial docket. The documents in the initial dockets described the Agency's rationales for not conducting additional risk assessments for the registration review of the pesticides included in the table in Unit II.A. These proposed registration review decisions continue to be supported by those rationales included in documents in the initial dockets.

Following public comment, the Agency will issue final registration review decisions for products containing the pesticides listed in the table in Unit II.A.

The registration review program is being conducted under congressionally mandated time frames, and EPA recognizes the need both to make timely decisions and to involve the public. Section 3(g) of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), as amended, required EPA to establish by regulation procedures for reviewing pesticide registrations, originally with a goal of reviewing each pesticide's registration every 15 years to ensure that a pesticide continues to meet the FIFRA standard for registration. The Agency's final rule to implement this program was issued in August 2006 and became effective in October 2006, and appears at 40 CFR part 155, subpart C. The Pesticide Registration Improvement Act of 2003 (PRIA) was amended and extended in September 2007. FIFRA, as amended by PRIA in 2007, requires EPA to complete registration review decisions by October 1, 2022, for all pesticides registered as of October 1, 2007.

The registration review final rule at 40 CFR 155.58(a) provides for a minimum 60–day public comment period on all proposed registration review decisions. This comment period is intended to provide an opportunity for public input and a mechanism for initiating any necessary amendments to the proposed decision. All comments should be submitted using the methods in **ADDRESSES**, and must be received by EPA on or before the closing date. These comments will become part of the docket for the pesticides included in the table in Unit II.A. Comments received after the close of the comment period will be marked "late." EPA is not required to consider these late comments.

The Agency will carefully consider all comments received by the closing date and will provide a "Response to Comments Memorandum" in the docket. The final registration review decision will explain the effect that any comments had on the decision and provide the Agency's response to significant comments.

Background on the registration review program is provided at: *http://www.epa.gov/oppsrrd1/registration_review*. Links to earlier documents related to the registration review of these pesticides are provided at: *http://www.epa.gov/oppsrrd1/registration_review/reg_review_status.htm*.

B. What is the Agency's Authority for Taking this Action?

Section 3(g) of FIFRA and 40 CFR part 155, subpart C, provide authority for this action.

List of Subjects

Environmental protection, Administrative practice and procedure, Pesticides and pests, *Streptomyces* Strain K 61, Wood Oils and Gums.

Dated: June 16, 2010.

W. Michael McDavit,

Acting Director, Biopesticide and Pollution Prevention Division, Office of Pesticide Programs.

[FR Doc. 2010–18542 Filed 7–27–10; 8:45 am]

BILLING CODE 6560–50–S

ENVIRONMENTAL PROTECTION AGENCY

[EPA–HQ–OPP–2008-0723; FRL–8838–1]

Methidathion; Registration Review Proposed Decision; Notice of Availability

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: This notice announces the availability of EPA's proposed registration review decision for the pesticide methidathion and opens a public comment period on the proposed decision. Registration review is EPA's periodic review of pesticide registrations to ensure that each pesticide continues to satisfy the statutory standard for registration, that is, that the pesticide can perform its intended function without unreasonable adverse effects on human health or the environment. Through this program, EPA is ensuring that each pesticide's registration is based on current scientific and other knowledge, including its effects on human health and the environment.

DATES: Comments must be received on or before September 27, 2010.

ADDRESSES: Submit your comments, identified by docket identification (ID) number EPA–HQ–OPP–2008–0723, 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's telephone number is (703) 305–5805.

Instructions: Direct your comments to docket identification (ID) number EPA–HQ–OPP–2008–0723. 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's telephone number is (703) 305–5805.

FOR FURTHER INFORMATION CONTACT: *For pesticide-specific information, contact*: Jose Gayoso, Chemical Review Manager, Pesticide Re-evaluation Division (7508P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001; telephone number: (703) 347–8652; fax number: (703) 308–8005; e-mail address: *gayoso.jose@epa.gov*.

For general information on the registration review program, contact: Kevin Costello, Pesticide Re-evaluation Division (7508P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001; telephone number: (703) 305–5026; fax number: (703) 308–8090; e-mail address: *costello.kevin@epa.gov*.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this Action Apply to Me?

This action is directed to the public in general and may be of interest to a wide range of stakeholders including environmental, human health, farmworkers, and agricultural advocates; the chemical industry; pesticide users; and members of the public interested in the sale, distribution, or use of pesticides. Since others also may 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 chemical review manager 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. Background

A. What Action is the Agency Taking?

Pursuant to 40 CFR 155.58, this notice announces the availability of EPA's proposed registration review decision for the pesticide, methidathion, case number 0034, and opens a 60–day public comment period on the proposed decision. Methidathion is a non-systemic, organophosphate (OP) used as an insecticide/acaricide on a wide variety of terrestrial food and feed crops and terrestrial non-food crops. The pesticide acts through inhibition of acetylcholinesterase and is used to kill a broad range of insects and mites. There are no residential uses.

The registration review docket for a pesticide includes earlier documents related to the registration review of the case. For example, the review opened with the posting of a Summary Document, containing a Preliminary Work Plan for public comment. A Final Work Plan was posted to the docket following public comment on the initial docket.

As stated in the Methidathion Preliminary Work Plan and Methidathion Final Work Plan for registration review, the Agency had intended to revise the existing risk assessments for methidathion. However, after the publication of the Methidathion Final Work Plan, pursuant to section 6(f)(1) of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), as amended, the Agency announced receipt of requests to voluntarily cancel all methidathion product registrations from the registrants of methidathion. After a 30–day comment period, EPA granted the voluntary cancellation requests establishing effective cancellation dates (75 FR 30824) (FRL–8828–4) for all of the products registered for use in the United States containing the active ingredient methidathion.

Following public comment, the Agency will issue a final registration review decision for products containing methidathion.

The registration review program is being conducted under congressionally mandated timeframes, and EPA recognizes the need both to make timely decisions and to involve the public. Section 3(g) of FIFRA, as amended, required EPA to establish, by regulation, procedures for reviewing pesticide registrations, originally with a goal of reviewing each pesticide's registration every 15 years to ensure that a pesticide continues to meet the FIFRA standard for registration. The Agency's final rule to implement this program was issued in August 2006, and became effective in

October 2006, and appears at 40 CFR part 155, subpart C. The Pesticide Registration Improvement Act of 2003 (PRIA) was amended and extended in September 2007. FIFRA, as amended by PRIA in 2007, requires EPA to complete registration review decisions by October 1, 2022, for all pesticides registered as of October 1, 2007.

The registration review final rule at 40 CFR 155.58(a) provides for a minimum 60–day public comment period on all proposed registration review decisions. This comment period is intended to provide an opportunity for public input and a mechanism for initiating any necessary amendments to the proposed decision. All comments should be submitted using the methods in **ADDRESSES**, and must be received by EPA on or before the closing date. These comments will become part of the docket for methidathion. Comments received after the close of the comment period will be marked "late." EPA is not required to consider these late comments.

The Agency will carefully consider all comments received by the closing date and will provide a "Response to Comments Memorandum" in the docket. The final registration review decision will explain the effect that any comments had on the decision and provide the Agency's response to significant comments.

Background on the registration review program is provided at: *http://www.epa.gov/oppsrrd1/registration_review*. Links to earlier documents related to the registration review of methidathion are provided at: *http://www.epa.gov/oppsrrd1/registration_review/methidathion/index.htm*.

B. What is the Agency's Authority for Taking this Action?

Section 3(g) of FIFRA and 40 CFR part 155, subpart C, provide authority for this action.

List of Subjects

Environmental protection, Administrative practice and procedure, Pesticides and pests, Methidathion.

Dated: July 21, 2010.

Richard P. Keigwin, Jr.,

Director, Pesticide Re-evaluation Division, Office of Pesticide Programs.

[FR Doc. 2010–18539 Filed 7–27–10; 8:45 am]

BILLING CODE 6560–50–S

ENVIRONMENTAL PROTECTION AGENCY

[FRL–9181–4]

EPA Office of External Affairs and Environmental Education Staff Office; Request for Nominations of Candidates for the National Environmental Education Advisory Council

AGENCY: Environmental Protection Agency.

ACTION: Notice.

SUMMARY: The U.S. Environmental Protection Agency (EPA or Agency) Office of External Affairs and Environmental Education Staff Office is soliciting applications for environmental education professionals for consideration on the National Environmental Education Advisory Council (NEEAC). There is currently a vacancy on the Advisory Council that must be filled: one College and University representative (2010–2013). Additional avenues and resources may be utilized in the solicitation of applications.

DATES: Applications should be submitted by September 30, 2010 per instructions below.

ADDRESSES: Submit non-electronic application materials to Ginger Potter, Designated Federal Officer, National Environmental Education Advisory Council, U.S. Environmental Protection Agency, Office of External Affairs and Environmental Education (MC:1704A), 1200 Pennsylvania Ave., NW., Washington, DC 20460, Ph: 202–564–0443, FAX: 202–564–2754, e-mail: *potter.ginger@epa.gov.*

FOR FURTHER INFORMATION CONTACT: For information regarding this Request for Nominations, please contact Ms. Ginger Potter, Designated Federal Officer (DFO), EPA National Environmental Education Advisory Council, at *potter.ginger@epa.gov* or (202) 564–0443. General information concerning NEEAC can be found on the EPA Web site at: *http://www.epa.gov/enviroed.*

SUPPLEMENTARY INFORMATION: *Background:* Section 9(a) and (b) of the National Environmental Education Act of 1990 (Pub. L. L–101–619) mandates a National Environmental Education Advisory Council. The Advisory Council provides the Administrator with advice and recommendations on EPA implementation of the National Environmental Education Act. In general, the Act is designed to increase public understanding of environmental issues and problems, and to improve the training of environmental education professionals. EPA will achieve these goals, in part, by awarding grants and/or establishing partnerships with other Federal agencies, state and local education and natural resource agencies, not-for-profit organizations, universities, and the private sector to encourage and support environmental education and training programs. The Council is also responsible for preparing a national biennial report to Congress that will describe and assess the extent and quality of environmental education, discuss major obstacles to improving environmental education, and identify the skill, education, and training needs for environmental professionals.

The National Environmental Education Act requires that the Council be comprised of eleven (11) members appointed by the Administrator of EPA. Members represent a balance of perspectives, professional qualifications, and experience. The Act specifies that members must represent the following sectors: Primary and secondary education (one of whom shall be a classroom teacher)—two members; colleges and universities—two members; business and industry—two members; non profit organizations involved in environmental education—two members; state departments of education and natural resources—one member each; senior Americans—one member. Members are chosen to represent various geographic regions of the country, and the Council strives for a diverse representation. The professional backgrounds of Council members should include education, science, policy, or other appropriate disciplines. Each member of the Council shall hold office for a one (1) to three (3) year period. Members are expected to participate in up to two (2) meetings per year and monthly or more conference calls per year. Members of the Council shall receive compensation and allowances, including travel expenses, at a rate fixed by the Administrator.

Expertise Sought: The NEEAC staff office seeks candidates with demonstrated experience and/or knowledge in any of the following environmental education issue areas: (a) Integrating environmental education into state and local education reform and improvement; (b) state, local and tribal level capacity building; (c) cross-sector partnerships; (d) leveraging resources for environmental education; (e) design and implementation of environmental education research; (f) evaluation methodology; professional development for teachers and other education professionals; and (g)

targeting under-represented audiences, including low-income, multi-cultural, senior citizens and other adults.

The NEEAC staff office is also looking for individuals who demonstrate the ability to make the time commitment, strong leadership skills, strong analytical skills, strong communication and writing skills, the ability to stand apart and evaluate programs in an unbiased manner, team players, have the conviction to follow-through and to meet deadlines, and the ability to review items on short notice.

How to Submit Applications: Any interested and qualified individuals may be considered for appointment on the National Environmental Education Advisory Council. Applications should be submitted in electronic format to the Designated Federal Officer *potter.ginger@epa.gov* and contain the following: contact information including name, address, phone and fax numbers and an e-mail address; a curriculum vitae or résumé; the specific area of expertise in environmental education and the sector/slot the applicant is applying for; recent service on other national advisory committees or national professional organizations and; a one-page commentary on the applicant's philosophy regarding the need for, development, implementation and/or management of environmental education nationally. Additionally, a supporting letter of endorsement is required. This letter may also be submitted electronically as described above.

Persons having questions about the application procedure or who are unable to submit applications by electronic means, should contact Ginger Potter, DFO, at the contact information provided above in this notice. Non-electronic submissions must contain the same information as the electronic. The NEEAC Staff Office will acknowledge receipt of the application. The NEEAC Staff Office will develop a short list of candidates for more detailed consideration. The short list candidates will be required to fill out the Confidential Disclosure Form for Special Government Employees Serving Federal Advisory Committees at the U.S. Environmental Protection Agency (EPA Form 3110–48). This confidential form allows government officials to determine whether there is a statutory conflict between that person's public responsibilities (which include membership on a Federal advisory committee) and private interests and activities and the appearance of a lack of impartiality as defined by Federal regulation. The form may be viewed and downloaded from the following URL address: *http://www.epa.gov/sab/pdf/epaform3110-48.pdf.*

Dated: July 22, 2010.

Ginger Potter,

Designated Federal Officer.

[FR Doc. 2010–18555 Filed 7–27–10; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

[EPA–HQ–OPP–2005–0494; FRL–8831–7]

Rotenone; Notice of Receipt of Requests to Voluntarily Cancel 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 requests by the registrants to voluntarily cancel their rotenone registrations. The requests would not terminate the last rotenone products registered for use in the United States. EPA intends to grant these requests at the close of the comment period for this announcement unless the Agency receives substantive comments within the comment period that would merit its further review of the requests, or unless the registrants withdraw their requests. If these requests are granted, any sale, distribution, or use of products listed in this notice will be permitted after the registration has been cancelled only if such sale, distribution, or use is consistent with the terms as described in the final order.

DATES: Comments must be received on or before August 27, 2010.

ADDRESSES: Submit your comments, identified by docket identification (ID) number EPA–HQ–OPP–2005–0494, 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–2005–0494. 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: Veronica Dutch, Pesticide Re-evaluation Division (7508P), Office of Pesticide

Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001; telephone number: (703) 308-8585; e-mail address: *dutch.veronica@epa.gov.*

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this Action Apply to Me?

This action is directed to the public in general, and may be of interest to a wide range of stakeholders including environmental, human health, and agricultural advocates; the chemical industry; pesticide users; and members of the public interested in the sale, distribution, or use of pesticides. Since others also may 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.

II. Background on the Receipt of Requests to Cancel

This notice announces receipt by EPA of requests from registrants to cancel rotenone product registrations. Rotenone is an insecticide/miticide/piscicide used to control flying and crawling insects and invasive fish. In letters received by the Agency, the registrants requested EPA to cancel affected pesticide product registrations identified in Table 1 of Unit III. Specifically, the registrants have requested voluntary cancellation of products containing rotenone. The registrants' requests will not terminate the last rotenone product registered in the United States.

III. What Action is the Agency Taking?

This notice announces receipt by EPA of requests from registrants to cancel 16 rotenone product registrations. The affected products and the registrants making the requests are identified in Tables 1 and 2 of this unit, respectively.

Unless a request is withdrawn by the registrant or if the Agency determines that there are substantive comments that warrant further review of this request, EPA intends to issue an order canceling the affected registrations.

Table 1.—Rotenone Product Registrations with Pending Requests for Cancellation

Registration Number	Product Name	Chemical Name(s)
000004-00017	Rotenone 1.0% Dust	Cube Resins other than rotenone Rotenone
000004-00224	Rotenone 5% Insect Control	Cube Resins other than rotenone Rotenone
000004-00315	Bonide Liquid Rotenone/Pyrethrins Spray	Cube Resins other than rotenone Rotenone
000004-00404	Bonide Garden Rotenone Dust	Cube Resins other than rotenone Rotenone
000004-00423	Bonide Rotenone Garden Dust or Spray	Cube Resins other than rotenone Rotenone
000270-00275	Equi-Dust	Cube Resins other than rotenone Pyrethrins Rotenone
000769-00414	Powdered Cube	Piperonyl butoxide Pyrethrins Rotenone
000769-00857	Science Red Arrow Insect Spray	Piperonyl butoxide Cube Resins other than rotenone Pyrethrins Rotenone

Table 1.—Rotenone Product Registrations with Pending Requests for Cancellation—Continued

Registration Number	Product Name	Chemical Name(s)
000869-00186	Green Light Rotenone	Cube Resins other than rotenone Rotenone
002217-00145	Garden Protector	Cube Resins other than rotenone Rotenone
008660-00050	1% Rotenone Garden Dust	Cube Resins other than rotenone Rotenone
028293-00042	Unicorn Ear Mite Control	Cube Resins other than rotenone Rotenone
030573-00002	Pyrellin E.C.	Cube Resins other than rotenone Pyrethrins Rotenone
033955-00270	Acme 1% Rotenone Garden Guard	Cube Resins other than rotenone Rotenone
034911-00021	Hi-Yield Rotenone 100 Insecticide Dust	Rotenone
047000-00026	Pet Dust	Cube Resins other than rotenone Rotenone

Table 2 of this unit includes the names and addresses of record for the registrants of the products listed in Table 1 of this unit, in sequence by EPA company number. This number corresponds to the first part of the EPA registration numbers of the products listed in Table 1 of this unit.

Table 2.—Registrants Requesting Voluntary Cancellation

Company Number	Company Name and Address
4	Bonide Products, Inc. P.O. Box 1019 Salem, VA 24153-3805
270	Farnam Companies, Inc. 301 West Osborn Road Phoenix, AZ 85013
769	Value Gardens Supply, LLC P.O. Box 585 Saint Joseph, MO 64502
869	Green Light Company 1600 Riviera Avenue, Suite 200 Walnut Creek, CA 94596
2217	PBI/Gordon Corp. 1217 West 12th St. P.O. Box 014090 Kansas City, MO 64101-0090
8660	United Industries Corporation P.O. Box 142642 St. Louis, MO 63114-0642

Table 2.—Registrants Requesting Voluntary Cancellation—Continued

Company Number	Company Name and Address
28293	Phaeton Corporation P.O. Box 1019 Salem, VA 24153
30573	Wright Webb Corporation P.O. Box 1572 Fort Myers, FL 33902
33955	PBI/Gordon Corp 1217 West 12th. St. P.O. Box 014090 Kansas City, MO 64101-0090
34911	Hi-Yield Chemical Company 6860 N. Dallas Pkwy., Suite 200 Plano, TX 75024
47000	Chem-Tech, LTD. 4515 Fleur Dr. #303 Des Moines, IA 50321

IV. 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 or amended to terminate one or more uses. FIFRA further provides that, before acting on the request, EPA must publish a notice of receipt of any such request in the **Federal Register**.

Section 6(f)(1)(B) of FIFRA requires that before acting on a request for voluntary cancellation, EPA must provide a 30–day public comment period on the request for voluntary cancellation or use termination. In addition, FIFRA section 6(f)(1)(C) requires that EPA provide a 180–day comment period on a request for voluntary cancellation or termination of any minor agricultural use before granting the request, unless:

1. The registrants request a waiver of the comment period, or

2. The EPA Administrator determines that continued use of the pesticide would pose an unreasonable adverse effect on the environment.

The rotenone registrants have requested that EPA waive the 180–day comment period. Accordingly, EPA will provide a 30–day comment period on the proposed requests.

V. Procedures for Withdrawal of Requests

Registrants who choose to withdraw a request for product cancellation or use deletion should submit the withdrawal in writing to the person listed under **FOR FURTHER INFORMATION CONTACT**. If the products(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.

VI. Provisions for Disposition of Existing Stocks

Existing stocks are those stocks of registered pesticide products that are currently in the United States and that were packaged, labeled, and released for shipment prior to the effective date of the action. If the requests for voluntary

cancellation are granted, the Agency intends to publish the cancellation order in the **Federal Register**.

In any order issued in response to these requests for cancellation of product registrations, EPA proposes to include the following provisions for the treatment of any existing stocks of the products listed in Table 1 of Unit III.

Because the Agency has potential risk concerns associated with these pesticide products, upon cancellation of the products identified in Table 1 of Unit III., EPA anticipates allowing registrants to sell and distribute existing stocks of these products until May 2011. Thereafter, registrants will be prohibited from selling or distributing the pesticides identified in Table 1 of Unit III., except for export consistent with FIFRA section 17 or for proper disposal. Persons other than registrants will generally be allowed to sell, distribute, or use existing stocks until May 2011.

List of Subjects

Environmental protection, Pesticides and pests.

Dated: June 10, 2010.

Richard P. Keigwin,

Director, Pesticide Re-evaluation Division, Office of Pesticide Programs.

[FR Doc. 2010–18377 Filed 7–27–10; 8:45 am]

BILLING CODE 6560–50–S

FEDERAL DEPOSIT INSURANCE CORPORATION

Agency Information Collection Activities: Submission for OMB Review; Comment Request

AGENCY: Federal Deposit Insurance Corporation (FDIC).

ACTION: Notice of information collection to be submitted to OMB for review and approval under the Paperwork Reduction Act.

SUMMARY: In accordance with requirements of the Paperwork Reduction Act of 1995 ("PRA"), 44 U.S.C. 3501 *et. seq.,* the FDIC may not conduct or sponsor, and the 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 FDIC, 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 the renewal of existing information collections, as required by the PRA. On May 18, 2010 (75 FR 27781), the FDIC solicited public comment for a 60-day period on renewal of the following information collections: Application for Consent to Exercise Trust Powers (3064–0025), and Insurance Sales Consumer Protections (3064–0140). No comments were received. Therefore, the FDIC hereby gives notice of submission of its requests for renewal to OMB for review.

DATES: Comments must be submitted on or before August 27, 2010.

ADDRESSES: Interested parties are invited to submit written comments by any of the following methods:

- *http://www.FDIC.gov/regulations/laws/federal/notices.html.*
- *E-mail: comments@fdic.gov.* Include the name of the collection in the subject line of the message.
- *Mail:* Leneta G. Gregorie (202–898–3719), Counsel, Room F–1064, Federal Deposit Insurance Corporation, 550 17th Street, NW., Washington, DC 20429.
- *Hand Delivery:* Comments may be hand-delivered to the guard station at the rear of the 17th Street Building (located on F Street), on business days between 7 a.m. and 5 p.m.

All comments should refer to the relevant OMB control number. A copy of the comments may also be submitted to the OMB Desk Officer for the FDIC: Office of Information and Regulatory Affairs, Office of Management and Budget, New Executive Office Building, Washington, DC 20503.

FOR FURTHER INFORMATION CONTACT: Leneta Gregorie (address above).

SUPPLEMENTARY INFORMATION:

1. *Title:* Application for Consent to Exercise Trust Powers.

OMB Number: 3064–0025.

Form Number: FDIC 6200/09.

Frequency of Response: On occasion.

Affected Public: Insured State nonmember banks wishing to exercise trust powers.

Estimated Number of Respondents: 15.

Estimated Time per Response for Eligible Depository Institutions: 8 hours.

Estimated Time per Response for Institutions that do not qualify as Eligible Institutions: 24 hours.

Total Annual Burden: 200 hours.

General Description of Collection: FDIC regulations (12 CFR 333.2) prohibit any insured State nonmember bank from changing the general character of its business without the prior written consent of the FDIC. The exercise of trust powers by a bank is usually considered to be a change in the general character of a bank's business if the bank did not exercise those powers previously. Therefore, unless a bank is currently exercising trust powers, it must file a formal application to obtain the FDIC's written consent to exercise trust powers. State banking authorities, not the FDIC, grant trust powers to their banks. The FDIC merely consents to the exercise of such powers. Applicants use form FDIC 6200/09 to obtain FDIC's consent.

2. *Title:* Consumer Protections for Depository Institution Sales of Insurance.

OMB Number: 3064–0140.

Form Number: None.

Frequency of Response: On occasion.

Affected Public: Insured State nonmember banks that sell insurance products; persons who sell insurance products in or on behalf of insured State nonmember banks.

Estimated Number of Respondents: 3,740.

Estimated Time per Response: 5 hours.

Total Annual Burden: 18,700 hours.

General Description of Collection: Respondents must prepare and provide certain disclosures to consumers (*e.g.,* that insurance products and annuities are not FDIC-insured) and obtain consumer acknowledgments, at two different times: (1) Before the completion of the initial sale of an insurance product or annuity to a consumer; and (2) at the time of application for the extension of credit (if insurance products or annuities are sold, solicited, advertised, or offered in connection with an extension of credit).

Request for Comment: Comments are invited on: (a) Whether these collections of information are necessary for the proper performance of the FDIC's functions, including whether the information has practical utility; (b) the accuracy of the estimates of the burden of the information collections, including the validity of the methodology and assumptions used; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the information collections on respondents, including through the use of automated collection techniques or other forms of information technology. All comments will become a matter of public record.

Dated at Washington, DC, this 22nd day of July 2010.

Federal Deposit Insurance Corporation.

Robert E. Feldman,

Executive Secretary.

[FR Doc. 2010–18419 Filed 7–27–10; 8:45 am]

BILLING CODE 6714–01–P

FEDERAL DEPOSIT INSURANCE CORPORATION

Update to Notice of Financial Institutions for Which the Federal Deposit Insurance Corporation Has Been Appointed Either Receiver, Liquidator, or Manager

AGENCY: Federal Deposit Insurance Corporation.

ACTION: Update listing of financial institutions in liquidation.

SUMMARY: Notice is hereby given that the Federal Deposit Insurance Corporation (Corporation) has been appointed the sole receiver for the following financial institutions effective as of the Date Closed as indicated in the listing. This list (as updated from time to time in the **Federal Register**) may be relied upon as "of record" notice that the Corporation has been appointed receiver for purposes of the statement of policy published in the July 2, 1992 issue of the **Federal Register** (57 FR 29491). For further information concerning the identification of any institutions which have been placed in liquidation, please visit the Corporation Web site at *http://www.fdic.gov/bank/individual/failed/banklist.html* or contact the Manager of Receivership Oversight in the appropriate service center.

Dated: July 19, 2010.

Federal Deposit Insurance Corporation.

Pamela Johnson,

Regulatory Editing Specialist.

INSTITUTIONS IN LIQUIDATION

[In alphabetical order]

FDIC Ref. No.	Bank name	City	State	Date closed
10263	First National Bank of the South	Spartanburg	SC	7/16/2010
10258	Mainstreet Savings Bank, FSB	Hastings	MI	7/16/2010
10259	Metro Bank of Dade County	Miami	FL	7/16/2010
10260	Olde Cypress Community Bank	Clewiston	FL	7/16/2010
10261	Turnberry Bank	Aventura	FL	7/16/2010
10262	Woodlands Bank	Bluffton	SC	7/16/2010

[FR Doc. 2010–18411 Filed 7–27–10; 8:45 am]

BILLING CODE P

FEDERAL ELECTION COMMISSION

Sunshine Act Notices

AGENCY: Federal Election Commission.

Cancellation

DATE AND TIME: Wednesday, July 21, 2010, at 10 a.m.

PLACE: 999 E Street, NW., Washington, DC (Ninth floor).

STATUS: This meeting, open to the public, was canceled.

DATE AND TIME: Tuesday, July 27, 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. 2010–18297 Filed 7–27–10; 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 applications 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 August 23, 2010.

A. Federal Reserve Bank of Dallas (E. Ann Worthy, Vice President) 2200 North Pearl Street, Dallas, Texas 75201-2272:

1. Austin Bancorp, Inc., Jacksonville, Texas; JSA Family Limited Partnership, Jacksonville, Texas; Jane Austin Chapman Limited Partnership, L.P., Frankston, Texas; and TEB, Inc., Shreveport, Louisiana, to merge with Frankston Bancorp, Inc., Frankston, Texas, and thereby indirectly acquire FDB, Inc., Dover, Delaware, and First State Bank, Frankston, Texas.

Board of Governors of the Federal Reserve System, July 23, 2010.

Robert deV. Frierson,

Deputy Secretary of the Board.

[FR Doc. 2010–18462 Filed 7–27–10; 8:45 am]

BILLING CODE 6210–01–S

FEDERAL MARITIME COMMISSION

Notice of Agreement Filed

The Commission hereby gives notice of the filing of the following agreement under the Shipping Act of 1984. Interested parties may submit comments on the agreement to the Secretary, Federal Maritime Commission, Washington, DC 20573, within ten days of the date this notice appears in the **Federal Register**. A copy of the agreement is available through the Commission's Web site (*http://www.fmc.gov*) or by contacting the Office of Agreements at (202)-523–5793 or *tradeanalysis@fmc.gov*.

Agreement No.: 011794–013.

Title: COSCON/KL/YMUK/Hanjin Worldwide Slot Allocation & Sailing Agreement.

Parties: COSCO Container Lines Company, Limited; Kawasaki Kisen Kaisha, Ltd.; Yangming (UK) Ltd.; and Hanjin Shipping Co., Ltd.

Filing Party: Amy Cano; Nixon Peabody LLP; 555 West Fifth Street, 46th Floor; Los Angeles, CA 90013.

Synopsis: The amendment changes the number of vessels and increases the TEU capacities for two of the parties.

By Order of the Federal Maritime Commission.

Dated: July 23, 2010.

Karen V. Gregory,

Secretary.

[FR Doc. 2010–18526 Filed 7–27–10; 8:45 am]

BILLING CODE 6730–01–P

FEDERAL MARITIME COMMISSION

Ocean Transportation Intermediary License Applicants

Notice is hereby given that the following applicants have filed with the Federal Maritime Commission an application for a license as a Non-Vessel-Operating Common Carrier (NVO) and/or Ocean Freight Forwarder (OFF)—Ocean Transportation Intermediary (OTI) pursuant to section 19 of the Shipping Act of 1984 as amended (46 U.S.C. chapter 409 and 46 CFR part 515). Notice is also hereby given of the filing of applications to amend an existing OTI license or the Qualifying Individual (QI) for a license.

Interested persons may contact the Office of Transportation Intermediaries, Federal Maritime Commission, Washington, DC 20573.

American Cargo, Inc. (NVO & OFF), 1509 S. Sierra Vista Avenue, #C, Alhambra, CA 91801. *Officer:* Shunkun He, CEO, (Qualifying Individual). *Application Type:* New NVO & OFF License.

Avenue 8 Group Inc. dba Avenue International (NVO & OFF), 9080 Telstar Avenue, #321, El Monte, CA 91731. *Officers:* Ana Fregoso, Vice President, (Qualifying Individual). Ryan Luu, President. *Application Type:* New NVO & OFF License.

BYTR International Inc. (OFF), 13152 Rivergate Trail West, Jacksonville, FL 32223. *Officer:* Bahtiyar Yurdakul, President (Qualifying Individual). *Application Type:* License Transfer.

Douglas Enrique Cabrera dba Cargo-Envios Express (NVO & OFF), 2500 Cruze Place, Hyattsville, MD 20783. *Officer:* Douglas Enrique Cabrera, President (Qualifying Individual). *Application Type:* New NVO & OFF License.

Cargomar Express, Inc. (NVO & OFF), 6713 NW. 84th Avenue, Miami, FL 33166. *Officer:* Lainder Araujo, President/Secretary (Qualifying Individual). *Application Type:* New NVO & OFF License.

CJC Logistics LLC (NVO & OFF), 186 Alps Road, Wayne, NJ 07470. *Officers:* Oliver Rosca, President, (Qualifying Individual). Maria L. Rosca, CFO. *Application Type:* Add NVO Service.

Global Cargo Connection (NVO), 370 Amapola Avenue, Suite 108, Torrance, CA 90501. *Officer:* Steve Lee, President (Qualifying Individual). *Application Type:* Trade Name Change.

Jason Michael Pitcock dba JPL (NVO & OFF), 8831 Vista Springs Drive Spring, TX 77379. *Officer:* Jason M. Pitcock, Sole Proprietor (Qualifying Individual). *Application Type:* New NVO & OFF License.

Joker Logistics USA, Inc. (NVO & OFF), 11301 Metro Airport Center Drive, #170, Romulus, MI 48174. *Officer:* Michael Unsworth, Vice President of Customs (Qualifying Individual), Roland Mischke, Director/President/Secretary. *Application Type:* QI Change.

Korchina Logistics USA, Inc. (NVO & OFF), 18120 S. Broadway, Unit A, Gardena, CA 90248. *Officers:* Young C. Jang, Secretary (Qualifying Individual). Eric Sun, President/CEO/Director. *Application Type:* New NVO & OFF License.

Mega Shipping, Inc. (NVO), 9550 Flair Drive, #508, El Monte, CA 91731. *Officers:* Yuwei Chen, CEO/Secretary/CFO (Qualifying Individual). Application Type: New NVO License.

Oliveira Marine Shipping, Inc. (NVO & OFF), 1200 Acushnet Avenue, New Bedford, MA 02746. *Officers:* Arnaldo S. Oliveira, President (Qualifying Individual). *Application Type:* Add NVO Service.

Pas Global Logistics, Inc. (NVO & OFF), 8555 Cashio Street, #305, Los Angeles, CA 90035. *Officer:* Seung H. Moon, President/Secretary/Treasurer (Qualifying Individual). *Application Type:* New NVO & OFF License.

PNGL (USA) Inc. (NVO & OFF), Unit 2K, Pacifica Industrial Park, 17121 S. Central Avenue, Carson, CA 90746. *Officers:* Lilliane Sagherian, Vice President, Werner Staub, President/Secretary/CFO (Qualifying Individuals). *Application Type:* QI Change.

Safeway Shipping and Clearing Services, Inc (NVO & OFF), 3615 Willowbend Boulevard, #414, Houston, TX 77054. *Officer:* Julius Okunola, Chairman/Executive Director (Qualifying Individual), Abiola Iyiola, Director. *Application Type:* New NVO & OFF License.

Sunjin Shipping (U.S.A.), Inc. (NVO & OFF), 149–15 177th Street, Jamaica, NY 11413. *Officers:* Key Y. Chung, President (Qualifying Individual), Inho Hwang, Treasurer. *Application Type:* Add NVO Service.

TGP Logistics Inc. (OFF), 11490 Westheimer, #850, Houston, TX 77077. *Officers:* Myrian T. Morales, Assistant Vice President & Projects Coordinator (Qualifying Individual), Colin B. Charnock, Managing Director. *Application Type:* New OFF License.

U.S. Africa Freight, Inc. dba U.S. 2 Africa dba U.S. Africa Shipping (OFF), 930 Hoffner Avenue, Orlando, FL 23809. *Officers:* Esthela Montgomery, Secretary (Qualifying Individual), Neil Barclay, Director. *Application Type:* New OFF License.

YRC Logistics Global, LLC (NVO & OFF), 10990 Roe Avenue, MS E101, Overland Park, KS 66211. *Officers:* Tina M. Jansen, VP Import Compliance & Services (Qualifying Individual), John Carr, President. *Application Type:* QI Change.

Zapcargo Logistics, LLC (NVO), 10735 SW. 216 Street, #408, Miami, FL 33170. *Officers:* Maurice V. Lloyd, Managing Director (Qualifying Individual). *Application Type:* New OFF License.

Dated: July 23, 2010.

Karen V. Gregory,

Secretary.

[FR Doc. 2010–18529 Filed 7–27–10; 8:45 am]

BILLING CODE 6730–01–P

FEDERAL MARITIME COMMISSION

Ocean Transportation Intermediary License Reissuance

Notice is hereby given that the following Ocean Transportation Intermediary licenses have been reissued by the Federal Maritime Commission pursuant to section 19 of the Shipping Act of 1984 (46 U.S.C. chapter 409) and the regulations of the Commission pertaining to the licensing of Ocean Transportation Intermediaries, 46 CFR part 515.

License No.	Name/Address	Date reissued
003095F	Flamingo International, Inc. 7185 NW 87th Avenue, Miami, FL 33178	May 1, 2010.
018012N	Speedex Air & Ocean, Inc. 13337 South Street, Suite 34, Cerritos, CA 90703	June 14, 2010.
021623N	Victory Worldwide Inc. 1500 Midway Court, Suite W–104, Elk Grove Village, IL 60007.	May 15, 2010.

Sandra L. Kusumoto,

Director, Bureau of Certification and Licensing.

[FR Doc. 2010–18532 Filed 7–27–10; 8:45 am]

BILLING CODE 6730–01–P

FEDERAL MARITIME COMMISSION

Ocean Transportation Intermediary License; Rescission of Order of Revocation

Notice is hereby given that the Order revoking the following license is being rescinded by the Federal Maritime Commission pursuant to section 19 of the Shipping Act of 1984 (46 U.S.C. chapter 409) and the regulations of the Commission pertaining to the licensing of Ocean Transportation Intermediaries, 46 CFR part 515.

License Number: 003486F.

Name: Mozart Forwarding, Inc.

Address: 535 Seaview Avenue, Bridgeport, CT 06607.

Order Published: FR: 3/10/2010 (Volume 75, No. 46 Pg. 11181).

Sandra L. Kusumoto,

Director, Bureau of Certification and Licensing.

[FR Doc. 2010–18527 Filed 7–27–10; 8:45 am]

BILLING CODE 6730–01–P

FEDERAL MARITIME COMMISSION

Ocean Transportation Intermediary License Revocations

The Federal Maritime Commission hereby gives notice that the following Ocean Transportation Intermediary licenses have been revoked pursuant to section 19 of the Shipping Act of 1984 (46 U.S.C. chapter 409) and the regulations of the Commission pertaining to the licensing of Ocean Transportation Intermediaries, 46 CFR part 515, effective on the corresponding date shown below:

LICENSE NUMBER: 2242F.

NAME: Carlos E. Plazas dba Plazas International Company.

ADDRESS: 825 College Blvd., Suite 416, Oceanside, CA 92057.

DATE REVOKED: July 6, 2010.

REASON: Surrendered license voluntarily.

LICENSE NUMBER: 2380F.

NAME: HAV International Freight Corp.

ADDRESS: JKF International Airport, Bldg. 75, Jamaica, NY 11430.

DATE REVOKED: May 3, 2010.

REASON: Failed to maintain a valid bond.

LICENSE NUMBER: 002638F.

NAME: Intercorp Forwarders, Ltd.

ADDRESS: 167 Maple Avenue, Sea Cliff, NY 11579.

DATE REVOKED: May 5, 2010.

REASON: Failed to maintain a valid bond.

LICENSE NUMBER: 2866F.

NAME: Jong Pyo Kim.

ADDRESS: 17100 Pioneer Blvd., Suite 345, Artesia, CA 90701.

DATE REVOKED: June 16, 2010.

REASON: Failed to maintain a valid bond.

LICENSE NUMBER: 003095N.

NAME: Flamingo International, Inc.

ADDRESS: 7185 NW 87th Avenue, Miami, FL 33178.

DATE REVOKED: May 1, 2010.

REASON: Failed to maintain a valid bond.

LICENSE NUMBER: 3298F.

NAME: Rical Express, Inc.

ADDRESS: 1550 E. Higgins Road, Suite 129, Elk Grove Village, IL 60007.

DATE REVOKED: May 25, 2010.

REASON: Surrendered License Voluntarily.

LICENSE NUMBER: 3713F.

NAME: Fresh Commodities Carrier, Inc.

ADDRESS: 11942 Reagan Street, Los Alamitos, CA 90720.

DATE REVOKED: May 21, 2010.

REASON: Failed to maintain a valid bond.

LICENSE NUMBER: 3782F.

NAME: Meyer Shipping Corp.

ADDRESS: 1733 49th Street, Brooklyn, NY 11204.

DATE REVOKED: May 5, 2010.

REASON: Failed to maintain a valid bond.

LICENSE NUMBER: 4141F.

NAME: Barnett Trading, Inc.

ADDRESS: 217 Humphrey Street, Marblehead, MA 01945.

DATE REVOKED: May 20, 2010.

REASON: Failed to maintain a valid bond.

LICENSE NUMBER: 004309F.

NAME: East West North South Forwarding, Inc.

ADDRESS: 3511 NW 113th Court, Miami, FL 33178.

DATE REVOKED: May 21, 2010.

REASON: Failed to maintain a valid bond.

LICENSE NUMBER: 4373F.

NAME: Elite Airfreight, Inc.

ADDRESS: 16303 Air Center Blvd., Houston, TX 77032.

DATE REVOKED: May 16, 2010.

REASON: Failed to maintain a valid bond.

LICENSE NUMBER: 004482NF.

NAME: Glodex, Corp.

ADDRESS: 7249 NW 54th Street, Miami, FL 33166.

DATE REVOKED: June 27, 2010.

REASON: Failed to maintain valid bonds.

LICENSE NUMBER: 004662N.

NAME: Sanyo Logistics Corporation.

ADDRESS: 3625 Del Amo Blvd., Suite 105, Torrance, CA 90503.

DATE REVOKED: June 7, 2010.

REASON: Failed to maintain a valid bond.

LICENSE NUMBER: 10509N.

NAME: Rical Container Line, Ltd. (USA).

ADDRESS: 1550 E. Higgins Road. Suite 129, Elk Grove Village, IL 60007.

DATE REVOKED: May 25, 2010.

REASON: Surrendered License Voluntarily.

LICENSE NUMBER: 013604N.
NAME: Carlos B. Sanchez dba R & S Trading.
ADDRESS: Lerida 310, Urb Valencia, Rio Piedras, PR 00924.
DATE REVOKED: June 3, 2010.
REASON: Failed to maintain a valid bond.

LICENSE NUMBER: 015941F.
NAME: Cargo Plus, Inc.
ADDRESS: 8333 Wessex Drive, Pennsauken, NJ 08109.
DATE REVOKED: June 23, 2010.
REASON: Failed to maintain a valid bond.

LICENSE NUMBER: 16283N.
NAME: Sea Air Surface Distribution, Inc.
ADDRESS: 2018 Mount Forest Drive, Kingwood, TX 78521.
DATE REVOKED: May 30, 2010.
REASON: Failed to maintain a valid bond.

LICENSE NUMBER: 17860N.
NAME: Remnant Shipping, Inc.
ADDRESS: 16921 S. Western Avenue, Suite 205, Gardena, CA 90247.
DATE REVOKED: June 26, 2010.
REASON: Failed to maintain a valid bond.

LICENSE NUMBER: 18012F.
NAME: Speedex Air & Ocean, Inc.
ADDRESS: 13337 South Street, Suite 34, Cerritos, CA 90703.
DATE REVOKED: June 14, 2010.
REASON: Failed to maintain a valid bond.

LICENSE NUMBER: 018268N.
NAME: Duncan B. Greenwood dba G&F West Indies Shipping.
ADDRESS: 1416 Bluehill Avenue, Suite 1, Boston, MA 02126.
DATE REVOKED: June 24, 2010.
REASON: Failed to maintain a valid bond.

LICENSE NUMBER: 018305N.
NAME: Mc Logix, Inc.
ADDRESS: 18030 S. Figueroa Street, Gardena, CA 90248.
DATE REVOKED: June 9, 2010.
REASON: Failed to maintain a valid bond.

LICENSE NUMBER: 018443N.
NAME: State Street Shipping Agency, Inc. dba Sabrina Shipping.
ADDRESS: One Saint Louis Centre, Suite 3002, Mobile, AL 36602
DATE REVOKED: June 17, 2010.
REASON: Failed to maintain a valid bond.

LICENSE NUMBER: 018486N.
NAME: AAA Cargo LLC.
ADDRESS: 14536 Roscoe Blvd., Suite 101, Panorama City, CA 91402.
DATE REVOKED: June 26, 2010.
REASON: Failed to maintain a valid bond.

LICENSE NUMBER: 18547N.
NAME: Pallets in Motion.
ADDRESS: 426 W. Florence Avenue, Inglewood, CA 90301.
DATE REVOKED: June 26, 2010.
REASON: Failed to maintain a valid bond.

LICENSE NUMBER: 018798N.
NAME: Beyond Shipping, Inc.
ADDRESS: 721 Brea Canyon Road, Suite 4, Walnut, CA 91789.
DATE REVOKED: June 14, 2010.
REASON: Failed to maintain a valid bond.

LICENSE NUMBER: 019014N.
NAME: Ni Midstar, LLC.
ADDRESS: 370 W. Anchor Dr., #210, Dakota Dunes, SD 57049.
DATE REVOKED: June 17, 2010.
REASON: Surrendered license voluntarily.

LICENSE NUMBER: 019125N.
NAME: Monumental Shipping & Moving Corp.
ADDRESS: 103–10 Astoria Blvd., East Elmhurst, NY 11369.
DATE REVOKED: June 8, 2010.
REASON: Surrendered license voluntarily.

LICENSE NUMBER: 019371N.
NAME: Ridge International Freight, Ltd. dba RIF Line.
ADDRESS: 19707 44th Avenue, Suite 207–A, Lynnwood, WA 98036.
DATE REVOKED: June 18, 2010.
REASON: Failed to maintain a valid bond.

LICENSE NUMBER: 019373NF.
NAME: SYL Cargo USA, Inc.
ADDRESS: 8513 NW 72nd Street, Miami, FL 33166.
DATE REVOKED: June 16, 2010.
REASON: Failed to maintain valid bonds.

LICENSE NUMBER: 019607F.
NAME: Carolina Forwarding & Brokerage, LLC.
ADDRESS: 3220 Carmel Bay Drive, Mount Pleasant, SC 29466.
DATE REVOKED: June 17, 2010.
REASON: Surrendered License Voluntarily.

LICENSE NUMBER: 020242F.
NAME: Journey Moving and Storage Corp dba International Sea & Air.
ADDRESS: 21–A Progress Street, Edison, NJ 08820.
DATE REVOKED: June 19, 2010.
REASON: Failed to maintain a valid bond.

LICENSE NUMBER: 020151F.
NAME: United Global Logistics, LLC.
ADDRESS: 1139 E. Jersey Street, Suite 417, Elizabeth, NJ 07208.
DATE REVOKED: May 27, 2010.
REASON: Failed to maintain a valid bond.

LICENSE NUMBER: 020436N.
NAME: Asia Forwarders, Inc.
ADDRESS: 13434 Village Drive, Cerritos, CA 90703.
DATE REVOKED: June 18, 2010.
REASON: Failed to maintain a valid bond.

LICENSE NUMBER: 020482N.
NAME: AA Connection, LLC.
ADDRESS: 12810 NE 178th Street, Suite 235, Woodinville, WA 98072.
DATE REVOKED: June 18, 2010.
REASON: Surrendered License Voluntarily.

LICENSE NUMBER: 020802NF.
NAME: Michael McGovern dba Scotia Ocean Services, Ltd.
ADDRESS: 15925 Morales Road, Suite A–200, Houston, TX 77032.
DATE REVOKED: May 7, 2010.
REASON: Failed to maintain valid bonds.

LICENSE NUMBER: 020821NF.
NAME: Gold Coast Shipping, LLC.
ADDRESS: 2964 Main Street, Hartford, CA 06120.
DATE REVOKED: June 11, 2010.
REASON: Failed to maintain valid bonds.

LICENSE NUMBER: 020890N.
NAME: Aegis International, Inc.
ADDRESS: 300 Sunset Road, Suite 301, Burlington TWP, NJ 08016.
DATE REVOKED: May 6, 2010.
REASON: Failed to maintain a valid bond.

LICENSE NUMBER: 021623F.
NAME: Victory Worldwide Inc.
ADDRESS: 1500 Midway Court, Suite W–104, Elk Grove Village, IL 60007.
DATE REVOKED: May 15, 2010.
REASON: Failed to maintain a valid bond.

LICENSE NUMBER: 021286F.
NAME: Elzado Enterprises Incorporated.
ADDRESS: 14940 Grant Lane, Leisure City, FL 33033
DATE REVOKED: June 7, 2010.
REASON: Failed to maintain a valid bond.

LICENSE NUMBER: 021354NF.
NAME: Jaemar International Inc.
ADDRESS: 6420 Richmond Avenue, Houston, TX 77057
DATE REVOKED: June 25, 2010.
REASON: Failed to maintain valid bonds.

LICENSE NUMBER: 021385NF.
NAME: CJ GLS America, Inc.
ADDRESS: 404 Foxrun Avenue, Opelika, AL 36801
DATE REVOKED: May 14, 2010.
REASON: Failed to maintain valid bonds.

LICENSE NUMBER: 021472F.
NAME: Sunstar Forwarding, Inc.

ADDRESS: 445 Grayrock Drive, Crozet, VA 22932
DATE REVOKED: May 7, 2010.
REASON: Failed to maintain a valid bond.

LICENSE NUMBER: 021494NF.
NAME: Anchor Advantage, LLC.
ADDRESS: 15 West Cranberry Lane, Greenville, SC 29615.
DATE REVOKED: June 24, 2010.
REASON: Surrendered License Voluntarily.

LICENSE NUMBER: 021586N.
NAME: Chronos International Cargo Corp.
ADDRESS: 6030 NW 99th Avenue, Suite 407, Doral, FL 33178.
DATE REVOKED: May 12, 2010.
REASON: Failed to maintain a valid bond.

LICENSE NUMBER: 021740NF.
NAME: Dart Express (SFO), LLC.
ADDRESS: 5101 South Broad Street.
DATE REVOKED: July 2, 2010.
REASON: Surrendered License Voluntarily.

LICENSE NUMBER: 021741N.
NAME: Dart Express (LAX), LLC.
ADDRESS: 5101 South Broad Street, Philadelphia, PA 19112.
DATE REVOKED: July 2, 2010.
REASON: Surrendered License Voluntarily.

LICENSE NUMBER: 021792N.
NAME: TSL International Inc.
ADDRESS: 136 Bay 14th Street, Brooklyn, NY 11214.
DATE REVOKED: May 1, 2010.
REASON: Failed to maintain a valid bond.

LICENSE NUMBER: 021802N.
NAME: J & D America Inc.
ADDRESS: 248 West 35th Street, New York, NY 10001
DATE REVOKED: June 11, 2010.
REASON: Failed to maintain a valid bond.

LICENSE NUMBER: 021809F.
NAME: Mark VII ETS, LLC.
ADDRESS: 328 Office Square Lane, Suite 201, Virginia Beach, VA 23462.
DATE REVOKED: May 9, 2010.
REASON: Failed to maintain a valid bond.

LICENSE NUMBER: 022027NF.
NAME: AGL Logistics Inc.
ADDRESS: 1255 Corporate Center Drive, Suite 101, Montery Park, CA 91754.
DATE REVOKED: June 23, 2010.
REASON: Failed to maintain valid bonds.

LICENSE NUMBER: 022112N.
NAME: Overseas Shipping Ltd.
ADDRESS: 2914 North Calvert Street, Baltimore, MD 21218.
DATE REVOKED: June 21, 2010.
REASON: Surrendered License Voluntarily.

LICENSE NUMBER: 022183NF.
NAME: Express Logistics Group, Inc.
ADDRESS: 14439 South Avalon Blvd., Gardena, CA 90248
DATE REVOKED: July 2, 2010.
REASON: Surrendered License Voluntarily.

Sandra L. Kusumoto,
Director, Bureau of Certification and Licensing.

[FR Doc. 2010–18530 Filed 7–27–10; 8:45 am]
BILLING CODE 6730–01–P

GENERAL SERVICES ADMINISTRATION

[FMR Bulletin PBS–2010–B4; Docket 2010–0005; Sequence 10]

Federal Management Regulation; FMR Bulletin PBS–2010–B4; Redesignation of Federal Building

AGENCY: Public Buildings Service (P), General Services Administration.

ACTION: Notice of a bulletin.

SUMMARY: The attached bulletin announces the redesignation of a Federal building.

DATES: *Expiration Date:* This bulletin expires December 31, 2010. However, the building redesignation announced by this bulletin will remain in effect until canceled or superseded.

FOR FURTHER INFORMATION CONTACT: U.S. General Services Administration, Public Buildings Service (P), Attn: David E. Foley, 1800 F Street, NW., Washington, DC 20405, e-mail at *david.foley@gsa.gov.* (202) 501–1100.

Dated: July 16, 2010.

Martha Johnson,
Administrator of General Services.

U.S. GENERAL SERVICES ADMINISTRATION

REDESIGNATION OF FEDERAL BUILDING-

TO: Heads of Federal Agencies

SUBJECT: Redesignation of Federal Building

1. *What is the purpose of this bulletin*? This bulletin announces the redesignation of a Federal building.

2. *When does this bulletin expire*? This bulletin expires December 31, 2010. However, the building redesignation announced by this bulletin will remain in effect until canceled or superseded.

3. *Redesignation.* The former and new name of the redesignated building is as follows:

Former Name	*New Name*
United States Department of the Interior Building 1849 C Street, NW Washington, DC 20240	Stewart Lee Udall Department of the Interior Building 1849 C Street, NW Washington, DC 20240

4. *Who should we contact for further information regarding redesignation of this Federal building*? U.S. General Services Administration, Public Buildings Service (P), Attn: David E. Foley, 1800 F Street, NW, Washington, DC 20405, telephone number: (202) 501–1100, e-mail at *david.foley@gsa.gov.*

Dated: July 16, 2010

Martha Johnson,
Administrator of General Services.

[FR Doc. 2010–18467 Filed 7–27–10; 8:45 am]
BILLING CODE 6820–23–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of the Secretary

Office of the Assistant Secretary for Preparedness and Response; Delegation of Authority

Notice is hereby given that I have delegated to the Assistant Secretary for Preparedness and Response (ASPR) the authorities vested in the Secretary of Health and Human Services under sections 1201–1232 of title 12 of the Public Health Service Act, parts A through C of title 12, (42 U.S.C. 300d through 300d–32), as amended, to administer grants and related authorities for trauma and emergency care.

This delegation rescinds and supersedes all previous delegations insofar as it pertains to the authority to carry out sections 1201 through 1232.

Exercise of this authority shall be in accordance with established policies, procedures, guidelines and regulations as prescribed by the Secretary.

I hereby affirm and ratify any actions taken by you or your subordinates that involved the exercise of the authorities delegated herein prior to the effective date of the delegation.

This delegation is effective immediately.

Dated: July 16, 2010.

Kathleen Sebelius,

Secretary, U.S. Department of Health and Human Services.

[FR Doc. 2010–18544 Filed 7–27–10; 8:45 am]

BILLING CODE 4150–37–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of the Secretary

Office of the Assistant Secretary for Planning and Evaluation; Request for Comments on the Departmental FY 2010–2015 Strategic Plan

AGENCY: Office of the Secretary, Health and Human Services.

ACTION: Request for Comments on the Draft Strategic Plan FY 2010–2015.

SUMMARY: The Department of Health and Human Services (HHS) is seeking public comment on its draft Strategic Plan for fiscal years 2010–2015.

DATES: Submit comments on or before August 14.

ADDRESSES: Written comments can be provided online, or by e-mail, fax or U.S. mail.

E-mail: HHSStrategicPlan@hhs.gov.

Fax: (202) 690–8252.

Mail: U.S. Department of Health and Human Services, Office of the Assistant Secretary for Planning and Evaluation, Office of Planning and Policy Support, Attn: Strategic Plan Comments, 200 Independence Avenue, SW., Room 408B, Washington, DC 20201.

FOR FURTHER INFORMATION CONTACT: Audrey Mirsky-Ashby, (202) 401–6640.

SUPPLEMENTARY INFORMATION: The Department of Health and Human Services Draft FY 2010–2015 Strategic Plan is provided as part of the strategic planning process under the Government Performance and Results Act (GPRA) to ensure that Agency stakeholders are given an opportunity to comment on this plan.

This document integrates the Department's mission into a presentation of performance goals under four strategic goals. These five strategic goals are (1) Transform Health Care, (2) Advance Scientific Knowledge and Innovation, (3) Advance the Health, Safety, and Well-Being of the American People, (4) Increase Efficiency, Transparency, and Accountability of HHS Programs, and (5) Strengthen the Nation's Health and Human Services Infrastructure and Workforce.

The strategic planning process is an opportunity for the Department to further refine and strengthen the strategic goal structure currently in place. For comparison purposes, the current HHS Strategic Plan FY 2007–2012 can be viewed at *http://aspe.hhs.gov/hhsplan/.*

The Department has made significant progress in its strategic and performance planning efforts. As we build on this progress we look forward to receiving your comments by August 14. The text of the draft strategic plan is available in a "pdf" downloadable format through the Department of Health and Human Services Web site: *http://www.hhs.gov/open/.*

For those who may not have Internet access, a hard copy can be requested from the contact point, Audrey Mirsky-Ashby, 202–401–6640.

Dated: July 21, 2010.

Sherry Glied,

Assistant Secretary for Planning and Evaluation.

[FR Doc. 2010–18547 Filed 7–27–10; 8:45 am]

BILLING CODE 4151–05–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Proposed Collection; Comment Request; Online Skills Training for PCPs on Substance Abuse

SUMMARY: Under the provisions of Section 3506(c)(2)A of the Paperwork Reduction Act of 1995, the National Institute on Drug Abuse, the National Institutes of Health has submitted to the Office of Management and Budget (OMB) a request to review and approve the information collection listed below. The purpose of this notice is to allow 60 days for public comment.

Proposed Collection:

Title: Online Skills Training for PCPs on Substance Abuse.

Type of Information Collection Request: New.

Need and Use of Information Collection: This research will evaluate the effectiveness of the Online Skills Training for PCPs on Substance Abuse, via the Web site SBIRTTraining.com, to positively impact the knowledge, attitudes, intended behaviors and clinical skills of primary care physicians in the U.S. who treat substance abuse patients. The Online Skills Training for PCPs on Substance Abuse is a new program developed with funding from the National Institute on Drug Abuse. The primary goal is to assess the impact of the training program on knowledge, attitude, intended behavior, and clinical skills. A secondary goal is to assess learner satisfaction with the program. If the program is a success, there will be a new, proven resource available to primary care physicians to improve their ability to assess and treat substance use disorders. In order to evaluate the effectiveness of the program, information will be collected from primary care physicians before exposure to the Web based materials (pre-test), after exposure to the Web based materials (post-test), and 4–6 weeks after the program has been completed (follow-up).

Frequency of Response: On occasion.

Affected Public: Primary care physicians who treat patients who have substance abuse.

Type of Respondents: Physicians.

The annual reporting burden is as follows:

Estimated Number of Respondents: 80.

Estimated Number of Responses per Respondent: 3.

Average Burden Hours per Response: 0.75.

Estimated Total Annual Burden Hours Requested: 180.

The annualized cost to respondents is estimated at: $13,500. There are no Capital Costs, Operating Costs, and/or Maintenance Costs to report.

Type of respondents	Estimated number of respondents	Estimated number of responses per respondent	Average burden hours per response	Estimated annual burden hours requested
Primary care physicians	80	3	0.75	180

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: Quandra Scudder, Project Officer, NIH/NIDA/CCTN, Room 3105, MSC 9557, 6001 Executive Boulevard, Bethesda, MD 20892–9557 or e-mail your request, including your address to *scudderq@nida.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.

Dated: July 21, 2010.

Mary Affeldt,

Executive Officer (OM Director), NIDA.

[FR Doc. 2010–18511 Filed 7–27–10; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Submission for OMB Review; Comment Request; Application for the Pharmacology Research Associate Program

SUMMARY: Under the provisions of Section 3507(a)(1)(D) of the Paperwork Reduction Act of 1995, the National Institute of General Medical Sciences (NIGMS), the National Institutes of Health (NIH) has submitted to the Office of Management and Budget (OMB) a request to review and approve the information collection listed below. This proposed information collection was previously published in the **Federal Register** on May 18, 2010, pages 27789–27790, and allowed 60 days for public comment. One comment was received on 6/25/2010. The public respondent requested that eligibility for this program be offered to American citizens only. As stated in A.1., Justification, of the Supporting Statement A, applicants for this program must be U.S. citizens or permanent residents of the United States who have been awarded a terminal degree, or who have been certified by a university as meeting all the requirements leading to a doctorate may be hired as PRAT Fellows. The purpose of this notice is to allow an additional 30 days for public comment. The National Institutes of Health may not conduct or sponsor, and the respondent is not required to respond to, an information collection that has been extended, revised, or implemented on or after October 1, 1995, unless it displays a currently valid OMB control number.

Proposed Collection: Title: Application for the Pharmacology Research Associate Program.

Type of Information Collection Request: Extension of a currently approved collection.

Need and Use of Information Collection: The Pharmacology Research Associate (PRAT) Program will use the applicant and referee information to award opportunities for training and experience in laboratory or clinical investigation to individuals with a Ph.D. degree in pharmacology or a related science, M.D., or other professional degree through appointments as PRAT Fellows at the National Institutes of Health or the Food and Drug Administration. The goal of the program is to develop leaders in pharmacological research for key positions in academic, industrial, and Federal research laboratories.

Frequency of Response: Once a year.

Affected Public: Individuals or households; Businesses or other for-profit.

Type of Respondents: Applicants and Referees.

The annual reporting burden is as follows:

Type and number of respondents	Estimated number of responses per respondent	Estimated total responses	Average burden hours per responses	Estimated total annual burden hours requested
Applicants—25	1	25	8.00	200
Referees—75	1	75	1.75	131.25

Total Number of Respondents: 100.

Total Number of Responses: 100.

Total Hours: 331.25.

The annualized cost to respondents is estimated at:

Applicants: $10,250.00.

Referees: $6,562.50.

There are no Capital Costs, Operating Costs, and/or Maintenance Costs to report.

Request for Comments: Written comments and/or suggestions from the public and affected agencies should address one or more of the following 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; and (4) 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.

Direct Comments to OMB: Written comments and/or suggestions regarding the item(s) contained in this notice, especially regarding the estimated public burden and associated response time, should be directed to the: Office of Management and Budget, Office of Regulatory Affairs, *OIRA_submission@omb.eop.gov* or by fax to 202–395–6974, Attention: Desk Officer for NIH. To request more information on the proposed project or to obtain a copy of the data collection plans and instruments, contact: Ms. Kimberly Allen, NIGMS, NIH, Natcher Building, Room 2AN–18H, 45 Center Drive, MSC 6200, Bethesda, MD 20892–6200, or call non-toll-free number 301–594–2755 or e-mail your request, including your address to *allenki@nigms.nih.gov.*

Comments Due Date: Comments regarding this information collection are best assured of having their full effect if received within 30 days of the date of this publication.

Dated: July 19, 2010.

Sally Lee,

Executive Officer, NIGMS, National Institute of General Medical Sciences, National Institutes of Health.

[FR Doc. 2010–18509 Filed 7–27–10; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2009–N–0495]

Draft Guidance for Industry and Food and Drug Administration Staff; Medical Devices; Neurological and Physical Medicine Device Guidance Document; Reopening of Comment Period

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; reopening of comment period.

SUMMARY: The Food and Drug Administration (FDA) is reopening until September 7, 2010, the comment period for the notice that appeared in the **Federal Register** of April 5, 2010 (75 FR 17143). In the notice, FDA requested comments on draft guidance documents for 11 neurological and physical medicine devices. FDA is reopening the comment period to allow further comment and to receive any new information.

DATES: Submit either electronic or written comments by September 7, 2010.

ADDRESSES: Submit electronic comments to *http://www.regulations.gov*. Submit written comments to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Robert J. DeLuca, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, rm. G214, Silver Spring, MD 20993–0002, e-mail: *Robert.DeLuca@fda.hhs.gov*, 301–796–6630.

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of April 5, 2010 (75 FR 17093), FDA published a notice announcing the availability of draft special controls guidance documents for 11 neurological and physical medicine devices. Interested persons were originally given until July 6, 2010, to comment on the draft guidance documents. The agency expressed specific interest in comments on the types of claims appropriate for devices included within the 11 classifications and, for devices that remain subject to premarket review, the data sponsors should submit to support those claims.

II. Request for Comments

Following publication of the April 5, 2010, notice, FDA received requests to allow interested persons additional time to comment. The requests asserted that the 90-day time period was insufficient to respond fully to FDA's specific requests for comments and to allow potential respondents to thoroughly evaluate and address pertinent issues. The agency has considered the requests and is reopening the comment period until September 7, 2010. The agency believes the additional comment period allows adequate time for interested persons to submit comments without significantly delaying rulemaking on these important issues.

III. How to Submit Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) either electronic or written comments regarding this document. It is only necessary to send one set of comments. It is no longer necessary to send two copies of mailed comments. Identify comments with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

Dated: July 22, 2010.

David Dorsey,

Acting Deputy Commissioner for Policy, Planning and Budget.

[FR Doc. 2010–18406 Filed 7–27–10; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Government-Owned Inventions; Availability for Licensing

AGENCY: National Institutes of Health, Public Health Service, HHS.

ACTION: Notice.

SUMMARY: The inventions listed below are owned by an agency of the U.S. Government and are available for licensing in the U.S. in accordance with 35 U.S.C. 207 to achieve expeditious commercialization of results of federally-funded research and development. Foreign patent applications are filed on selected inventions to extend market coverage for companies and may also be available for licensing.

ADDRESSES: Licensing information and copies of the U.S. patent applications listed below may be obtained by writing to the indicated licensing contact at the Office of Technology Transfer, National Institutes of Health, 6011 Executive Boulevard, Suite 325, Rockville, Maryland 20852–3804; telephone: (301) 496–7057; fax: (301) 402–0220. A signed Confidential Disclosure Agreement will be required to receive copies of the patent applications.

Software System With Applications in Clinical Prognosis, Personalized Medicine and Clinical Research

Description of Invention: Available for licensing is software that can provide prognostic information for different diseases and in particular for cancer. The software can determine whether a particular genotype has a significant association with survival time for an

individual receiving treatment. For example, it can determine if a specific genetic pattern is associated with an increased or decreased time to recurrence of a particular type of cancer for patients on a given treatment regimen.

Applications:

• Applications in clinical research:

—Studying relationship between genotypes and survival times.

—Evaluation of treatment regimens.

• Applications in drug discovery programs.

• Clinical prognosis.

• Personalized medicine.

Development Status:

• The invention has been fully developed.

• The software will be readily available in executable form if so requested.

Inventor: Brian T. Luke (SAIC/NCI).

Patent Status: HHS Reference No. E–182–2010/0—Software. Patent protection is not being pursued for this technology.

Licensing Status: Available for licensing.

Licensing Contacts:

• Uri Reichman, PhD, MBA; 301–435–4616; *UR7a@nih.gov.*

• Michael Shmilovich, Esq.; 301–435–5019; *shmilovm@mail.nih.gov.*

Collaborative Research Opportunity: The NCI is seeking statements of capability or interest from parties interested in collaborative research to further develop, evaluate, or commercialize this technology. Please contact John Hewes, PhD, at 301–435–3121 or *hewesj@mail.nih.gov* for more information.

Software for Accurate Segmentation of Cell Nuclei in Breast Tissue

Description of Invention: Automatic segmentation of cell nuclei is critical in several high-throughput cytometry and pathology applications (1), such as spatial analysis of genetic loci by fluorescence *in situ* hybridization ("FISH"), whereas manual segmentation is laborious (2). Current automated segmentation methods have varying performance in the presence of distortions introduced during sample preparation, non-uniform illumination, clustering of the individual objects of interest (cells or cell nuclei), and seldom assess boundary accuracy.

Researchers at the National Cancer Institute-Frederick, NIH, have developed an automatic algorithm to segment cell nuclei (3) and FISH signals from two-dimensional images of breast tissue. This automated system integrates a series of advanced image processing methods to overcome the delays inherent to current manual methods for segmenting (delineating) individual cell nuclei in tissue samples. The system automatically selects a subset of nuclei that with high likelihood are accurately segmented. This system has been validated using both simulated and actual datasets that have been accurately analyzed by manual methods. The system generalizes to independent analysis of many spatial parameters useful for studying spatial gene positioning in interphase nuclei, and potentially has a wide range of diagnostic pathology, cytological and high throughput screening applications.

Applications:

• Investigations on genomic organization (nuclear architecture and non-random gene positioning) in the individual nuclei in tissues.

• Other pathology and cytological and high throughput screening applications requiring precise, quantitative analysis of a subset of cell nuclei in the sample.

Advantages:

• Automatic.

• Efficient, robust and effective in extracting individual nuclei with FISH labels.

• Facilitates reproducible and unbiased spatial analysis of DNA sequences in interphase nuclei.

Development Status:

• Early stage.

• Negotiations are underway with several companies to scale up development of the system and to undertake pre-clinical validation for gene positioning in the nuclei of breast sections as a possible early-stage diagnostic or prognostic test for cancer.

Inventors: Kaustav Nandy *et al.* (NCI).

Related Publications:

1. Gudla PR, Nandy K, Collins J, Meaburn KJ, Misteli T, Lockett SJ. A high-throughput system for segmenting nuclei using multiscale techniques. Cytometry A. 2008 May;73(5):451–466. [PubMed: 18338778].

2. Meaburn KJ, Gulda PR, Khan S, Lockett SJ, Misteli T. Disease-specific gene repositioning in breast cancer. J Cell Biol. 2009 Dec 14;187(6):801–812. [PubMed: 19995938].

3. Nandy K, Gudla PR, Meaburn KJ, Misteli T, Lockett SJ. Automatic nuclei segmentation and spatial FISH analysis for cancer detection. Conf Proc IEEE Eng Med Biol Soc 2009;2009:6718–6721. [PubMed: 19963931].

Patent Status: HHS Reference No. E–106–2010/0—Research Tool. Patent protection is not being pursued for this technology.

Licensing Status: Available for licensing.

Licensing Contact: Patrick P. McCue, PhD; 301–435–5560; *mccuepat@mail.nih.gov.*

Collaborative Research Opportunity: The inventers, working for the Office of the Director, National Cancer Institute, are seeking statements of capability or interest from parties interested in collaborative research (using the Cooperative Research and Development Agreement (CRADA) or Material Transfer Agreement (MTA)) to further develop, evaluate, or commercialize the software for accurate segmentation of cell nuclei and FISH signals in tissue sections. Collaborators working in the field of quantitative and automated pathology may be interested. Please contact John Hewes, PhD, at 301–435–3121 or *hewesj@mail.nih.gov* for more information.

Use of Cucurbitacins and Withanolides for the Treatment of Cancer

Description of Invention: Certain members of the cucurbitacin and Withanolide family have been identified that can sensitize some tumor cell lines to cell death (apoptosis) on subsequent exposure of the cells to pro-apoptotic receptor agonists (PARAS) of the TRAIL "death receptors". These PARAS include TRAIL itself, and agonist antibodies to two of its receptors death receptor-4 (DR4 or TRAIL–R1) and death receptor 5 (DR5, TRAIL–R2).

The protein TRAIL has a very interesting characteristic that it can preferentially cause death of cancer cells whereas normal non-transformed cells are unaffected. Thus use of TRAIL or agonist antibodies to its so-called "death receptors" has been a current focus in cancer therapy.

Applications:

• Use of the compounds with known TRAIL or agonist antibodies such as Mapatumumab (currently being developed by Human Genome Sciences).

• Use of the compounds in combination with immunotherapeutic approaches for the treatment of cancer.

Advantages: CUCURBITACINS AND WITHANOLIDES can be successfully developed in combination with known TRAIL agonist have the potential of new cancer combination therapies without major toxicities.

Development Status: In vivo studies are ongoing.

Inventors: Thomas J. Sayers *et al.* (NCI).

Publication: NL Booth *et al.* A cell-based high-throughput screen to identify synergistic TRAIL sensitizers. Cancer Immunol Immunother. 2009 Aug;58(8):1229–1244. [PubMed: 19089423].

Patent Status: U.S. Provisional Application No. 61/287,139 filed 16 Dec 2009 (HHS Reference No. E–050–2010/0–US–01).

Licensing Status: Available for licensing.

Licensing Contact: Sabarni Chatterjee, PhD; 301–435–5587; *chatterjeesa@mail.nih.gov.*

Collaborative Research Opportunity: The Center for Cancer Research, Laboratory of Experimental Immunology, Cancer Inflammation Program, is seeking statements of capability or interest from parties interested in collaborative research to further develop, evaluate, or commercialize the use of certain cucurbatacins or withanolides in combination with pro-apoptotic agonists of TRAIL death receptors for cancer therapy. Please contact John Hewes, PhD, at 301–435–3121 or *hewesj@mail.nih.gov* for more information.

Nitroxyl (HNO) Releasing Compounds and Uses Thereof in Treating Diseases

Description of Invention: This technology discloses HNO releasing compounds and methods of treating various diseases with such compounds. HNO has recently emerged as a prospective pharmacological agent. Studies of the chemistry of HNO have led to an understanding that HNO is vastly different from nitric oxide (NO), the one-electron oxidation product of HNO. HNO displays unique cardiovascular properties and has been shown to have positive effects in failing hearts without changing heart rate. HNO has also been shown to have beneficial effects in ischemia reperfusion injury. In addition to the cardiovascular effects observed, HNO has shown initial promise in the realm of cancer therapy. HNO has been demonstrated to inhibit a key glycolytic enzyme. Due to the Warburg effect, inhibiting glycolysis is an attractive target for inhibiting tumor proliferation. HNO has recently been shown to inhibit tumor proliferation in mouse xenografts. Additionally, HNO inhibits tumor angiogenesis and induces cancer cell apoptosis.

Applications:

• Potential treatment for cardiovascular disease, ischemia, and cancer.

• Tool to probe the role of HNO in normal physiology and disease states.

Inventors: Larry K. Keefer (NCI).

Related Publications:

1. CH Switzer, *et al.* The emergence of nitroxyl (HNO) as a pharmacological agent. Biochim Biophys Acta 2009 Jul;1787(7):835–840. [PubMed: 19426703].

2. LK Keefer. Nitric oxide (NO)- and nitroxyl (HNO)-generating diazeniumdiolates (NONOates): emerging commercial opportunities. Curr Top Med Chem. 2005;5(7):625–636. [PubMed: 16101424].

Patent Status: U.S. Provisional Application No. 61/315,604 filed 19 Mar 2010 (HHS Reference No. E–019–2010/0–US–01).

Licensing Status: Available for licensing.

Licensing Contact: Steve Standley, PhD; 301–435–4074; *sstand@od.nih.gov.*

Collaborative Research Opportunity: The Center for Cancer Research, Laboratory of Comparative Carcinogenesis, is seeking statements of capability or interest from parties interested in collaborative research to further develop, evaluate, or commercialize agents that generate HNO in physiological media for therapeutic benefit. Please contact John Hewes, PhD, at 301–435–3121 or hewesj@mail.nih.gov for more information.

Prolonging Survival in Melanoma Patients: Early Stage Diagnosis and Treatment by Detecting and Inhibiting NUAK2 Overexpression

Description of Invention: Melanoma accounts for only 4% of skin cancers, but is responsible for over 75% of skin cancer deaths worldwide. There are few treatment options available for melanoma and all current options show limited effectiveness. Melanoma is most treatable in its early stages, but most cases are not identified until the disease has progressed to the point where treatment is less effective. As normal melanocytes transform into melanoma tumor cells and metastasize, many changes occur in their gene expression patterns. Identifying genes whose expression levels impact melanoma patient survival is a key factor in developing better early detection tests and more effective treatment modalities for the disease.

NUAK2 is a stress-activated kinase and a member of the SNF–1/AMPK kinase family, a conserved family of serine/threonine kinases ubiquitous to all eukaryotes. This enzyme is normally involved in helping cells cope with glucose starvation, promoting cell-cell detachment for motility, and protecting cells from CD95-mediated apoptosis. SNF–1/AMPK kinases, such as NUAK2, also regulate cell cycle machinery by influencing the function of cyclin-dependent kinases (CDKs), such as CDK2. When deregulated, SNF–1/AMPK family members are known to contribute to cancer development and tumor progression in various cancers.

Scientists at the National Institutes of Health (NIH) have identified the *NUAK2* gene (also known as *SNARK*) as a factor to predict the clinical outcome for melanoma patients. *NUAK2* was selected as a gene of interest through extensive analysis of over 120 primary melanomas using a microarray-based comparative genomic hybridization approach which showed that genetic aberrations in *NUAK2* correlated with disease. The most prominent discovery was that gain at the *NUAK2* locus and deletion at the *PTEN* locus strongly correlated with more severe acral melanoma. Overexpression of phospho-Akt (p-Akt), caused by the *PTEN* deletion, combined with the overexpression of *NUAK2* were found to be associated with rapid disease progression, poor patient survival, and increased tumor thickness, especially in acral melanoma models. The scientists are developing diagnostic tests for *NUAK2* to better detect melanomas at an early stage when the disease is most treatable. They are also developing therapeutic small hairpin RNAs (shRNAs) to inhibit *NUAK2* gene expression and thereby reduce melanoma tumor thickness and prevent aggressive disease progression. The shRNAs utilized to silence these target genes are incorporated into lentiviral vectors, which have the potential to be delivered into humans. These scientists also observed that *NUAK2* overexpression correlated with increased expression of various CDKs. So, they are testing the effectiveness of CDK inhibitors in targeting melanomas that specifically exhibit genetic aberrations in *NUAK2* and *PTEN* leading to *NUAK2* and p-Akt overexpression. These new potential diagnostics and therapeutics centered on *NUAK2* could provide important pharmaceutical tools to detect and treat melanoma at various stages of disease.

Applications:

• Diagnostic tools and kits to identify melanoma at an early stage of disease where treatments are more effective and the mortality rate is reduced. Diagnostic tests for NUAK2 expression may be most useful in detecting acral melanoma, which is one of the most prominent forms of melanoma in Hispanic, Asian, and African-American populations.

• Therapeutic nucleic acids to inhibit melanoma disease progression by targeting specific genes important in poor clinical outcomes, such as *NUAK2* and *PTEN.*

Advantages:

• Genetic aberrations in the *NUAK2* and *PTEN* genes show a high correlation with poor clinical outcomes in

melanoma patients. Diagnostic tests specifically directed at *NUAK2* are anticipated to be highly predictive of the aggression level and course of disease in individual patients. Gaining information about melanoma before late-stage symptoms are observed should give clinicians more opportunity to treat patients before the cancer metastasizes out of control.

• Few therapies exist for melanoma and the treatments utilized by clinicians are prone to toxic side effects. Targeted therapies, such as shRNAs directed against *NUAK2* could combine more effective inhibition of melanoma with fewer harsh side effects.

Development Status: This technology is in a preclinical stage of development.

Market: There remains a long-felt public health need to develop new therapeutics and diagnostics for treating melanoma. Melanoma is the most serious type of skin cancer, accounting the majority of skin cancer deaths, and the percentage of people who develop melanoma has more than doubled in the past 30 years. With the increase in Hispanic and Asian populations in the United States, the incidence of acral melanoma has risen to become a major public health problem as it accounts for between 30%–70% of melanoma cases in dark-skinned individuals. In the United States alone in 2009, it is estimated that 68,720 new cases of melanoma were diagnosed and 8,650 people were expected to die of the disease. In 2005, the American Academy of Dermatology and the Society for Investigative Dermatology released a comprehensive study that quantified the estimated total direct cost associated with the treatment of melanoma in 2004 at $291 million in the United States. Currently, there are more than 200 therapeutics in active development to target melanoma—from early pre-clinical to marketed drugs. Clearly, a sizable portion of the melanoma diagnostic and therapeutic markets is available, since no one course of treatment is effective for all patients and very few diagnostic tools exist to identify melanoma at early stages.

Inventors: Vincent J. Hearing (NCI) and Takeshi Namiki (formerly NCI).

Publications:

1. T Namiki, *et al.* Genomic alterations in primary cutaneous melanomas detected by metaphase comparative genomic hybridization with laser capture or manual microdissection: 6p gains may predict poor outcome. Cancer Genet Cytogenet. 2005 Feb;157(1):1–11. [PubMed: 15676140].

2. JH Kim, *et al.* SNARK, a novel downstream molecule of EBV latent membrane protein 1, is associated with resistance to cancer cell death. Leuk Lymphoma. 2008 Jul;49(7):1392–1398. [PubMed: 18452098].

Patent Status: U.S. Provisional Application No. 61/321,136 filed 05 April 2010 (HHS Reference No. E–281–2009/0–US–01).

Licensing Status: Available for licensing.

Licensing Contact: Samuel E. Bish, PhD; 301–435–5282; *bishse@mail.nih.gov.*

Collaborative Research Opportunity: The Center for Cancer Research, Laboratory of Cell Biology, is seeking statements of capability or interest from parties interested in collaborative research to further develop, evaluate, or commercialize Prolonging Survival in Melanoma Patients. Please contact John Hewes, PhD, at 301–435–3121 or *hewesj@mail.nih.gov* for more information.

Immortalized Human Bronchial Epithelial Cell Line

Description of Invention: Normal cells can be cultured *in vitro* for a limited period of time before they exhibit a "crisis" or senescence, wherein they display abnormal cell morphology and significant reduction or cessation of cell proliferation. Investigators at the National Cancer Institute developed immortalized cell line by isolating bronchial epithelial cells from non-cancerous individuals and subsequent infection with an adenovirus 12–SV40 virus hybrid. Unlike normal cells, the immortalized cells be cultured continuously *in vitro* in suitable medium and retain features of normal human bronchial epithelial cells, including the absence of invasive behavior *in vitro* or *in vivo.* These cells can also be transfected with oncogenes and used as a model for multistage carcinogenesis, or employed to assay a biological or chemical agent's ability to induce differentiation and carcinogenesis as well as test potential chemotherapeutic agents.

Applications:

• Model to study multistage bronchial carcinogenesis.

• Identification of potential chemotherapeutic drugs.

• Identification of carcinogenic agents.

Advantages: Immortalized cells that retain normal human bronchial characteristics.

Market:

• Global cancer market is worth more than eight percent of total global pharmaceutical sales.

• Cancer industry is predicted to expand to $85.3 billion by 2010.

Inventors: Curtis C. Harris (NCI) *et al.*

Relevant Publication: RR Reddel *et al.* Transformation of human bronchial epithelial cells by infection with SV40 or adenovirus-12 SV40 hybrid virus, or transfection via stronium phosphate coprecipitation with a plasmid containing SV40 early region genes. Cancer Res. 1988 Apr 1;48(7):1904–1909. [PubMed: 2450641].

Patent Status: HHS Reference No. E–287–1987/0—Research Material. Patent protection is not being pursued for this technology.

Licensing Status: Available for licensing.

Licensing Contact: Jennifer Wong; 301–435–4633; *wongje@mail.nih.gov.*

Collaborative Research Opportunity: The Center for Cancer Research, Laboratory of Human Carcinogenesis, is seeking statements of capability or interest from parties interested in collaborative research to further develop, evaluate, or commercialize Immortalized Human Bronchial Epithelial Cell Line. Please contact John Hewes, PhD, at 301–435–3121 or *hewesj@mail.nih.gov* for more information.

Dated: July 22, 2010.

Richard U. Rodriguez,

Director, Division of Technology Development and Transfer, Office of Technology Transfer, National Institutes of Health.

[FR Doc. 2010–18487 Filed 7–27–10; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Government-Owned Inventions; Availability for Licensing

AGENCY: National Institutes of Health, Public Health Service, HHS.

ACTION: Notice.

SUMMARY: The inventions listed below are owned by an agency of the U.S. Government and are available for licensing in the U.S. in accordance with 35 U.S.C. 207 to achieve expeditious commercialization of results of federally-funded research and development. Foreign patent applications are filed on selected inventions to extend market coverage for companies and may also be available for licensing.

ADDRESSES: Licensing information and copies of the U.S. patent applications listed below may be obtained by writing to the indicated licensing contact at the Office of Technology Transfer, National Institutes of Health, 6011 Executive

Boulevard, Suite 325, Rockville, Maryland 20852–3804; telephone: 301/496–7057; fax: 301/402–0220. A signed Confidential Disclosure Agreement will be required to receive copies of the patent applications.

Therapeutics for the Treatment and Prevention of Atherosclerosis and Cardiovascular Disease

Description of Invention: This technology consists of peptides and peptide-analogues that enhance clearance of excess cholesterol in cells and do not exhibit the cytotoxicity that has hampered development of similar potential therapeutics.

Briefly, apolipoprotein A–1 (ApoA–1) promotes cholesterol efflux from cells and its concentration is inversely correlated with atherosclerotic events. The isolated peptidic component of ApoA–1 that acts within the cholesterol secretion pathway is therapeutic towards atherosclerosis but exhibits cytotoxic effects. In contrast, our inventors have derivatized that ApoA–1 peptide which is both less cytotoxic and more active than the underivatized component in initial studies. This potential therapeutic is similar to high density lipoprotein (HDL) therapy and may complement statin-mediated reduction of pro-atherogenic lipoproteins.

Potential Applications:

- Treatment and prevention of atherosclerosis
- Treatment and prevention of cardiovascular disease, coronary artery disease, heart attack, stroke, and inflammation
- Therapeutic or preventative coating for a heart or vascular implant
- Alternative to HDL therapy

Potential Advantages:

- Enhanced cytotoxicity profile
- Enhanced hydrophilicity profile
- Complements statin-based therapies
- Oral delivery approaches in development

Development Status: Early stage with *in vitro* proof of concept data.

Market: The CDC indicates that heart attacks account for 26% of deaths in the United States of which atherosclerosis is a significant contributing factor or cause. Global sales for cardiovascular therapeutics are expected to exceed $50b in 2010.

Inventors: Amar A. Sethi (NHLBI) *et al.*

Patent Status: U.S. Provisional Application No. 61/265,291 filed 30 Nov 2009 (HHS Reference No. E–047–2009/0–US–01).

Licensing Status: Available for licensing.

Licensing Contact: Fatima Sayyid, M.H.P.M.; 301–435–4521; *Fatima.Sayyid@nih.hhs.gov.*

Use of Immunosuppressive Agents for Treatment of Age-related Macular Degeneration (AMD) and Diabetic Retinopathy

Description of Invention: AMD belongs to a group of disorders in which the immune system may play an important role. This invention discloses that patients with AMD gain additional therapeutic benefit from combination treatment of immunosuppressive agents and standard-of-care in comparison to standard-of-care alone. This invention slows the progression of choroidal neovascularization (CNV) and may have implications for related pathologies, including diabetic retinopathy. Clinical data from a small, randomized pilot clinical trial are available.

Applications:

- A method of treatment for AMD.
- A method of treatment for diabetic retinopathy.
- A method of treatment for diseases associated with CNV.

Advantages:

- Likely to be synergistic with existing therapeutics.
- May enable repurposing of some exiting immunosuppressive agents.

Development Status: In clinical trials.

Market: An estimated three million individuals in the United States will have an advanced form of AMD by 2020 (Klein R *et al.* The epidemiology of age-related macular degeneration. Am J Ophthalmol. 2004;137(3):486–95).

Inventors: Robert B. Nussenblatt and Frederick L. Ferris (NEI).

Publication: In preparation.

Patent Status: U.S. Provisional Application No. 61/254,439 filed 23 Oct 2009 (HHS Reference No. E–198–2008/0–US–01).

Licensing Status: Available for licensing.

Licensing Contact: Norbert Pontzer, J.D., Ph.D.; 301–435–5502; *pontzern@mail.nih.gov.*

Collaborative Research Opportunity: The National Eye Institute, Laboratory of Immunology, is seeking statements of capability or interest from parties interested in collaborative research to further develop, evaluate, or commercialize the use of immunosuppressive agents in the treatment of age related macular degeneration. This is in light of new findings that immune mechanisms appear to be central to the expression of the clinical disease we know as AMD. Please contact Alan Hubbs, Ph.D. at 301–594–4263 or *hubbsa@mail.nih.gov* for more information.

Dated: July 22, 2010.

Richard U. Rodriguez,

Director, Division of Technology Development and Transfer, Office of Technology Transfer, National Institutes of Health.

[FR Doc. 2010–18490 Filed 7–27–10; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Office of the Director; 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 materials, 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: Advisory Committee to the Director, NIH.

Date: August 9, 2010.

Time: 2 p.m. to 3 p.m. e.s.t.

Agenda: To review and evaluate grant applications (Telephone Conference Call).

Place: National Institutes of Health, Building 31, Conference Room 6, 9000 Rockville Pike, Bethesda, MD 20892.

Contact Person: Lawrence A. Tabak, PhD, DDS, Acting Director, Division of Program Coordination, Planning, and Strategic Initiatives, Office of the Director, National Institutes of Health, 31 Center Drive, Building 31, Room 2C39, Bethesda, MD 20892, 301–496–3571, *lawrence_tabak@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.

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.

Dated: July 22, 2010.

Jennifer Spaeth,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. 2010–18496 Filed 7–27–10; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Mental Health; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App), notice is hereby given of the following 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 contract proposals and the discussions could disclose confidential trade secrets or commercial property such as patentable materials, 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 Mental Health Special Emphasis Panel, CNS HIV Anti-Retroviral Therapy Effects Research as a Resource (CHARTER as a Resource).

Date: August 11, 2010.

Time: 3:30 p.m. to 5 p.m.

Agenda: To review and evaluate contract proposals.

Place: National Institutes of Health, Neuroscience Center, 6001 Executive Boulevard, Rockville, MD 20852 (Telephone Conference Call).

Contact Person: David W. Miller, PhD, Scientific Review Officer, Division of Extramural Activities, National Institute of Mental Health, NIH, Neuroscience Center, 6001 Executive Blvd., Room 6140, MSC 9608, Bethesda, MD 20892–9608, 301–443–9734, *millerda@mail.nih.gov.*

Name of Committee: National Institute of Mental Health Special Emphasis Panel, CNS HIV Anti-Retroviral Therapy Effects Research Extension (CHARTER Extension).

Date: August 11, 2010.

Time: 12:30 p.m. to 3 p.m.

Agenda: To review and evaluate contract proposals.

Place: National Institutes of Health, Neuroscience Center, 6001 Executive Boulevard, Rockville, MD 20852 (Telephone Conference Call).

Contact Person: David W. Miller, PhD, Scientific Review Officer, Division of Extramural Activities, National Institute of Mental Health, NIH, Neuroscience Center, 6001 Executive Blvd., Room 6140, MSC 9608, Bethesda, MD 20892–9608, 301–443–9734, *millerda@mail.nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.242, Mental Health Research Grants; 93.281, Scientist Development Award, Scientist Development Award for Clinicians, and Research Scientist Award; 93.282, Mental Health National Research Service Awards for Research Training, National Institutes of Health, HHS)

Dated: July 21, 2010.

Jennifer Spaeth,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. 2010–18497 Filed 7–27–10; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Cancer Institute; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Cancer Institute Initial Review Group; Subcommittee G—Education.

Date: October 19–20, 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: Jeannette F Korczak, PhD, Scientific Review Officer, Resources and Training Review Branch, Division of Extramural Activities, National Cancer Institute, NIH, 6116 Executive Blvd., Room 8115, Bethesda, MD 20892, 301–496–9767, *korczakj@mail.nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.392, Cancer Construction; 93.393, Cancer Cause and Prevention Research; 93.394, Cancer Detection and Diagnosis Research; 93.395, Cancer Treatment Research; 93.396, Cancer Biology Research; 93.397, Cancer Centers Support; 93.398, Cancer Research Manpower; 93.399, Cancer Control, National Institutes of Health, HHS)

Dated: July 22, 2010.

Jennifer Spaeth,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. 2010–18501 Filed 7–27–10; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Mental Health; Notice of Meeting

Pursuant to section 10(a) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of a meeting of the Services Subcommittee of the Interagency Autism Coordinating Committee (IACC).

The purpose of the meeting of the Services Subcommittee is to discuss plans for a 2010 IACC Workshop on services and supports being held in November 2010. The Subcommittee meeting will be conducted as a telephone conference call.

Name of Committee: Interagency Autism Coordinating Committee (IACC).

Type of Meeting: Services Subcommittee.

Date: August 10, 2010.

Time: 2 p.m.–3:30 p.m. Eastern Time.

Agenda: The subcommittee plans to discuss the implementation of an IACC workshop on services and supports that will be held on November 8, 2010.

Place: No in-person meeting; conference call only.

Registration: No registration required.

Conference Call Access: Dial: 800–369–3340. Access code: 8415008.

Contact Person: Ms. Lina Perez, Office of Autism Research Coordination, Office of the Director, National Institute of Mental Health, NIH, 6001 Executive Boulevard, NSC, Room 8200, Bethesda, MD 20892–9669, Phone: 301–443–6040, E-mail: *IACCPublicInquiries@mail.nih.gov.*

Please Note: This meeting will be open to the public through a conference call phone number. Individuals who participate using this service and who need special assistance, such as captioning of the conference call or other reasonable accommodations, should submit a request at least 7 days prior to the meeting.

Members of the public who participate using the conference call phone number will be able to listen to the meeting but will not be heard.

This phone call may end prior to or later than 3:30 p.m., depending on the needs of the subcommittee.

This notice is being published less than 15 days prior to the meeting due to the urgent need to discuss the organization and the implementation of the IACC workshop so that the IACC has time to inform the public of the workshop.

Information about the IACC is available on the Web site: *http://www.iacc.hhs.gov.*

Dated: July 22, 2010.

Jennifer Spaeth,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. 2010–18505 Filed 7–27–10; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2010–N–0001]

Radiological Devices Panel of the Medical Devices Advisory Committee; Notice of Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

This notice announces a forthcoming meeting of a public advisory committee of the Food and Drug Administration (FDA). The meeting will be open to the public.

Name of Committee: Radiological Devices Panel of the Medical Devices Advisory Committee.

General Function of the Committee: To provide advice and recommendations to the agency on FDA's regulatory issues.

Date and Time: The meeting will be held on September 24, 2010, from 8 a.m. to 6 p.m.

Location: Hilton Washington DC North/Gaithersburg, Salons A, B, C and D, 620 Perry Pkwy., Gaithersburg, MD.

Contact Person: Shanika Craig, Food and Drug Administration, Center for Devices and Radiological Health, 10903 New Hampshire Ave., Bldg 66, rm. 1613, Silver Spring, MD 20993–0002, 301–796–6639, or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area), code 3014512526. Please call the Information Line for up-to-date information on this meeting. A notice in the **Federal Register** about last minute modifications that impact a previously announced advisory committee meeting cannot always be published quickly enough to provide timely notice. Therefore, you should always check the agency's Web site and call the appropriate advisory committee hot line/phone line to learn about possible modifications before coming to the meeting.

Agenda: On September 24, 2010, the committee will discuss, make recommendations, and vote on a premarket approval application for the Selenia C Digital Breast Tomosynthesis System, sponsored by Hologic, Inc. The Selenia C Digital Breast Tomosynthesis System is intended for use in the same clinical applications as traditional mammographic systems.

FDA intends to make background material available to the public no later than 2 business days before the meeting. If FDA is unable to post the background material on its Web site prior to the meeting, the background material will be made publicly available at the location of the advisory committee meeting, and the background material will be posted on FDA's Web site after the meeting. Background material is available at *http://www.fda.gov/AdvisoryCommittees/Calendar/default.htm*. Scroll down to the appropriate advisory committee link.

Procedure: Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Written submissions may be made to the contact person on or before September 16, 2010. Oral presentations from the public will be scheduled between approximately 1 p.m. and 2 p.m., immediately following lunch. Those desiring to make formal oral presentations should notify the contact person and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation on or before September 9, 2010. Time allotted for each presentation may be limited. If the number of registrants requesting to speak is greater than can be reasonably accommodated during the scheduled open public hearing session, FDA may conduct a lottery to determine the speakers for the scheduled open public hearing session. The contact person will notify interested persons regarding their request to speak by September 10, 2010.

Persons attending FDA's advisory committee meetings are advised that the agency is not responsible for providing access to electrical outlets.

FDA welcomes the attendance of the public at its advisory committee meetings and will make every effort to accommodate persons with physical disabilities or special needs. If you require special accommodations due to a disability, please contact AnnMarie Williams, Conference Management Staff, 301–796–5966, at least 7 days in advance of the meeting.

FDA is committed to the orderly conduct of its advisory committee meetings. Please visit our Web site at *http://www.fda.gov/AdvisoryCommittees/AboutAdvisoryCommittees/ucm111462.htm* for procedures on public conduct during advisory committee meetings.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2).

Dated: July 22, 2010.

Jill Hartzler Warner,

Acting Associate Commissioner for Special Medical Programs.

[FR Doc. 2010–18416 Filed 7–27–10; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Environmental Health Sciences; 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 Environmental Health Sciences Special Emphasis Panel; Supplemental Center Grants For Community Outreach.

Date: August 12, 2010.

Time: 3 p.m. to 5 p.m.

Agenda: To review and evaluate grant applications.

Place: Nat. Inst. of Environmental Health Sciences, Building 101, Rodbell Auditorium, 111 T. W. Alexander Drive, Research Triangle Park, NC 27709 (Telephone Conference Call).

Contact Person: Linda K. Bass, PhD, Scientific Review Administrator, Scientific Review Branch, Division of Extramural Research and Training, Nat. Institute Environmental Health Sciences, P.O. Box 12233, MD EC–30, Research Triangle Park, NC 27709, (919) 541–1307, *malone@niehs.nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.115, Biometry and Risk Estimation Health Risks from Environmental Exposures; 93.142, NIEHS Hazardous Waste Worker Health and Safety Training; 93.143, NIEHS Superfund Hazardous Substances—Basic Research and Education; 93.894, Resources and Manpower Development in the Environmental Health Sciences; 93.113, Biological Response to Environmental Health Hazards; 93.114, Applied Toxicological Research and Testing, National Institutes of Health, HHS)

Dated: July 22, 2010.

Jennifer Spaeth,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. 2010–18508 Filed 7–27–10; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Cancer Institute; Amended Notice of Meeting

Notice is hereby given of a change in the meeting of the National Cancer Institute Special Emphasis Panel, October 21, 2010, 8 a.m. to October 21, 2010, 5 p.m., Doubletree Hotel Bethesda, (Formerly Holiday Inn Select), 8120 Wisconsin Avenue, Bethesda, MD, 20814 which was published in the **Federal Register** on July 9, 2010, 75 FR 39547.

This FRN amendment has been processed to change the location of this meeting from the Doubletree Hotel Bethesda, 8120 Wisconsin Avenue, Bethesda MD 20814 to the Legacy Hotel and Meeting Center, 1775 Rockville Pike, Rockville MD 20852. The meeting is closed to the public.

Dated: July 22, 2010.

Jennifer Spaeth,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. 2010–18503 Filed 7–27–10; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Cancer Institute; 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/or 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 grant applications and/or contract proposals, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Cancer Institute Special Emphasis Panel, Nanotechnology Imaging and Sensing Platforms for Improved Diagnosis of Cancer.

Date: August 31, 2010.

Time: 12 p.m. to 1:30 p.m.

Agenda: To review and evaluate contract proposals.

Place: National Institutes of Health, 6116 Executive Boulevard, Room 210, Rockville, MD 20852 (Telephone Conference Call).

Contact Person: Kenneth L. Bielat, PhD, Scientific Review Officer, Special Review Logistics Branch, Division of Extramural Activities, National Cancer Institute, 6116 Executive Boulevard, Room 7147, Bethesda, MD 20892–8329, 301–496–7576, *bielatk@mail.nih.gov.*

Name of Committee: National Cancer Institute Special Emphasis Panel, Basic, Translational and Clinical Oncology.

Date: September 28–29, 2010.

Time: 8 a.m. to 5 p.m.

Agenda: To review and evaluate grant applications.

Place: Doubletree Hotel & Executive Meeting Ctr. Bethesda, 8120 Wisconsin Avenue, Bethesda, MD 20814.

Contact Person: David G. Ransom, PhD, Scientific Review Officer, Research Programs Review Branch, Division of Extramural Activities, National Cancer Institute, NIH, 6116 Executive Blvd, Rm 8133, Bethesda, MD 20892–8328, 301–451–4757, *david.ransom@nih.gov.*

Name of Committee: National Cancer Institute Special Emphasis Panel, Drug Discovery, Biomarkers, Therapeutics.

Date: September 28–29, 2010.

Time: 8 a.m. to 5 p.m.

Agenda: To review and evaluate grant applications.

Place: Doubletree Hotel Bethesda, (Formerly Holiday Inn Select), 8120 Wisconsin Avenue, Bethesda, MD 20814.

Contact Person: Peter J. Wirth, PhD, Scientific Review Officer, Research Programs Review Branch, Division of Extramural Activities, National Cancer Institute, 6116 Executive Boulevard, Room 8129, Bethesda, MD 20892–8328, 301–496–7565, *pw2q@nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.392, Cancer Construction; 93.393, Cancer Cause and Prevention Research; 93.394, Cancer Detection and Diagnosis Research; 93.395, Cancer Treatment Research; 93.396, Cancer Biology Research; 93.397, Cancer Centers Support; 93.398, Cancer Research Manpower; 93.399, Cancer Control, National Institutes of Health, HHS)

Dated: July 22, 2010.

Jennifer Spaeth,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. 2010–18498 Filed 7–27–10; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Prospective Grant of Exclusive License: Use of Leptin and Leptin Analogs for the Treatment of Lipodystrophy

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 404.7(a)(1)(i), that the National Institutes of Health (NIH), Department of Health and Human Services, is contemplating the grant of an exclusive patent license to practice the invention embodied in U.S. Patent Application No. 60/336,394, filed on October 22, 2001 (HHS Ref. No. E–064–2004/0–US–01); PCT Application No. PCT/US02/033875, filed on October 22, 2002 (HHS Ref. No. E–064–2004/0–PCT–02); U.S. Patent Application No. 10/279,129, filed on October 22, 2002 (HHS Ref. No. E–064–2004/0–US–03); Japanese Patent Application No. 2003–537565, filed on October 22, 2002 (HHS Ref. No. E–064–2004/0–JP–04); Mexican Patent No. 250445, filed on October 22, 2002 and granted on October 16, 2007 (HHS Ref. No. E–064–2004/0–MX–05); Polish Patent Application No. P–374301, filed on October 22, 2002 (HHS Ref. No. E–064–2004/0–PL–6); Canadian Patent Application No. 2464277, filed on October 22, 2002 (HHS Ref. No. E–064–2004/0–CA–07); European Patent Application No. 02793811.7, filed on October 22, 2002 (HHS Ref. No. E–064–2004/0–EP–08); U.S. Patent No. 7,183,254, filed on July 18, 2003 and granted on 2/27/2007 (HHS Ref. No. E–064–2004/0–US–09); U.S. Patent Application No. 11/606,805, filed on October 29, 2006 (HHS Ref. No. E–064–2004/0–US–10); Mexican Patent Application No. 2007/006095, filed on May 14, 2007 (HHS Ref. No. E–064–2004/0–MX–11); Australian Patent Application No. 2002359288, filed on October 22, 2002 (HHS Ref. No. E–064–2004/0–AU–12); Hong Kong Patent Application No. 4106574.7, filed on September 1, 2004 (HHS Ref. No. E–064–2004/0–HK–13); European Patent Application No. 10165256.8, filed on June 8, 2010 (HHS Ref. No. E–064–2004/0–EP–14); and Japanese Patent Application No. 2010–137501, filed on June 16, 2010 (HHS Ref. No. E–064–2004/0–JP–15), all entitled "Use of Leptin for Treating Human Lipoatrophy and Method of Determining Predisposition to Said Treatment", to

Amylin Pharmaceuticals, Inc., having a place of business in San Diego, California, U.S.A. The patent rights in this invention have been assigned to the United States of America, the University of Texas Southwestern Medical Center at Dallas, and Amgen, Inc.

The contemplated exclusive license territory may be worldwide, and the field of use may be limited to "use of leptin and leptin analogs for the treatment of lipodystrophy or a metabolic condition associated with lipodystrophy in humans, including lipodystrophy associated with or secondary to HIV infection".

DATES: Only written comments and/or application for a license which are received by the NIH Office of Technology Transfer on or before August 27, 2010 will be considered.

ADDRESSES: Requests for copies of the patents, inquiries, comments, and other materials relating to the contemplated license should be directed to: Tara L. Kirby, PhD, Senior Licensing and Patenting Manager, Office of Technology Transfer, National Institutes of Health, 6011 Executive Boulevard, Suite 325, Rockville, MD 20852–3804; Telephone: 301–435–4426; Facsimile: 301–402–0220; E-mail: *tarak@mail.nih.gov.*

SUPPLEMENTARY INFORMATION: This technology relates to leptin, a protein hormone that plays a key role in regulating energy intake and expenditure. This hormone is released from adipose tissue and inhibits appetite in the brain by counteracting peptide hormones responsible for stimulating hunger, and also stimulates the synthesis of another peptide hormone, α-MSH, which acts as an appetite suppressant.

Lipodystrophy, a disorder characterized by pathological deposition of adipose tissue (fat), is caused by a deficiency or complete absence of leptin. Patients with severe lipodystrophy have abnormalities in adipose tissue distribution with loss of subcutaneous fat, and suffer from multiple metabolic disorders—extreme insulin resistance, very high triglyceride levels, diabetes and steatosis (fat accumulation in tissues like liver and muscle)—that are associated with increased risk of severe pancreatitis, early diabetes complications, cirrhosis and early cardiovascular death. Leptin replacement therapy in such patients leads to clear and dramatic metabolic benefits, including a reduction in insulin resistance and triglyceride levels, which are refractory to other treatment.

This technology relates to the use of leptin, a leptin analog, or a leptin derivative to treat lipoatrophy, as well as methods and kits for determining a predisposition of a lipoatrophic patient to respond to treatment with leptin, a leptin analog, or a leptin derivative.

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 404.7. The prospective exclusive license may be granted unless, within 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 404.7.

Applications for a license in the prospective 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 in response 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: July 22, 2010.

Richard U. Rodriguez,

Director, Division of Technology Development and Transfer, Office of Technology Transfer, National Institutes of Health.

[FR Doc. 2010–18492 Filed 7–27–10; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HOMELAND SECURITY

Federal Emergency Management Agency

[Docket ID FEMA–2010–0037]

Hazardous Fire Risk Reduction, East Bay Hills, CA

AGENCY: Federal Emergency Management Agency, DHS.

ACTION: Notice of extension of comment period.

SUMMARY: The Federal Emergency Management Agency (FEMA) is extending the comment period on its notice of intent to prepare an Environmental Impact Statement (EIS) evaluating the environmental impacts of funding a combination of hazardous fuel reduction projects within the East Bay Hills area in Alameda and Contra Costa Counties, California.

DATES: Comments must be submitted by October 1, 2010.

ADDRESSES: You may submit comments, identified by Docket ID FEMA–2010–0037, by one of the following methods:

• *Federal eRulemaking Portal: http://www.regulations.gov.* Search for Docket ID FEMA–2010–0037 and follow the instructions for submitting comments.

• *Fax:* 703–483–2999.

• *Mail/Hand Delivery/Courier:* Office of Chief Counsel, Federal Emergency Management Agency, 500 C Street, SW., Room 835, Washington, DC 20472–3100.

Instructions: All submissions received must include the agency name and Docket ID. Regardless of the method used for submitting comments or material, all submissions will be posted, without change, to the Federal eRulemaking Portal at *http://www.regulations.gov,* and will include any personal information you provide. Therefore, submitting this information makes it public. You may wish to read the Privacy Act notice that is available via a link in the footer of *http://www.regulations.gov.*

Docket: For access to the docket for this notice or comments submitted by the public on this notice, go to the Federal eRulemaking Portal at *http://www.regulations.gov* search for docket ID FEMA–2010–0037. These documents may also be inspected at FEMA, Office of Chief Counsel, Room 835, 500 C Street, SW., Washington, DC 20472–3100.

FOR FURTHER INFORMATION CONTACT: Alessandro Amaglio, Regional Environmental Officer, Region IX, FEMA, 111 Broadway, Suite 1200, Oakland, CA 94607–4052 and phone number at (510) 627–7027.

SUPPLEMENTARY INFORMATION: On June 10, 2010, (75 FR 32960), FEMA published a notice of intent to prepare an EIS and request for comments for four hazard mitigation applications for fuel reduction projects in the East Bay Hills area in California pursuant to Section 102(2)(C) of the National Environmental Policy Act of 1969 (NEPA), the Council on Environmental Quality (CEQ) regulations implementing NEPA, and FEMA's Environmental Considerations regulations.

FEMA is extending the public comment period on the notice of intent to prepare an EIS to accommodate comments that the Federal, State, Tribal, and local government agencies and interested members of the public may have after the public scoping meetings.

Authority: 42 U.S.C. 4331 *et seq.;* 40 CFR part 1500; 44 CFR part 10.

Dated: July 19, 2010.

W. Craig Fugate,

Administrator, Federal Emergency Management Agency.

[FR Doc. 2010–18484 Filed 7–27–10; 8:45 am]

BILLING CODE 9111–A6–P

DEPARTMENT OF HOMELAND SECURITY

Federal Emergency Management Agency

[Docket ID FEMA–2008–0010]

National Fire Academy Board of Visitors

AGENCY: Federal Emergency Management Agency, DHS.

ACTION: Notice of cancellation of meeting.

SUMMARY: The National Fire Academy Board of Visitors public teleconference meeting scheduled for August 2, 2010 is cancelled.

FOR FURTHER INFORMATION CONTACT: Teressa Kaas, 16825 South Seton Avenue, Emmitsburg, Maryland 21727, telephone (301) 447–1117, fax (301) 447–1173, and e-mail *teressa.kaas@dhs.gov.*

SUPPLEMENTARY INFORMATION: The Federal Emergency Management Agency (FEMA) published a Notice in the **Federal Register** on July 9, 2010 (75 FR 39561) announcing a National Fire Academy Board of Visitors public teleconference meeting on August 2, 2010. The meeting is cancelled. If the meeting is rescheduled, FEMA will publish a Notice in the **Federal Register** announcing the new date for the meeting.

Dated: July 20, 2010.

Denis G. Onieal,

Acting Deputy United States Fire Administrator, United States Fire Administration, Federal Emergency Management Agency.

[FR Doc. 2010–18454 Filed 7–27–10; 8:45 am]

BILLING CODE 9111–45–P

DEPARTMENT OF THE INTERIOR

Bureau of Ocean Energy Management, Regulation, and Enforcement (BOEMRE); Cancellation of Oil and Gas Lease Sale 220 in the Mid-Atlantic Planning Area on the Outer Continental Shelf (OCS)

AGENCY: Bureau of Ocean Energy Management, Regulation, and Enforcement, Interior.

ACTION: Cancellation of Offshore Virginia Lease Sale 220.

SUMMARY: On May 27, 2010, the President announced the Secretary of the Interior's decision to cancel offshore Virginia Lease Sale 220 that was scheduled for 2011. Cancellation of Sale 220 will allow time to develop and implement measures to improve the safety of oil and gas development in Federal waters, provide greater environmental protection, and substantially reduce the risk of catastrophic events. The Call for Information and Interest/Nominations and Notice of Intent to prepare an Environmental Impact Statement for OCS Oil and Gas Lease Sale 220 was published in **Federal Register** Vol. 73, No. 220, on Thursday, November 13, 2008. The findings of the National Commission on the BP Deepwater Horizon Oil Spill and Offshore Drilling, (the National Commission was established by Executive Order 13543, dated May 21, 2010, as published in the **Federal Register** on May 26, 2010, (75 FR 29397)), environmental reviews, science-based analysis and public input will inform the Secretary's decisions about whether to move forward with other leases sales in the Mid-Atlantic Planning Area in the future 2012–2017 leasing program.

FOR FURTHER INFORMATION CONTACT: Ms. Renee Orr, Bureau of Ocean Energy Management, Regulation, and Enforcement, Chief, Leasing Division, at (703) 787–1215 or *renee.orr@mms.gov.*

Dated: July 7, 2010.

Michael R. Bromwich,

Director, Bureau of Ocean Energy Management, Regulation, and Enforcement.

[FR Doc. 2010–18510 Filed 7–27–10; 8:45 am]

BILLING CODE 4310–MR–P

DEPARTMENT OF THE INTERIOR

Bureau of Ocean Energy Management, Regulation, and Enforcement (BOEMRE); Cancellation of Oil and Gas Lease Sale 215 in the Western Planning Area (WPA) on the Outer Continental Shelf (OCS) in the Gulf of Mexico (GOM)

AGENCY: Bureau of Ocean Energy Management, Regulation, and Enforcement, Interior.

ACTION: Cancellation of WPA Gulf of Mexico Lease Sale 215.

SUMMARY: On May 27, 2010, the President announced the Secretary of the Interior's decision to cancel WPA Sale 215 that was scheduled to occur on August 18, 2010. Cancellation of Sale 215 will allow time to develop and implement measures to improve the safety of oil and gas development in Federal waters, provide greater environmental protection, and substantially reduce the risk of catastrophic events. The Notice of Availability of the Proposed Notice of Sale for OCS Oil and Gas Lease Sale 215 in the WPA in the GOM was published in **Federal Register** Vol. 75, No 64, on Monday, April 5, 2010. The findings of the National Commission on the BP Deepwater Horizon Oil Spill and Offshore Drilling, (the National Commission was established by Executive Order 13543, dated May 21, 2010, as published in the **Federal Register** on May 26, 2010 (75 FR 29397)), environmental reviews, science-based analysis, and public input will inform the Secretary's decisions about whether to move forward with other leases sales in the Gulf of Mexico that are currently scheduled for 2011 and 2012.

FOR FURTHER INFORMATION CONTACT: Ms. Renee Orr, Bureau of Ocean Energy Management, Regulation, and Enforcement, Chief, Leasing Division, at (703) 787–1215 or *renee.orr@mms.gov.*

Dated: July 7, 2010.

Michael R. Bromwich,

Director, Bureau of Ocean Energy Management, Regulation, and Enforcement.

[FR Doc. 2010–18516 Filed 7–27–10; 8:45 am]

BILLING CODE 4310–MR–P

DEPARTMENT OF THE INTERIOR

Office of the Secretary

Vendor Outreach Workshop for Small Businesses in the Midwest Region of the United States

AGENCY: Office of the Secretary, Interior.

ACTION: Notice.

SUMMARY: The Office of Small and Disadvantaged Business Utilization of the Department of the Interior is hosting a Vendor Outreach Workshop for small businesses in the midwest region of the United States that are interested in doing business with the Department. This outreach workshop will review market contracting opportunities for the attendees. Business owners will be able to share their individual perspectives with Contracting Officers, Program Managers and Small Business Specialists from the Department. Following the workshop, businesses will also participate in a matchmaking event that will allow businesses to talk with Department representatives during roundtable discussions.

DATES: The workshop will be held on August 12, 2010, from 8:30 a.m. to 4 p.m.

ADDRESSES: The workshop will be held at the Colorado Convention Center, 700 14th Street, Denver, Colorado 80202. Register online at: *http://www.doi.gov/osdbu.*

FOR FURTHER INFORMATION CONTACT: Mark Oliver, Director, Office of Small and Disadvantaged Business Utilization, 1951 Constitution Ave., NW., MS–320 SIB, Washington, DC 20240, telephone 1–877–375–9927 (Toll-Free).

SUPPLEMENTARY INFORMATION: In accordance with the Small Business Act, as amended by Public Law 95–507, the Department has the responsibility to promote the use of small and small disadvantaged businesses for its acquisition of goods and services. The Department is proud of its accomplishments in meeting its business goals for small, small disadvantaged, 8(a), woman-owned, HUBZone, and service-disabled veteran-owned businesses. In Fiscal Year 2009, the Department awarded 56 percent of its $2.6 billion in contracts to small businesses.

This fiscal year, the Office of Small and Disadvantaged Business Utilization is reaching out to our internal stakeholders and the Department's small business community by conducting several vendor outreach workshops. The Department's presenters will focus on contracting and subcontracting opportunities and how small businesses can better market services and products. Over 3,000 small businesses have been targeted for this event. If you are a small business interested in working with the Department, we urge you to register online at: *http://www.doi.gov/osdbu* and attend the workshop.

These outreach events are a new and exciting opportunity for the Department's bureaus and offices to improve their support for small business. Additional scheduled events are posted on the Office of Small and Disadvantaged Business Utilization Web site at *http://www.doi.gov/osdbu.*

Mark Oliver,

Director, Office of Small and Disadvantaged Business Utilization.

[FR Doc. 2010–18425 Filed 7–27–10; 8:45 am]

BILLING CODE 4210–RK–P

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

[LLAK930000.L16100000.DF0000]

Notice of Intent To Prepare an Integrated Activity Plan and Environmental Impact Statement for the National Petroleum Reserve—Alaska

AGENCY: Bureau of Land Management, Interior.

ACTION: Notice of Intent.

SUMMARY: The Bureau of Land Management (BLM), Alaska State Office, Anchorage, Alaska, intends to prepare an Integrated Activity Plan (IAP) with an associated Environmental Impact Statement (EIS) for the National Petroleum Reserve-Alaska (NPR–A) planning area. This notice announces the beginning of the scoping period to solicit public input and comments.

DATES: The public scoping period will begin upon publication of this notice in the **Federal Register**. Formal scoping will end no sooner than 60 days from publication of this notice; a final end date will be announced through a press release and the BLM–Alaska Web site, *http://www.blm.gov/ak.* Comments on management decisions, resources to be addressed, and issues for analysis will help define the proposed actions and alternatives for the NPR–A IAP/EIS. You can submit comments in writing to the addresses listed below. The BLM will announce all public meetings, times, and locations through the local news media and on the agency Web site. The BLM will hold public scoping meetings in Anaktuvuk Pass, Anchorage, Atqasuk, Barrow, Fairbanks, Nuiqsut, and Wainwright. The BLM may hold additional public scoping meetings in other communities if there is strong community interest.

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

- *Web site: http://www.blm.gov/ak.*
- *Fax:* 907–271–5479.
- *Mail:* BLM Alaska State Office, Attention—NPR–A Planning Team, 222 West 7th Avenue, #13, Anchorage, Alaska 99513–7599.

FOR FURTHER INFORMATION CONTACT: Jim Ducker, 907– 271–3130; e-mail: *jducker@blm.gov;* or by mail: Bureau of Land Management, 222 West 7th Avenue, #13, Anchorage, Alaska 99513–7599. You may also request to be added to the mailing list. Documents pertinent to this plan may be examined at the following Web site: *http://www.blm.gov/ak.*

SUPPLEMENTARY INFORMATION: This document provides notice that the BLM intends to prepare an IAP with an associated EIS for the NPR–A planning area. The NPR–A IAP/EIS will consider management of BLM-administered lands within the NPR–A. The lands in the NPR–A total approximately 22.1 million acres of surface and subsurface lands, and an additional 200,000 subsurface-only acres underlying Native Corporation-owned surface lands.

The Naval Petroleum Reserves Production Act (42 U.S.C. 6501, *et seq.*), as amended, excludes the NPR–A from the application of Section 202 of the Federal Land Policy and Management Act (43 U.S.C. 1701, *et seq.*), as amended, which is the basis for the BLM's Resource Management Plans. The BLM conducts its planning within NPR–A through IAPs. The BLM complies with all applicable laws in the preparation of an IAP, including the National Environmental Policy Act, the Endangered Species Act, Marine Mammal Protection Act, and the National Historic Preservation Act. The BLM will work collaboratively with interested parties to identify the management decisions best suited to local, regional, and national needs and concerns.

The purpose of the public scoping process is to determine the management decisions and resources to be addressed and the issues for analysis. This information will influence the development of the proposed action and alternatives, and guide the environmental analysis.

You may submit written comments on management decisions and resources to be addressed and issues for analysis to the BLM at any of the public scoping meetings, or use any of the methods listed in the **ADDRESSES** section above. The result of this planning effort will supersede the current plans for the Northwest (2004) NPR–A, Northeast (2008) NPR–A, and Colville River Special Area (2008). 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. BLM personnel, through discussions within the BLM and with other agencies, individuals, and outside groups, have identified preliminary issues for analysis and the proposed scope of this plan. Most issues relate to management of oil and gas activities and the protection of resources and residents

of the region from those impacts in the NPR–A. Of special note are impacts to the resources and uses of the area near Teshekpuk Lake and to the Western Arctic Caribou Herd. The BLM has developed the following preliminary criteria for developing the proposed actions and alternatives:

- The plan will consider the lands and waters administered by the BLM within the NPR–A.
- All decisions in the plan will be consistent with the Naval Petroleum Reserve Production Act of 1976, including the requirements to manage the NPR–A consistent with the total energy needs for the Nation and to protect the environmental, fish and wildlife, and historical and scenic values of the NPR–A.
- The existing plans defer oil and gas leasing in approximately 1.57 million acres in northwestern NPR–A and 430,000 acres north and east of Teshekpuk Lake. The lands in northwestern NPR–A are deferred from leasing until 2014 and the lands near Teshekpuk Lake until 2018. The new plan will make management decisions for these areas that will become effective at the expiration of their respective deferral periods.
- Action alternatives will be consistent with requirements for protection of spectacled and Stellar's eiders described in the U.S. Fish and Wildlife Service's 2008 Biological Opinion for the northern NPR–A planning areas and any new Biological Opinion received as a part of this planning effort.
- The plan will address oil and gas leasing and will use scoping to identify other management decisions and resources to be addressed.
- The resource protection measures applied to oil and gas authorizations will be as consistent as possible in all areas covered by the plan, recognizing the differing values within the NPR–A.
- The BLM will consider subsistence resources and users and minimize adverse impacts to subsistence uses in accordance with Section 810 of the Alaska National Interest Lands Conservation Act (ANILCA).
- The plan will protect valid existing rights.
- The BLM will consider plans and policies of adjacent land owners/managers.

Julia Dougan,

Acting State Director.

[FR Doc. 2010–18469 Filed 7–27–10; 8:45 am]

BILLING CODE 4310–JA–P

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

[CACA 47740, LLCAD07000, L51030000.FX0000, LVRAB109AA01]

Notice of Availability of the Final Environmental Impact Statement for the Imperial Valley Solar, LLC Project, California and the Proposed California Desert Conservation Area Plan Amendment

AGENCY: Bureau of Land Management, Interior.

ACTION: Notice of availability.

SUMMARY: In accordance with the National Environmental Policy Act of 1969, as amended (NEPA), and the Federal Land Policy and Management Act of 1976, as amended (FLPMA), the Bureau of Land Management (BLM) has prepared a Proposed Resource Management Plan (RMP) Amendment/Final Environmental Impact Statement (EIS) for the Imperial Valley Solar, LLC (IVS) Project and by this notice is announcing its availability.

DATES: The BLM planning regulations state that any person who meets the conditions described in the regulations may protest the BLM's Proposed RMP Amendment. A person who meets the conditions must file the protest within 30 days after the date the Environmental Protection Agency publishes its notice of availability in the **Federal Register**. The BLM will also be accepting additional public comments on the RMP/EIS within 30 days after the date that the Environmental Protection Agency publishes its Notice of Availibility in the **Federal Register**. Comments can be sent to Jim Stobaugh at the addresses given below. All substantive comments will be reviewed and responded to in the Record of Decision.

ADDRESSES: Copies of the Proposed RMP Amendment/Final EIS are available for public inspection at the El Centro Field Office, 1661 S. 4th Street, El Centro, California 92243. Interested persons may also review the Proposed RMP Amendment/Final EIS on the following Web site: *http://www.blm.gov/ca/st/en/fo/elcentro/nepa/stirling.html.* All protests must be in writing and mailed to one of the following addresses:

Regular mail	Overnight mail
BLM Director (210), Attention: Brenda Williams, P.O. Box 66538, Washington, DC 20035.	BLM Director (210), Attention: Brenda Williams, 1620 L Street, NW., Suite 1075, Washington, DC 20036.

All comments must be in writing and sent to Jim Stobaugh, BLM Project Manager, by mail at Bureau of Land Management, P.O. Box 12000, Reno, Nevada 89520; or by e-mail at *Jim_Stobaugh@blm.gov.*

FOR FURTHER INFORMATION CONTACT: Jim Stobaugh, BLM Project Manager, by telephone at (775) 861–6478; through mail at Bureau of Land Management, P.O. Box 12000, Reno, Nevada 89520; or by e-mail at *Jim_Stobaugh@blm.gov.*

SUPPLEMENTARY INFORMATION: Stirling Energy Systems (SES) filed right-of-way (ROW) application CACA–47740 for the SES Solar Two Project. Afrter merging with Tessera Soar the applicant changed its name to Imperial Valley Solar, LLC. The project name, SES Solar Two, has also been changed to the Imperial Valley Solar, LLC project. The proposed IVS Project is a concentrated solar electrical generating facility capable of generating 709 megawatts (MW) of renewable power. The entire project encompasses approximately 6,144 acres of BLM-managed lands. The project site is in Imperial County, California, approximately 4 miles east of Ocotillo and 14 miles west of El Centro. Generally, the site is bounded on the north by the San Diego Metropolitan Transit System/San Diego and Arizona Eastern Railway and on the south by Interstate Highway 8. The eastern boundary is approximately 1.5 miles west of Dunaway Road and the western boundary is the westerly section line in Section 22 in Township 16 South, Range 12 East. An additional 110-acre laydown construction area is proposed east of Dunaway Road.

IVS proposes to use SunCatcher technology on the site. A SunCatcher is a 25-kilowatt solar dish designed to automatically track the sun and collect and focus solar energy onto a power conversion unit (PCU), which generates electricity. The system consists of a 38-foot high by 40-foot wide solar concentrator in a dish structure that supports an array of curved glass mirror facets. These mirrors concentrate solar energy onto the solar receiver of the PCU.

The project also includes an electrical transmission line, water supply pipeline, and access road. A new 230-kilovolt (kV) substation would be constructed in approximately the center of the project site near a main services complex that is also part of the proposal. The substation would be connected to the existing San Diego Gas and Electric Imperial Valley Substation by a 10.3-mile long, double-circuit 230-kV transmission line. Approximately 7.6 miles of this new line would be outside

the project area, but is included in the analysis. The transmission line would occupy approximately 92 acres.

The BLM has entered into a MOU with the California Energy Commission (CEC) to conduct a joint environmental review of solar thermal projects that are proposed on Federal land managed by the BLM, with the CEC as the lead agency preparing the environmental documents. The BLM and CEC have agreed through the MOU to conduct the review of the IVS Project in a single combined NEPA/California Environmental Quality Act process and document.

The Notice of Intent to Prepare an EIS/Staff Assessment and Proposed Land Use Plan Amendment for the Proposed Imperial Valley Solar Project in Imperial County, California was published on October 17, 2008 (see 73 FR 61902). The BLM held two public scoping meetings in El Centro, California, on November 24 and December 18, 2008. The formal scoping period ended January 2, 2010. The BLM invited the National Park Service to enter a Memorandum of Understanding (MOU), as a cooperating agency in the EIS, for its special expertise concerning the Juan Batista de Anza National Historic Trail.

In addition, the BLM and the U.S. Army Corps of Engineers (Corps) entered into an MOU to formalize the Corps as a Federal cooperating agency in developing the Final EIS. The Corps' requirements under the Clean Water Act (CWA), Section 404(b)(1) Guidelines are to identify and authorize only the Least Environmentally Damaging Practicable Alternative which maximizes avoidance and minimizes impacts to aquatic resources of the United States. The Corps and the applicant are working with the BLM and CEC to identify the project proposal that would reasonably comply with the Corps' requirements under the CWA and 404(b)(1) Guidelines.

The Notice of Availability of the Draft Environmental Impact Statement/Staff Assessment for the Stirling Energy Systems Solar Two Project and Possible California Desert Conservation Area Plan Amendment was published in the **Federal Register** on February 22, 2010 (see 75 FR 7624). Comments on the Draft RMP Amendment/Draft EIS/Staff Assessment received from the public and internal BLM review were considered and incorporated, as appropriate, into the proposed plan amendment.

Public comments resulted in the addition of clarifying text, but did not significantly change the proposed land use plan decision.

The BLM's purpose and need for the Solar Two project EIS/SA is to respond to IVS LLC's application under Title V of FLPMA (43 U.S.C. 1761) for a ROW grant to construct, operate, and decommission a solar thermal facility on public lands in compliance with FLPMA, the BLM ROW regulations, and other applicable Federal laws.

The BLM will decide whether to approve, approve with modification, or deny a ROW grant to IVS, LLC for the proposed IVS project. The BLM will also consider amending the California Desert Conservation Area (CDCA) Plan (1980, as amended) through this analysis. The CDCA Plan, while recognizing the potential compatibility of solar generation facilities on public lands, requires that all sites associated with power generation or transmission not identified in that plan be considered through the BLM's land use plan amendment process. If the BLM decides to grant a ROW, the BLM would also amend the CDCA Plan.

In the Final EIS analysis, the BLM's proposed action is to authorize the IVS Project and approve a CDCA Plan amendment in response to the application received from IVS. In addition to analyzing the proposed action, the BLM has analyzed the following alternatives: Authorize a smaller 300 MW alternative and amend the CDCA Plan; authorize the project as described in the Drainage Avoidance #1 alternative that may reduce impacts to primary water drainages of the United States and amend the CDCA Plan; and authorize the project as described in the more restrictive Drainage Avoidance #2 alternative that may substantially reduce impacts in eastern and western high flow water drainages of the United States and amend the CDCA Plan. As required under the California Environmental Quality Act and NEPA, the EIS analyzes a No Action alternative that would not require a CDCA Plan amendment. The BLM has also analyzed a No Project alternative to deny the project, but amend the CDCA Plan to potentially allow other solar energy power generation projects on the project site. The BLM additionally has analyzed a No Project alternative to deny the project and amend the CDCA Plan to prohibit solar energy power generation projects on the project site. The BLM has taken into consideration the provisions of the Energy Policy Act of 2005 and Secretarial Orders 3283 *Enhancing Renewable Energy Development on the Public Lands* and 3285A1 *Renewable Energy Development by the Department of the Interior* in responding to the IVS application.

The BLM evaluated the potential impacts of the proposed IVS Project in this EIS on air quality, biological resources, cultural resources, water resources, geological resources and hazards, land use, noise, paleontological resources, public health, socioeconomics, soils, traffic and transportation, visual resources, and other resources.

Instructions for filing a protest with the Director of the BLM regarding the Proposed RMP Amendment may be found in the Final EIS "Dear Reader" Letter and at 43 CFR 1610.5–2. Protests must be received by the Director by the close of the protest period to be accepted as valid. Protests that are postmarked by the close of the protest period, but received by the Director after the close of the protest period will only be accepted as valid if the protesting party also provides a faxed or e-mailed advance copy before the close of the protest period.

E-mailed and faxed protests will not be accepted as valid protests unless the protesting party also provides the original letter by either regular or overnight mail by the close of the protest period. Under these conditions, the BLM will consider the e-mailed or faxed protest as an advance copy that will receive full consideration. If you wish to provide the BLM with such advance notification, please direct faxed protests to the attention of the BLM protest coordinator at (202) 912–7212, and e-mails to *Brenda_Hudgens-Williams@blm.gov.*

All protests, including the follow-up letter to e-mails or faxes, must be in writing and mailed to the appropriate address, as set forth in the **ADDRESSES** section above.

Before including your phone number, e-mail address, or other personal identifying information in your protest, you should be aware that your entire protest—including your personal identifying information—may be made publicly available at any time. While you can ask us in your protest 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, Natural Resources.

Authority: 40 CFR 1506.6, 1506.10 and 43 CFR 1610.2, 1610.5.

[FR Doc. 2010–18471 Filed 7–27–10; 8:45 am]

BILLING CODE 4310–40–P

DEPARTMENT OF THE INTERIOR

National Park Service

Notice of Intent to Repatriate Cultural Items: U.S. Department of Agriculture, Forest Service, Coconino National Forest, Flagstaff, AZ, and American Museum of Natural History, New York City, NY

AGENCY: National Park Service, Interior.

ACTION: Notice.

Notice is here given in accordance with the Native American Graves Protection and Repatriation Act (NAGPRA), 25 U.S.C. 3005, of the intent to repatriate cultural items in the control of the U.S. Department of Agriculture, Forest Service, Coconino National Forest, Flagstaff, AZ, and in the possession of the American Museum of Natural History, New York City, NY, that meet the definition of unassociated funerary objects under 25 U.S.C. 3001.

This notice is published as part of the National Park Service's administrative responsibilities under NAGPRA, 25 U.S.C. 3003(d)(3). The determinations in this notice are the sole responsibility of the museum, institution, or Federal agency that has control of the cultural items. The National Park Service is not responsible for the determinations in this notice.

The four cultural items are two fragments of cotton cloth wrappings, one fragment of yucca matting and one cotton roll in two pieces (one of which is an extra-weft textile with an embroidered design in brown). According to museum records, the four items were removed by Earl Morris from an infant burial in a cave, in Clear Creek, AZ, in 1926. All items are curated at the American Museum of Natural History and have been in the possession of the museum since their excavation.

Archeologists who examined the cloth date the pieces to the late Prehistoric Period (between A.D. 1300 and A.D. 1400). Continuities of oral traditions, ethnographic materials, technology and architecture indicate that the prehistoric peoples of the upper Verde River Valley are ancestral to the Hopi Tribe of Arizona.

Officials of the American Museum of Natural History and the U.S. Department of Agriculture, Forest Service, Coconino National Forest, have determined that, pursuant to 25 U.S.C. 3001(3)(B), the four cultural items described above are reasonably believed to have been placed with or near individual human remains at the time of death or later as part of the death rite or ceremony and are believed, by a preponderance of the evidence, to have been removed from a specific burial site of a Native American individual. Officials of the American Museum of Natural History and the U.S. Department of Agriculture, Forest Service, Coconino National Forest, also have determined that, pursuant to 25 U.S.C. 3001(2), there is a relationship of shared group identity that can be reasonably traced between the unassociated funerary objects and the Hopi Tribe of Arizona.

Representatives of any other Indian tribe that believes itself to be culturally affiliated with the unassociated funerary objects should contact Dr. Frank E. Wozniak, NAGPRA Coordinator, Southwestern Region, USDA Forest Service, 333 Broadway Blvd., SE, Albuquerque, NM 87102, telephone (505) 842–3238, before August 27, 2010. Repatriation of the unassociated funerary objects to the Hopi Tribe of Arizona may proceed after that date if no additional claimants come forward.

The U.S. Department of Agriculture, Forest Service, Coconino National Forest, is responsible for notifying the Hopi Tribe of Arizona; Yavapai-Prescott Tribe of the Yavapai Reservation, Arizona; and the Zuni Tribe of the Zuni Reservation, New Mexico, that this notice has been published.

Dated: July 22, 2010

Sherry Hutt,

Manager, National NAGPRA Program.

[FR Doc. 2010–18434 Filed 7–27–10; 8:45 am]

BILLING CODE 4312–50–S

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 July 3, 2010. Pursuant to section 60.13 of 36 CFR part 60, written comments are being accepted concerning the significance of the nominated properties under the National Register criteria for evaluation. Comments 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 August 12, 2010.

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.

J. Paul Loether,

Chief, National Register of Historic Places/National Historic Landmarks Program.

COLORADO

Saguache County

Sargents Water Tank, Denver and Rio Grande Railroad, Western Line, (Railroads in Colorado, 1858–1948 MPS) 45 Front St, Sargents, 10000537

GEORGIA

Peach County

Fort Valley Downtown and Railroad Historic District, (Georgia County Courthouses TR) Centered around SR 49, Main St, Church St, and the railroad line, Fort Valley, 10000549

IDAHO

Ada County

Reclamation Service Boise Project Office, 214 Broadway Ave, Boise, 10000546

KANSAS

Sedgwick County

North Market Street Apartments Historic District, (Residential Resources of Wichita, Sedgwick County, Kansas 1870–1957) 718, 722, and 730 N Market St, Wichita, 10000548

MASSACHUSETTS

Essex County

Wood Worsted Mill, S Union and Merrimack St, Lawrence, 10000539

MISSOURI

St. Louis County

Affton High School, 8520 Mackenzie Rd, Affton, 10000551

St. Louis Independent City

Chippewa Trust Company Building, (South St. Louis Historic Working and Middle Class Streetcar Suburbs MPS) 3801–05 S Broadway, St. Louis, 10000538

Father Dunne's New Boys' Home and Protectorate, 3010 Washington Ave, St. Louis, 10000550

MONTANA

Fergus County

Reed's Fort Post Office, .1 mi SW from the junction of Brassey and 6th Ave on Casino Creek Dr, Lewistown, 10000545

Granite County

Garnet Historic District, 11 mi N of jct US 90 and Bear Gulch Rd, Bureau of Land Management, Garnet, 10000547

VIRGINIA

Fairfax County

Floris Historic District, Bounded by Centreville Rd, W Ox Rd, Monroe St, and Frying Pan Branch, Herndon, 10000543

Fauquier County

Calverton Historic District, Area including parts of Bristersburg and Catlett Rds, Calverton, 10000542

Portsmouth Independent City

Portsmouth Community Library, 904 Elm St, Portsmouth, 10000544

WISCONSIN

Dane County

Chase Grain Elevator, 123 Railroad St, Sun Prairie, 10000540

[FR Doc. 2010–18428 Filed 7–27–10; 8:45 am]

BILLING CODE 4312–51–P

DEPARTMENT OF THE INTERIOR

National Park Service

National Register of Historic Places; Notification of Pending Removal of Listed Property

Pursuant to section 60.15 of 36 CFR Part 60, comments are being accepted on the following property being considered for removal from the National Register of Historic Places. Comments 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 August 12, 2010.

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.

J. Paul Loether,

Chief, National Register of Historic Places/ National Historic Landmarks Program.

Request for REMOVAL has been made for the following resource:

KANSAS

Labette County

East Side School, 210 Iowa St, Oswego, 02000762

[FR Doc. 2010–18430 Filed 7–27–10; 8:45 am]

BILLING CODE 4312–51–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 July 10, 2010. Pursuant to section 60.13 of 36 CFR part 60, written comments are being accepted concerning the significance of the nominated properties under the National Register criteria for evaluation. Comments 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 August 12, 2010.

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.

J. Paul Loether,

Chief, National Register of Historic Places/ National Historic Landmarks Program.

ALABAMA

Marshall County

Guntersville Post Office Building, 520 Gunter Ave., Guntersville, 10000558

CALIFORNIA

Fresno County

Fulton Mall, Inyo St to Tuolumne St, Kern and Merced Malls-Congo Alley to Federal Alley, Mariposa Mall-Congo Alley to Van Ness Ave Fresno, 10000557

MONTANA

Ravalli County

St. Mary's Mission Historic District Boundary Increase, W end of 4th St, Stevensville, 10000552

NEW YORK

Delaware County

Galli—Curci, Amelita, Estate, 352 and 374 Galli Curci Rd, Fleischmanns, 10000556

Erie County

Hotel Lafayette, 391 Washington St, Buffalo, 10000555

Hamilton County

Mohican II, Steel Pier, Lake George, 10000554

New York County

133 East 80th Street, 133 E 80th St, New York, 10000553

VIRGINIA

Accomack County

Central High School, 32308 Lankford Hwy., Painter, 10000561

Augusta County

Maple Front Farm, 439 Cale Spring Rd., Middlebrook, 10000562

Mecklenburg County

Cedar Grove, 138 Lewis Mill Rd., Clarksville, 10000560

Roanoke Independent City

Apartment Building on Windsor Avenue and Brunswick St., 2049 Windsor Ave., Roanoke (Independent City), 10000559

[FR Doc. 2010–18429 Filed 7–27–10; 8:45 am]

BILLING CODE 4312–51–P

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

[ID–933–1430–ET; IDI–31741]

Public Land Order No. 7747; Partial Revocation, Juniper Butte Range; Idaho

AGENCY: Bureau of Land Management, Interior.

ACTION: Public Land Order.

SUMMARY: This order revokes a withdrawal created by a Public Law insofar as it affects a 5-acre parcel of land reserved on behalf of the United States Air Force in Owyhee County, Idaho for the Juniper Butte Range. This order also opens the land to all forms of appropriation under the general land laws, including the mining, mineral, and geothermal leasing laws.

DATES: *Effective Date:* July 28, 2010.

FOR FURTHER INFORMATION CONTACT: Cathie Foster, Bureau of Land Management, Idaho State Office, 1387

South Vinnell Way, Boise, Idaho 83709, 208–373–3863.

SUPPLEMENTARY INFORMATION: The land included in this revocation was withdrawn on behalf of the United States Air Force as part of the Juniper Butte Range under Public Law 105–261. The parcel of land described in this order, designated as ND–8, was never used by the United States Air Force, and they have determined that the withdrawal is no longer needed on this portion.

Order

By virtue of the authority vested in the Secretary of the Interior by Section 204 of the Federal Land Policy and Management Act of 1976, 43 U.S.C. 1714, and Section 2915(b)(3) of the Juniper Butte Range Withdrawal Act, 112 Stat. 2226, 2232, it is ordered as follows:

1. The withdrawal created by Public Law 105–261 (112 Stat. 2226) dated October 17, 1998, which withdrew land on behalf of the United States Air Force for the Juniper Butte Range, is hereby revoked insofar as it affects the following described land:

Boise Meridian

T. 13 S., R. 4 E.,
Sec. 13, lot 1.

The area described contains 5 acres, more or less, in Owyhee County.

2. At 9 a.m., on August 27, 2010, the land described in Paragraph 1 will be opened to all forms of appropriation under the general land laws, including the mining, mineral, and geothermal leasing laws, subject to valid existing rights, the provisions of existing withdrawals, other segregations of record, and the requirements of applicable law. All valid applications received at or prior to 9 a.m. shall be considered as simultaneously filed at that time. Those received thereafter shall be considered in the order of filing.

Dated: July 15, 2010.

Wilma A. Lewis,

Assistant Secretary—Land and Minerals Management.

[FR Doc. 2010–18470 Filed 7–27–10; 8:45 am]

BILLING CODE 4310–GG–P

INTERNATIONAL TRADE COMMISSION

[Investigation No. 337–TA–703]

In the Matter of Certain Mobile Telephones and Wireless Communication Devices Featuring Digital Cameras, and Components Thereof; Notice of Commission Determination To Review Initial Determination

AGENCY: U.S. International Trade Commission.

ACTION: Notice.

SUMMARY: Notice is hereby given that the U.S. International Trade Commission has determined to review the June 22, 2010, initial determination on claim construction ("ID") issued by the presiding administrative law judge ("ALJ") in the above-captioned investigation under section 337 of the Tariff Act of 1930, as amended, 19 U.S.C. 1337 ("section 337").

FOR FURTHER INFORMATION CONTACT: James A. Worth, Office of the General Counsel, U.S. International Trade Commission, 500 E Street, SW., Washington, DC 20436, telephone (202) 205–3065. Copies of non-confidential documents filed in connection with this investigation are or will be available for inspection during official business hours (8:45 a.m. to 5:15 p.m.) in the Office of the Secretary, U.S. International Trade Commission, 500 E Street, SW., Washington, DC 20436, telephone (202) 205–2000. General information concerning the Commission may also be obtained by accessing its Internet server (*http://www.usitc.gov*). The public record for this investigation may be viewed on the Commission's electronic docket (EDIS) at *http://edis.usitc.gov.* Hearing-impaired persons are advised that information on this matter can be obtained by contacting the Commission's TDD terminal on (202) 205–1810.

SUPPLEMENTARY INFORMATION: This investigation was instituted on February 23, 2010, based upon a complaint filed on behalf of Eastman Kodak Company of Rochester, New York on January 14, 2010, and supplemented on February 4, 2010. 75 FR 8112. The complaint alleged violations of section 337 of the Tariff Act of 1930 (19 U.S.C. 1337) in the importation into the United States, the sale for importation, and the sale within the United States after importation of certain mobile telephones and wireless communication devices featuring digital cameras, and components thereof, that infringe certain claims of U.S. Patent No. 6,292,218. The complaint named as respondents Apple, Inc., of Cupertino, Calif.; Research in Motion, Ltd., of Ontario, Canada; and Research in Motion Corp., of Irving, Texas.

On June 22, 2010, the ALJ issued the subject ID. All parties have petitioned for review of various portions of the ID.

The Commission has determined to review the subject ID in its entirety, and to solicit briefing with respect to the issues on review. The Commission is particularly interested in briefing on the question of the legal authority for addressing the issue of claim construction as a matter for summary determination and treating the claim construction ruling as an initial determination under the Commission's rules of practice and procedure as currently written. In this connection, the parties are requested to respond to the following hypothetical analysis:

As used in rule 210.18(a), the term "issues to be determined in the investigation" can be viewed as limited to claims and affirmative defenses; a "part" of such an issue includes an element (or subpart thereof) of a claim or affirmative defense. Thus, the following could be a non-exhaustive list of examples of issues or parts thereof that are covered by rule 210.18(a): violation, importation, infringement, domestic industry (technical or economic prong), invalidity on any basis (such as anticipation or obviousness), unenforceability. Claim construction may be a necessary underpinning to the resolution of certain issues or elements, and may be part of a summary determination that addresses an issue or element. On its own, however, claim construction might not be viewed as constituting such an issue or element.

Written Submissions: The parties to the investigation are requested to file written submissions on the issues under review. The submissions should be concise and thoroughly referenced to the record in this investigation, including references to exhibits and testimony. The written submissions must be filed no later than the close of business on August 5, 2010. Reply submissions must be filed no later than the close of business on August 16, 2010. No further submissions will be permitted unless otherwise ordered by the Commission.

Persons filing written submissions must file with the Office of the Secretary the original and 12 true copies thereof on or before the deadlines stated above. Any person desiring to submit a document (or portion thereof) to the Commission in confidence must request confidential treatment unless the

information has already been granted such treatment during the proceedings. All such requests should be directed to the Secretary of the Commission and must include a full statement of the reasons why the Commission should grant such treatment. See 19 CFR 201.6. Documents for which confidential treatment is granted by the Commission will be treated accordingly. All nonconfidential written submissions will be available for public inspection at the Office of the Secretary.

This action is taken under the authority of section 337 of the Tariff Act of 1930, as amended (19 U.S.C. 1337), and under sections 210.42–.46 of the Commission's Rules of Practice and Procedure (19 CFR 210.42–.46).

By order of the Commission.

Issued: July 22, 2010.

Marilyn R. Abbott,

Secretary to the Commission.

[FR Doc. 2010–18518 Filed 7–27–10; 8:45 am]

BILLING CODE 7020–02–P

INTERNATIONAL TRADE COMMISSION

[Investigation No. 337–TA–707]

In the Matter of Certain Dynamic Random Access Memory Semiconductors and Products Containing Same, Including Memory Modules; Notice of a Commission Determination Not To Review an Initial Determination Terminating the Investigation as to All Remaining Respondents

AGENCY: U.S. International Trade Commission.

ACTION: Notice.

SUMMARY: Notice is hereby given that the U.S. International Trade Commission has determined not to review an initial determination ("ID") (Order No. 10) of the presiding administrative law judge ("ALJ") terminating the above-captioned investigation as to all remaining respondents based on a settlement agreement.

FOR FURTHER INFORMATION CONTACT: Clint Gerdine, Esq., Office of the General Counsel, U.S. International Trade Commission, 500 E Street, SW., Washington, DC 20436, telephone (202) 708–2310. Copies of non-confidential documents filed in connection with this investigation are or will be available for inspection during official business hours (8:45 a.m. to 5:15 p.m.) in the Office of the Secretary, U.S. International Trade Commission, 500 E Street, SW., Washington, DC 20436, telephone (202) 205–2000. General information concerning the Commission may also be obtained by accessing its Internet server at *http://www.usitc.gov.* The public record for this investigation may be viewed on the Commission's electronic docket (EDIS) at *http://edis.usitc.gov.* Hearing-impaired persons are advised that information on this matter can be obtained by contacting the Commission's TDD terminal on (202) 205–1810.

SUPPLEMENTARY INFORMATION: The Commission instituted this investigation on March 25, 2010, based on a complaint filed on February 19, 2010, by Infineon Technologies AG of Germany and Infineon Technologies North America Corp. of Milpitas, California (collectively "complainants"). 75 FR 14467–68 (March 25, 2010). The complaint, as amended, alleges violations of section 337 of the Tariff Act of 1930, as amended, 19 U.S.C. 1337, in the importation into the United States, the sale for importation, and the sale within the United States after importation of certain dynamic random access memory semiconductors and products containing same, including memory modules, by reason of infringement of certain claims of U.S. Patent Nos. 5,480,051; 5,422,309; 5,397,664; and 7,071,074. The complaint further alleges that an industry in the United States exists as required by subsection (a)(2) of section 337. The complaint names numerous respondents including Buffalo Inc. of Japan and Buffalo Technology (USA), Inc. of Austin, Texas (collectively, "the Buffalo respondents").

On May 25, 2010, the Commission issued notice of its determination not to review the ALJ's ID terminating the Buffalo respondents based upon a consent order. On June 18, 2010, complainants and a majority of the remaining respondents moved to terminate the investigation as to all remaining respondents based upon a settlement agreement.

The ALJ issued the subject ID (Order No. 10) on June 29, 2010, granting the joint motion for termination. He found that the motion for termination satisfies Commission rules 210.21(a)(2), (b)(1). He further found, pursuant to Commission rule 210.50(b)(2), that termination of this investigation as to all remaining respondents by settlement agreement is in the public interest. No party petitioned for review of the ID. The Commission has determined not to review the ID.

The authority for the Commission's determination is contained in section 337 of the Tariff Act of 1930, as amended, 19 U.S.C. 1337, and in sections 210.21 and 210.42(h) of the Commission's Rules of Practice and Procedure, 19 CFR 210.21, 210.42(h).

By order of the Commission.

Issued: July 22, 2010.

Marilyn R. Abbott,

Secretary to the Commission.

[FR Doc. 2010–18528 Filed 7–27–10; 8:45 am]

BILLING CODE 7020–02–P

DEPARTMENT OF JUSTICE

Notice of Lodging of Consent Decree Under the Comprehensive Environmental Response, Compensation, and Liability Act

Notice is hereby given that on July 22, 2010, a proposed Consent Decree ("Decree") in *United States* v. *Champion Chemical Co., et al.,* Civil Action No. 96cv1521, *New Jersey Department of Environmental Protection* v. *Champion Chemical Co., et al.,* Civil Action No. 99cv5238, and *United States* v. *Imperial Oil Co., et al.,* Civil Action No. 07cv1486, was lodged with the United States District Court for the District of New Jersey.

The Decree resolves the following claims of the United States: (1) the United States' Motion to Enforce the Consent Decree, entered in 2001, in *United States* v. *Champion Chemical Co., et al.,* Civil Action No. 96cv1521, and *New Jersey Department of Environmental Protection* v. *Champion Chemical Co., et al.,* Civil Action No. 99cv5238; (2) the United States' claims in *United States* v. *Imperial Oil Co., et al.,* Civil Action No. 07cv1486; and (3) the United States' claims, pursuant to the Comprehensive Environmental Response, Compensation, and Liability Act ("CERCLA"), 42 U.S.C. 9601, *et seq.,* for recovery of response costs incurred by the United States Environmental Protection Agency ("EPA")in connection with the Imperial Oil Company, Inc./Champion Chemical Company Superfund Site in Marlboro Township, New Jersey ("Site"). The Decree requires the settling defendants to pay approximately $1.4 million plus all proceeds from (1) the sale of the Site, and (2) the settling defendants' remaining insurance coverage to the United States to resolve the listed claims.

The Department of Justice will receive for a period of thirty (30) days from the date of this publication comments relating to the Decree. Comments should be addressed to the Assistant Attorney General, Environmental and Natural Resources Division, and either e-mailed

to *pubcomment-ees.enrd@usdoj.gov* or mailed to P.O. Box 7611, U.S. Department of Justice, Washington, DC 20044–7611, and should refer to *United States* v. *Imperial Oil Co., et al.,* Civil Action No. 07cv1486 (D.N.J.), D.J. Ref. 90–11–2–946/1.

The Decree may be examined at U.S. EPA Region II, U.S. Environmental Protection Agency, 290 Broadway, New York, New York 10007. During the public comment period, the Decree may also be examined on the following Department of Justice Web site: *http://www.usdoj.gov/enrd/Consent_Decrees.html.* A copy of the Decree may also be obtained by mail from the Consent Decree Library, P.O. Box 7611, U.S. Department of Justice, Washington, DC 20044–7611 or by faxing or e-mailing a request to Tonia Fleetwood (*tonia.fleetwood@usdoj.gov*), fax no. (202) 514–0097, phone confirmation number (202) 514–1547. In requesting a copy from the Consent Decree Library, please enclose a check in the amount of $15.25 (25 cents per page reproduction cost) payable to the U.S. Treasury or, if by e-mail or fax, forward a check in that amount to the Consent Decree Library at the stated address.

Maureen Katz,

Assistant Chief, Environmental Enforcement Section, Environment and Natural Resources Division.

[FR Doc. 2010–18439 Filed 7–27–10; 8:45 am]

BILLING CODE 4410–15–M

DEPARTMENT OF JUSTICE

Notice of Lodging of Consent Decree Pursuant to the Comprehensive Environmental Response, Compensation, and Liability Act

Notice is hereby given that on July 15, 2010, a proposed consent decree in *United States, et al.* v. *PPL Electric Utilities Corporation, et al.,* Civil Action No. 10-cv-3477, was lodged with the United States District Court for the Eastern District of Pennsylvania.

The proposed consent decree resolves claims that the United States filed under Sections 106 and 107(a) of CERCLA, 42 U.S.C. 9606 and 9607(a), for performance of work and reimbursement of costs incurred and to be incurred in connection with response actions at the UGI Columbia Gas Plant Superfund Site ("Site") in Columbia Borough, Lancaster County, Pennsylvania. Under the proposed consent decree, the Settling Defendants, PPL Electric Utilities Corporation and UGI Utilities Inc., will reimburse the United States $606,114.53 for past response costs, will pay future response costs to be incurred by the United States, and will perform long-term monitoring, operation, and maintenance of the remedy for the Site. The proposed consent decree also resolves the Commonwealth of Pennsylvania's claims for past response costs under the Pennsylvania Hazardous Sites Cleanup Act ("HSCA"), 35 P.S. § 6020.101, *et eq.,* for an amount of $17,430.94.

The Department of Justice will receive, for a period of thirty (30) days from the date of this publication comments relating to the proposed consent decree. Comments should be addressed to the Assistant Attorney General, Environment and Natural Resources Division, and either e-mailed to *pubcomment-ees.enrd@usdoj.gov* or mailed to P.O. Box 7611, U.S. Department of Justice, Washington, DC, 20044–7611, and should refer to *United States, et al.* v. *PPL Electric Utilities Corporation, et al.,* DOJ No. 90–11–3–09216.

The proposed consent decree may be examined at the office of the United States Attorney's Office, 615 Chestnut Street, Suite 1250, Philadelphia, PA 19106 and at U.S. EPA Region III, 1650 Arch Street, Philadelphia, PA 19103. During the public comment period, the proposed consent decree may also be examined on the following Department of Justice Web site, *http://www.usdoj.gov/endr/Consent_Decrees.html.* A copy of the proposed consent decree may be obtained in person or by mail from the Consent Decree Library, P.O. Box 7611, U.S. Department of Justice, Washington, DC 20044–7611 or by faxing or e-mailing a request to Tonia Fleetwood (*tonia.fleetwood@usdoj.gov*), fax no. (202) 514–0097, phone confirmation number (202) 514–1547. In requesting a copy from the Consent Decree Library, please enclose a check in the amount of $___, (25 cents per page reproduction cost) payable to the U.S. Treasury or, if by e-mail or fax, forward a check in that amount to the Consent Decree Library at the stated address.

Maureen Katz,

Assistant Section Chief, Environmental Enforcement Section, Environment & Natural Resources Division.

[FR Doc. 2010–18440 Filed 7–27–10; 8:45 am]

BILLING CODE 4410–15–P

DEPARTMENT OF JUSTICE

Office of Justice Programs

[OJP (NIJ) Docket No. 1525]

Notice of Draft NIJ Criminal Justice Restraints Selection and Application Guide

AGENCY: National Institute of Justice, Office of Justice Programs, Department of Justice.

ACTION: Notice of Draft NIJ Criminal Justice Restraints Selection and Application Guide.

SUMMARY: In an effort to obtain comments from interested parties, the U.S. Department of Justice, Office of Justice Programs, National Institute of Justice (NIJ) will make available to the general public the draft "NIJ Criminal Justice Restraints Selection and Application Guide." The opportunity to provide comments on this document is open to industry technical representatives, criminal justice agencies and organizations, research, development and scientific communities, and all other stakeholders and interested parties. Those individuals wishing to obtain and provide comments on the draft documents under consideration are directed to the following Web site: *http://www.justnet.org.*

DATES: Comments must be received on or before August 27, 2010.

FOR FURTHER INFORMATION CONTACT: Casandra Robinson, by telephone at 202–305–2596 [**Note:** this is not a toll-free telephone number], or by e-mail at *casandra.robinson@usdoj.gov.*

Kristina Rose,

Acting Director, National Institute of Justice.

[FR Doc. 2010–18468 Filed 7–27–10; 8:45 am]

BILLING CODE 4410–18–P

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

Importer of Controlled Substances; Notice of Registration

By Notice dated April 20, 2010, and published in the **Federal Register** on April 26, 2010, (75 FR 21660), Mylan Pharmaceuticals Inc., 781 Chestnut Ridge Road, Morgantown, West Virginia 26505, made application by renewal to the Drug Enforcement Administration (DEA) to be registered as an importer of the basic classes of controlled substances listed in schedule II:

Drug	Schedule
Methylphenidate (1724)	II
Fentanyl (9801)	II
Oxycodone (9143)	II
Hydromorphone (9150)	II

The company plans to import the listed controlled substances in finished dosage form (FDF) from foreign sources for analytical testing and clinical trials in which the foreign FDF will be compared to the company's own domestically-manufactured FDF. This analysis is required to allow the company to export domestically-manufactured FDF to foreign markets.

No comments or objections have been received. DEA has considered the factors in 21 U.S.C. 823(a) and 952(a), and determined that the registration of Mylan Pharmaceuticals Inc., to import the basic classes of controlled substances is consistent with the public interest, and with United States obligations under international treaties, conventions, or protocols in effect on May 1, 1971, at this time. DEA has investigated Mylan Pharmaceuticals 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. 952(a) and 958(a), and in accordance with 21 CFR 1301.34, the above named company is granted registration as an importer of the basic classes of controlled substances listed.

Dated: July 19, 2010.

Joseph T. Rannazzisi,

Deputy Assistant Administrator, Office of Diversion Control, Drug Enforcement Administration.

[FR Doc. 2010–18486 Filed 7–27–10; 8:45 am]

BILLING CODE 4410–09–P

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

Importer of Controlled Substances; Notice of Registration

By Notice dated April 20, 2010, and published in the **Federal Register** on April 26, 2010, (75 FR 21661), Almac Clinical Services Inc., (ACSI), 2661 Audubon Road, Audubon, Pennsylvania 19403, made application by renewal to the Drug Enforcement Administration (DEA) to be registered as an importer of the basic classes of controlled substances listed in schedule II:

Drug	Schedule
Oxycodone (9143)	II
Hydromorphone (9150)	II
Fentanyl (9801)	II

The company plans to import small quantities of the listed controlled substances in dosage form to conduct clinical trials.

No comments or objections have been received. DEA has considered the factors in 21 U.S.C. 823(a) and 952(a), and determined that the registration of Almac Clinical Services Inc. (ACSI) to import the basic classes of controlled substances is consistent with the public interest, and with United States obligations under international treaties, conventions, or protocols in effect on May 1, 1971, at this time. DEA has investigated Almac Clinical Services Inc. (ACSI) 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. 952(a) and 958(a), and in accordance with 21 CFR 1301.34, the above named company is granted registration as an importer of the basic classes of controlled substances listed.

Dated: July 19, 2010.

Joseph T. Rannazzisi,

Deputy Assistant Administrator, Office of Diversion Control, Drug Enforcement Administration.

[FR Doc. 2010–18476 Filed 7–27–10; 8:45 am]

BILLING CODE 4410–09–P

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

Importer of Controlled Substances: Notice of Registration

By Notice dated April 26, 2010 and published in the **Federal Register** on April 30, 2010, (75 FR 22844), Penick Corporation, 33 Industrial Park Road, Pennsville, New Jersey 08070, made application by renewal to the Drug Enforcement Administration (DEA) to be registered as an importer of the basic classes of controlled substances listed in schedule II:

Drug	Schedule
Coca Leaves (9040)	II
Opium, raw (9600)	II
Poppy Straw (9650)	II
Concentrate of Poppy Straw (9670).	II

The company plans to import the listed controlled substances to manufacture bulk controlled substance intermediates 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 952(a) and determined that the registration of Penick Corporation to import the basic classes of controlled substances is consistent with the public interest and with United States obligations under international treaties, conventions, or protocols in effect on May 1, 1971, at this time. DEA has investigated Penick Corporation 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. 952(a) and 958(a), and in accordance with 21 CFR 1301.34, the above named company is granted registration as an importer of the basic classes of controlled substances listed.

Dated: July 19, 2010.

Joseph T. Rannazzisi,

Deputy Assistant Administrator, Office of Diversion Control, Drug Enforcement Administration.

[FR Doc. 2010–18475 Filed 7–27–10; 8:45 am]

BILLING CODE 4410–09–P

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

Manufacturer of Controlled Substances: Notice of Application

Pursuant to § 1301.33(a) of Title 21 of the Code of Federal Regulations (CFR), this is notice that on January 27, 2009, Johnson Matthey Pharmaceutical Materials, Inc., Pharmaceuticals Service, 25 Patton Road, Devens, Massachusetts 01434, made application to the Drug Enforcement Administration (DEA) to be registered as a bulk manufacturer of the basic classes of controlled substances listed in schedule II:

Drug	Schedule
Amphetamine (1100)	II
Methylphenidate (1724)	II
Nabilone (7379)	II
Alfentanil (9737)	II
Sufentanil (9740)	II
Remifentanil (9739)	II
Hydrocodone (9193)	II

The company plans to utilize this facility to manufacture small quantities

of the listed controlled substances in bulk and to conduct analytical testing in support of the company's primary manufacturing facility in West Deptford, New Jersey. The controlled substances manufactured in bulk at this facility will be distributed to the company's customers.

Any other such applicant, and any person who is presently registered with DEA to manufacture such substances, may file comments or objections to the issuance of the proposed registration pursuant to 21 CFR 1301.33(a).

Any such written 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, Virginia 22152; and must be filed no later than September 27, 2010.

Dated: July 19, 2010.

Joseph T. Rannazzisi,

Deputy Assistant Administrator, Office of Diversion Control, Drug Enforcement Administration.

[FR Doc. 2010–18474 Filed 7–27–10; 8:45 am]

BILLING CODE 4410–09–P

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

Manufacturer of Controlled Substances; Notice of Registration

By Notice dated March 5, 2010, and published in the **Federal Register** on March 19, 2010, (75 FR 13304), Halo Pharmaceutical Inc., 30 North Jefferson Road, Whippany, New Jersey 07981, 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
Hydromorphone (9150)	II

Dihydromorphine is an intermediate in the manufacture of Hydromorphone and is not for commercial distribution. The company plans to manufacture Hydromorphone HCL for sale to other manufacturers and for the manufacture of other controlled substance dosage units for distribution 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 Halo Pharmaceutical Inc., to manufacture the listed basic classes of controlled substances is consistent with the public interest at this time. DEA has investigated Halo Pharmaceutical 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: July 19, 2010.

Joseph T. Rannazzisi,

Deputy Assistant Administrator, Office of Diversion Control, Drug Enforcement Administration.

[FR Doc. 2010–18500 Filed 7–27–10; 8:45 am]

BILLING CODE 4410–09–P

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

Manufacturer of Controlled Substances; Notice of Registration

By Notice dated March 16, 2010, and published in the **Federal Register** on March 24, 2010, (75 FR 14190), Sigma Aldrich Research Biochemicals, Inc., 1–3 Strathmore Road, Natick, Massachusetts 01760–2447, 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
Cathinone (1235)	I
Methcathinone (1237)	I
Aminorex (1585)	I
Alpha-ethyltryptamine (7249)	I
Lysergic acid diethylamide (7315)	I
Tetrahydrocannabinols (7370)	I
4-Bromo-2,5-dimethoxyamphetamine (7391).	I
4-Bromo-2,5-dimethoxyphenethylamine (7392).	I
2,5-Dimethoxyamphetamine (7396).	I
3,4-Methylenedioxyamphetamine (7400).	I
N-Hydroxy-3,4-methylenedioxyamphetamine (7402).	I
3,4-Methylenedioxy-N-ethylamphetamine (7404).	I
3,4-Methylenedioxymethamphetamine (MDMA) (7405).	I
Psilocybin (7437)	I
5-Methoxy-N,N-diisopropyltryptamine (7439).	I
1-[1-(2-Thienyl)cyclohexyl]piperidine (TCP) (7470).	I
N-Benzylpiperazine (BZP) (7493)	I
Heroin (9200)	I
Normorphine (9313)	I
Amphetamine (1100)	II
Methamphetamine (1105)	II
Nabilone (7379)	II
1-Phenylcyclohexylamine (7460)	II
Phencyclidine (7471)	II
Cocaine (9041)	II
Codeine (9050)	II
Diprenorphine (9058)	II
Ecgonine (9180)	II
Levomethorphan (9210)	II
Levorphanol (9220)	II
Meperidine (9230)	II
Metazocine (9240)	II
Methadone (9250)	II
Morphine (9300)	II
Thebaine (9333)	II
Levo-alphacetylmethadol (9648)	II
Remifentanil (9739)	II
Carfentanil (9743)	II
Fentanyl (9801)	II

The company plans to manufacture reference standards.

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 Sigma Aldrich Research Biochemicals, Inc., to manufacture the listed basic classes of controlled substances is consistent with the public interest at this time. DEA has investigated Sigma Aldrich Research Biochemicals, 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: July 19, 2010.

Joseph T. Rannazzisi,

Deputy Assistant Administrator, Office of Diversion Control, Drug Enforcement Administration.

[FR Doc. 2010–18495 Filed 7–27–10; 8:45 am]

BILLING CODE 4410–09–P

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

Manufacturer of Controlled Substances; Notice of Registration

By Notice dated March 16, 2010, and published in the **Federal Register** on March 24, 2010, (75 FR 14189), Siegfried (USA), 33 Industrial Park Road, Pennsville, New Jersey 08070, 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
Methylphenidate (1724)	II
Amobarbital (2125)	II
Pentobarbital (2270)	II
Secobarbital (2315)	II
Glutethimide (2550)	II
Codeine (9050)	II
Oxycodone (9143)	II
Hydromorphone (9150)	II
Hydrocodone (9193)	II
Methadone (9250)	II
Methadone intermediate (9254)	II
Dextropropoxyphene, bulk (non-dosage forms) (9273).	II
Morphine (9300)	II
Oripavine (9330)	II
Oxymorphone (9652)	II

The company plans to manufacture the listed controlled substances in bulk for distribution 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 Siegfried (USA) to manufacture the listed basic classes of controlled substances is consistent with the public interest at this time. DEA has investigated Siegfried (USA) 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: July 19, 2010.

Joseph T. Rannazzisi,

Deputy Assistant Administrator, Office of Diversion Control, Drug Enforcement Administration.

[FR Doc. 2010–18485 Filed 7–27–10; 8:45 am]

BILLING CODE 4410–09–P

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

Manufacturer of Controlled Substances; Notice of Registration

By Notice dated February 26, 2010, and published in the **Federal Register** on March 5, 2010, (75 FR 10313), Mallinckrodt Inc., 3600 North Second Street, St. Louis, Missouri 63147, 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
Tetrahydrocannabinols (7370)	I
Codeine-N-oxide (9053)	I
Dihydromorphine (9145)	I
Difenoxin (9168)	I
Morphine-N-oxide (9307)	I
Normorphine (9313)	I
Norlevorphanol (9634)	I
Amphetamine (1100)	II
Methamphetamine (1105)	II
Methylphenidate (1724)	II
Nabilone (7379)	II
Codeine (9050)	II
Diprenorphine (9058)	II
Etorphine HCl (9059)	II
Dihydrocodeine (9120)	II
Oxycodone (9143)	II
Hydromorphone (9150)	II
Diphenoxylate (9170)	II
Ecgonine (9180)	II
Hydrocodone (9193)	II
Levorphanol (9220)	II
Meperidine (9230)	II
Methadone (9250)	II
Methadone Intermediate (9254)	II
Metopon (9260)	II
Dextropropoxyphene, bulk (9273)	II
Morphine (9300)	II
Oripavine (9330)	II
Thebaine (9333)	II
Opium extracts (9610)	II
Opium fluid extract (9620)	II
Opium tincture (9630)	II
Opium, powdered (9639)	II
Opium, granulated (9640)	II
Levo-alphacetylmethadol (9648)	II
Oxymorphone (9652)	II
Noroxymorphone (9668)	II
Alfentanil (9737)	II
Remifentanil (9739)	II
Sufentanil (9740)	II
Fentanyl (9801)	II

The firm plans to manufacture the listed controlled substances for internal use and for sale to other companies.

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 Mallinckrodt, Inc., to manufacture the listed basic classes of controlled substances is consistent with the public interest at this time. DEA has investigated Mallinckrodt, 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: July 19, 2010.

Joseph T. Rannazzisi,

Deputy Assistant Administrator, Office of Diversion Control, Drug Enforcement Administration.

[FR Doc. 2010–18483 Filed 7–27–10; 8:45 am]

BILLING CODE 4410–09–P

DEPARTMENT OF LABOR

Office of the Secretary

Submission for OMB Review; Comment Request

ACTION: Submission for OMB review; comment request.

SUMMARY: The Department of Labor (DOL) hereby announces the submission of the following public information collection request (ICR) to the Office of Management and Budget (OMB) for review and approval in accordance with the Paperwork Reduction Act of 1995 (Pub. L. 104–13, 44 U.S.C. chapter 35). A copy of this ICR, with applicable supporting documentation; including, among other things, a description of the likely respondents, proposed frequency of response, and estimated total burden may be obtained from the RegInfo.gov Web site at *http://www.reginfo.gov/public/do/PRAMain* or by contacting Linda Watts Thomas on 202–693–4223 (this is not a toll-free number) and e-mail mail to: *DOL_PRA_PUBLIC@dol.gov.*

Interested parties are encouraged to send written comments to the Office of Information and Regulatory Affairs, Attn: OMB Desk Officer for the Department of Labor—Employment and Training Administration (ETA), Room 10235, Washington, DC 20503,

Telephone: 202–395–7316/Fax 202–395–5806 (these are not toll-free numbers), E-mail: *OIRA_submission@omb.eop.gov* within 30 days from the date of this publication in the **Federal Register.** In order to ensure the appropriate consideration, comments should reference the applicable OMB Control Number (see below).

The OMB is particularly interested in comments which:

(1) Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;

(2) Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;

(3) Enhance the quality, utility, and clarity of the information to be collected; and

(4) Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.,* permitting electronic submission of responses.

Agency: Employment and Training Administration.

Type of Review: Extension without change to a currently approved collection.

Title of Collection: Jobs for Veterans Act Priority of Services Provisions.

OMB Control Number: 1205–0468.

Frequency: Quarterly.

Affected Public: Administrators of qualified job training programs, as defined in the Jobs for Veterans Act, section 4215(a)(2), Covered Entrants, and New Covered Participants.

Cost to Federal Government: $800,000.

Total Respondents: 237.

Total Number of Responses: 1,738,419.

Total Burden Hours: 159,429.

Total Hour Burden Cost (operating/maintaining): 0.

Description: The Department of Labor, as part of its continuing effort to reduce paperwork and respondent burden conducts a preclearance consultation program to provide the general public and Federal agencies with an opportunity to comment on proposed and/or continuing collections of information in accordance with the Paperwork Reduction Act of 1995(PRA95) (44 U.S.C. 3506(c)(2)(A)). This program helps to ensure that requested data can be provided in the desired format, reporting burden (time and financial resources) is minimized, collection instruments are clearly understood, and the impact of collection requirements on respondents can be properly assessed. Currently, the Employment and Training Administration is soliciting comments concerning the extension of OMB Control No. 1205–0468, Jobs for Veterans Act, Priority of Service Provisions (currently expires July 31, 2010). For additional information, see related notice published in the **Federal Register** on April 7, 2010, (Vol. 75, page 17771).

Dated: July 19, 2010.

Linda Watts Thomas,

Acting Departmental Clearance Officer.

[FR Doc. 2010–18461 Filed 7–27–10; 8:45 am]

BILLING CODE 4510–30–P

DEPARTMENT OF LABOR

Occupational Safety and Health Administration

[Docket No. OSHA–2010–0023]

Overhead and Gantry Cranes; Extension of the Office of Management and Budget's (OMB) Approval of Information Collection (Paperwork) Requirements

AGENCY: Occupational Safety and Health Administration (OSHA), Labor.

ACTION: Request for public comment.

SUMMARY: OSHA solicits public comment concerning its proposal to extend the Office of Management and Budget's (OMB) approval of the information collection requirements specified in the Standard on Overhead and Gantry Cranes (29 CFR 1910.179).

DATES: Comments must be submitted (postmarked, sent, or received) by September 27, 2010.

ADDRESSES:

Electronically: You may submit comments and attachments electronically at *http://www.regulations.gov,* which is the Federal eRulemaking Portal. Follow the instructions online for submitting comments.

Facsimile: If your comments, including attachments, are not longer than 10 pages, you may fax them to the OSHA Docket Office at (202) 693–1648.

Mail, hand delivery, express mail, messenger, or courier service: When using this method, you must submit three copies of your comments and attachments to the OSHA Docket Office, Docket No. OSHA–2010–0023, U.S. Department of Labor, Occupational Safety and Health Administration, Room N–2625, 200 Constitution Avenue, NW., Washington, DC 20210. Deliveries (hand, express mail, messenger, and courier service) are accepted during the Department of Labor's and Docket Office's normal business hours, 8:15 a.m. to 4:45 p.m., e.t.

Instructions: All submissions must include the Agency name and OSHA docket number (OSHA–2010–0023) for the Information Collection Request (ICR). All comments, including any personal information you provide, are placed in the public docket without change, and may be made available online at *http://www.regulations.gov.* For further information on submitting comments *see* the "Public Participation" heading in the section of this notice titled "**SUPPLEMENTARY INFORMATION.**"

Docket: To read or download comments or other material in the docket, go to *http://www.regulations.gov* or the OSHA Docket Office at the address above. All documents in the docket (including this **Federal Register** notice) are listed in the *http://www.regulations.gov* index; however, some information *(e.g.,* copyrighted material) is not publicly available to read or download through the Web site. All submissions, including copyrighted material, are available for inspection and copying at the OSHA Docket Office. You may also contact Theda Kenney at the address below to obtain a copy of the ICR.

FOR FURTHER INFORMATION CONTACT: Theda Kenney or Todd Owen, Directorate of Standards and Guidance, OSHA, U.S. Department of Labor, Room N–3609, 200 Constitution Avenue, NW., Washington, DC 20210; telephone (202) 693–2222.

SUPPLEMENTARY INFORMATION:

I. Background

The Department of Labor, as part of its continuing effort to reduce paperwork and respondent (*i.e.,* employer) burden, conducts a preclearance consultation program to provide the public with an opportunity to comment on proposed and continuing information collection requirements in accordance with the Paperwork Reduction Act of 1995 (44 U.S.C. 3506(c)(2)(A)). This program ensures that information is in the desired format, reporting burden (time and costs) is minimal, collection instruments are clearly understood, and OSHA's estimate of the information collection burden is accurate. The Occupational Safety and Health Act of 1970 (the OSH Act) (29 U.S.C. 651 *et*

seq.) authorizes information collection by employers as necessary or appropriate for enforcement of the OSH Act or for developing information regarding the causes and prevention of occupational injuries, illnesses, and accidents (29 U.S.C. 657). The OSH Act also requires that OSHA obtain such information with minimum burden upon employers, especially those operating small businesses, and to reduce to the maximum extent feasible unnecessary duplication of efforts in obtaining information (29 U.S.C. 657).

The paperwork provisions of the Standard specify requirements for: Marking the rated load of cranes; preparing certification records to verify the inspection of the crane hooks, hoist chains, and rope; preparing reports of rated load tests for repaired hooks or modified cranes. Records and reports must be maintained and disclosed upon request.

II. Special Issues for Comment

OSHA has a particular interest in comments on the following issues:

- Whether the proposed information collection requirements are necessary for the proper performance of the Agency's functions, including whether the information is useful;
- The accuracy of OSHA's estimate of the burden (time and costs) of the information collection requirements, including the validity of the methodology and assumptions used;
- The quality, utility, and clarity of the information collected; and
- Ways to minimize the burden on employers who must comply; for example, by using automated or other technological information collection and transmission techniques.

III. Proposed Actions

OSHA is requesting an adjustment decrease of 38,764 burden hours, from 360,144 hours to 321,380 hours. The decrease is a result of new information showing that there are 31,495 overhead and gantry cranes in use, down from the previously estimated 35,000.

Type of Review: Extension of a currently approved collection.

Title: Overhead and Gantry Cranes (29 CFR 1910.179).

OMB Number: 1218–0224.

Affected Public: Business or other for-profits.

Number of Respondents: 31,495.

Frequency: On occasion; Monthly; Semi-annually.

Average Time per Response: Varies from 5 minutes (.08 hour) to disclose certification records to 2 hours to obtain and post rated load information on cranes.

Estimated Total Burden Hours: 321,380.

Estimated Cost (Operation and Maintenance): $0.

IV. Public Participation—Submission of Comments on This Notice and Internet Access to Comments and Submissions

You may submit comments in response to this document as follows: (1) Electronically at *http://www.regulations.gov,* which is the Federal eRulemaking Portal; (2) by facsimile (fax); or (3) by hard copy. All comments, attachments, and other material must identify the Agency name and the OSHA docket number for the ICR (Docket No. OSHA–2010–0023). You may supplement electronic submissions by uploading document files electronically. If you wish to mail additional materials in reference to an electronic or facsimile submission, you must submit them to the OSHA Docket Office (see the section of this notice titled "**ADDRESSES**"). The additional materials must clearly identify your electronic comments by your name, date, and the docket number so the Agency can attach them to your comments.

Because of security procedures, the use of regular mail may cause a significant delay in the receipt of comments. For information about security procedures concerning the delivery of materials by hand, express delivery, messenger, or courier service, please contact the OSHA Docket Office at (202) 693–2350, (TTY (877) 889–5627).

Comments and submissions are posted without change at *http://www.regulations.gov.* Therefore, OSHA cautions commenters about submitting personal information such as social security numbers and date of birth. Although all submissions are listed in the *http://www.regulations.gov* index, some information (*e.g.,* copyrighted material) is not publicly available to read or download through this Web site. All submissions, including copyrighted material, are available for inspection and copying at the OSHA Docket Office. Information on using the *http://www.regulations.gov* Web site to submit comments and access the docket is available at the Web site's "User Tips" link. Contact the OSHA Docket Office for information about materials not available through the Web site, and for assistance in using the Internet to locate docket submissions.

V. Authority and Signature

David Michaels, PhD, MPH, Assistant Secretary of Labor for Occupational Safety and Health, directed the preparation of this notice. The authority for this notice is the Paperwork Reduction Act of 1995 (44 U.S.C. 3506 *et seq.*) and Secretary of Labor's Order No. 5–2007 (72 FR 31160).

Signed at Washington, DC, on July 22, 2010.

David Michaels,

Assistant Secretary of Labor for Occupational Safety and Health.

[FR Doc. 2010–18437 Filed 7–27–10; 8:45 am]

BILLING CODE 4510–26–P

DEPARTMENT OF LABOR

Occupational Safety and Health Administration

[Docket No. OSHA–2006–0028]

MET Laboratories, Inc.; Application for Expansion of Recognition

AGENCY: Occupational Safety and Health Administration (OSHA), Labor.

ACTION: Notice.

SUMMARY: This notice announces the application of MET Laboratories, Inc., (MET) for expansion of its recognition, and presents the Agency's preliminary finding to grant this request. This preliminary finding does not constitute an interim or temporary approval of this application.

DATES: Submit information or comments, or any request for extension of the time to comment, on or before August 12, 2010. All submissions must bear a postmark or provide other evidence of the submission date.

ADDRESSES: Submit comments by any of the following methods:

Electronically: Submit comments electronically at *http://www.regulations.gov*, which is the Federal eRulemaking Portal. Follow the instructions online for making electronic submissions.

Fax: If submissions, including attachments, are no longer than 10 pages, commenters may fax them to the OSHA Docket Office at (202) 693–1648.

Mail, hand delivery, express mail, or messenger or courier service: Submit one copy of the comments to the OSHA Docket Office, Docket No. OSHA–2006–0028, U.S. Department of Labor, Room N–2625, 200 Constitution Avenue, NW., Washington, DC 20210. Deliveries (hand, express mail, and messenger and courier service) are accepted during the Department of Labor's and Docket Office's normal business hours, 8:15 a.m.–4:45 p.m., e.t.

Instructions: All submissions must include the Agency name and the OSHA docket number (*i.e.,* OSHA–2006–0028).

OSHA will place all submissions, including any personal information provided, in the public docket without revision, and these submissions will be made available online at *http://www.regulations.gov.*

Docket: To read or download submissions or other material in the docket, go to *http://www.regulations.gov* or the OSHA Docket Office at the address above. All documents in the docket are listed in the *http://www.regulations.gov* index; however, some information (*e.g.,* copyrighted material) is not publicly available to read or download through the Web site. All submissions, including copyrighted material, are available for inspection and copying at the OSHA Docket Office.

Extension of comment period: Submit requests for an extension of the comment period on or before August 12, 2010 to the Office of Technical Programs and Coordination Activities, NRTL Program, Occupational Safety and Health Administration, U.S. Department of Labor, 200 Constitution Avenue, NW., Room N–3655, Washington, DC 20210, or by fax to (202) 693–1644.

FOR FURTHER INFORMATION CONTACT: MaryAnn Garrahan, Director, Office of Technical Programs and Coordination Activities, NRTL Program, Occupational Safety and Health Administration, U.S. Department of Labor, 200 Constitution Avenue, NW., Room N–3655, Washington, DC 20210; telephone: (202) 693–2110. For information about the NRTL Program, go to *http://www.osha.gov*, and select "N" in the site index.

SUPPLEMENTARY INFORMATION:

Notice of Expansion Application

The Occupational Safety and Health Administration (OSHA) is providing notice that MET Laboratories, Inc., (MET) applied for expansion of its current recognition as a Nationally Recognized Testing Laboratory (NRTL). MET's expansion request covers the use of additional test standards.

OSHA recognition of an NRTL signifies that the organization meets the legal requirements specified in 29 CFR 1910.7. Recognition is an acknowledgment that the organization can perform independent safety testing and certification of the specific products covered within its scope of recognition, and is not a delegation or grant of government authority. As a result of recognition, employers may use products approved by the NRTL to meet OSHA standards that require testing and certification.

The Agency processes applications by an NRTL for initial recognition, or for an expansion or renewal of this recognition, following requirements in Appendix A to 29 CFR 1910.7. This appendix requires that the Agency publish two notices in the **Federal Register** in processing an application. In the first notice, OSHA announces the application and provides its preliminary finding, and, in the second notice, the Agency provides its final decision on the application. These notices set forth the NRTL's scope of recognition or modifications of that scope. OSHA maintains an informational Web page for each NRTL that details its scope of recognition. These pages can be accessed from the Web site at *http://www.osha.gov/dts/otpca/nrtl/index.html.* Each NRTL's scope of recognition has three elements: (1) The type of products the NRTL may test, with each type specified by its applicable test standard; (2) the recognized site(s) that have the technical capability to perform the testing and certification activities for the applicable test standards within the NRTL's scope of recognition; and (3) the supplemental program(s) that the NRTL may use, each of which allows the NRTL to rely on other parties to perform activities necessary for testing and certification.

General Background on the Application

MET submitted two applications, dated October 6 and November 3, 2008, to expand its recognition to include 18 additional test standards. The NRTL Program staff determined that these standards are "appropriate test standards" within the meaning of 29 CFR 1910.7(c). In connection with this request, NRTL Program staff did not perform an on-site review of MET's recognized sites. However, the staff analyzed other information pertinent to the request and determined that MET has the capabilities to perform the testing to 12 of the standards, which are listed below. As a result, the Agency would approve these 12 test standards for the expansion.

MET seeks expansion of its recognition for testing and certification of products to the following test standards:[1]

UL 244A Solid State Controls for Appliances
UL 412 Refrigeration Unit Coolers
UL 458* Power Converters/Inverters and Power Converter/Inverter Systems for Land Vehicles and Marine Crafts
UL 466 Electric Scales
UL 561 Floor-Finishing Machines
UL 1230 Amateur Movie Lights
UL 1278 Movable and Wall or Ceiling Hung Electric Room Heaters
UL 1594 Sewing and Cutting Machines
UL 1795 Hydromassage Bathtubs
UL 1951 Electric Plumbing Accessories
UL 1996 Electric Duct Heaters
UL 2021 Fixed and Location Dedicated Electric Room Heaters

* This standard is approved for testing and certification of products for use within recreational vehicles and mobile homes.

OSHA's recognition of MET, or any NRTL, for a particular test standard is limited to equipment or materials (*i.e.,* products) for which OSHA standards require third-party testing and certification before use in the workplace. Consequently, if a test standard also covers any product(s) for which OSHA does not require such testing and certification, an NRTL's scope of recognition does not include that product(s).

The test standards listed above may be approved as American National Standards by the American National Standards Institute (ANSI). However, for convenience, we may use the designation of the standards-developing organization for the standard as opposed to the ANSI designation. Under the program's policy, any NRTL recognized for a particular test standard may use either the latest proprietary version of the test standard or the latest ANSI version of that standard. Contact ANSI to determine whether a test standard is currently ANSI approved.

Preliminary Finding on the Application

MET submitted an acceptable request for expansion of its recognition as an NRTL. OSHA's review of the application file and other pertinent documents indicates that MET can meet the requirements, as prescribed by 29 CFR 1910.7, for an expansion of its recognition to include the additional test standards listed above. This preliminary finding does not constitute interim or temporary approval of the application.

OSHA welcomes public comments, in sufficient detail, as to whether MET meets the requirements of 29 CFR 1910.7 for expansion of its recognition as a Nationally Recognized Testing Laboratory. Comments should consist of pertinent written documents and exhibits. Commenters needing more time to comment must submit a request in writing, stating the reasons for the request. OSHA must receive the written request for an extension by the due date for comments. OSHA will limit any

[1] The designations and titles of these test standards were current at the time of the preparation of this notice.

extension to 30 days unless the requester justifies a longer period. OSHA may deny a request for an extension if it is not adequately justified. You may obtain or review copies of MET's request and other pertinent documents, and all submitted comments, online at *http://www.regulations.gov* under Docket No. OSHA–2006–0028; or you may contact the Docket Office, Room N–2625, Occupational Safety and Health Administration, U.S. Department of Labor, at the above address. Docket No. OSHA–2006–0028 contains all materials in the record concerning MET's application.

The NRTL Program staff will review all timely comments and, after addressing the issues raised by these comments, will recommend whether to grant MET's expansion request. The Assistant Secretary will make the final decision on granting the request, and, in making this decision, may undertake other proceedings that are prescribed in Appendix A to 29 CFR 1910.7. OSHA will publish a public notice of this final decision in the **Federal Register**.

Authority and Signature

David Michaels, Assistant Secretary of Labor for Occupational Safety and Health, 200 Constitution Avenue, NW., Washington, DC 20210, directed the preparation of this notice. Accordingly, the Agency is issuing this notice pursuant to Sections 6(b) and 8(g) of the Occupational Safety and Health Act of 1970 (29 U.S.C. 655 and 657), Secretary of Labor's Order No. 5–2007 (72 FR 31160), and 29 CFR part 1911.

Signed at Washington, DC, on July 22, 2010.

David Michaels,

Assistant Secretary of Labor for Occupational Safety and Health.

[FR Doc. 2010–18438 Filed 7–27–10; 8:45 am]

BILLING CODE 4510–26–P

NATIONAL SCIENCE FOUNDATION

Notice of Permit Applications Received Under the Antarctic Conservation Act of 1978 (Pub. L. 95–541)

AGENCY: National Science Foundation.

ACTION: Notice of Permit Applications Received under the Antarctic Conservation Act of 1978, Public Law 95–541.

SUMMARY: The National Science Foundation (NSF) is required to publish notice of permit applications received to conduct activities regulated under the Antarctic Conservation Act of 1978. NSF has published regulations under the Antarctic Conservation Act at title 45 part 670 of the Code of Federal Regulations. This is the required notice of permit applications received.

DATES: Interested parties are invited to submit written data, comments, or views with respect to this permit application by August 27, 2010. This application may be inspected by interested parties at the Permit Office, address below.

ADDRESSES: Comments should be addressed to Permit Office, Room 755, Office of Polar Programs, National Science Foundation, 4201 Wilson Boulevard, Arlington, Virginia 22230.

FOR FURTHER INFORMATION CONTACT: Nadene G. Kennedy at the above address or (703) 292–7405.

SUPPLEMENTARY INFORMATION: The National Science Foundation, as directed by the Antarctic Conservation Act of 1978 (Pub. L. 95–541), as amended by the Antarctic Science, Tourism and Conservation Act of 1996, has developed regulations for the establishment of a permit system for various activities in Antarctica and designation of certain animals and certain geographic areas a requiring special protection. The regulations establish such a permit system to designate Antarctic Specially Protected Areas.

The applications received are as follows: Permit Application No. 2011–008.

1. *Applicant* Sam Feola, Director, Raytheon Polar Services Company, 7400 South Tucson Way, Centennial, CO 80112.

Activity for Which Permit Is Requested: Introduce into Antarctica. The applicant plans to import and use commercially available, freeze-dried marine bacterium, *Vibrio fisher,* NRRL B–11177, for experimental use at the McMurdo Station Crary Science and Engineering Center (CSEC). This bacterium is used as one of the reagents for the Microtox toxicity analyzer, Azur Environmental model 500, 0073486. The bacterium are used with a reconstituting reagent to determine toxicity levels. All laboratory plastic-ware (tubes, tips, etc) used with the bacteria will be autoclaved to destroy any residual bacteria.

Location: Crary Science and Engineering Center, McMurdo Station, Antarctica.

Dates: October 1, 2010 to September 30, 2014.

Nadene G. Kennedy,

Permit Officer, Office of Polar Programs.

[FR Doc. 2010–18433 Filed 7–27–10; 8:45 am]

BILLING CODE 7555–01–P

NUCLEAR REGULATORY COMMISSION

[NRC–2009–0187]

Notice of Availability of Draft Environmental Impact Statement and Public Meeting for the AREVA Enrichment Services, LLC Proposed Eagle Rock Uranium Enrichment Facility

AGENCY: Nuclear Regulatory Commission.

ACTION: Notice of Availability of Draft Environmental Impact Statement; Correction.

SUMMARY: This document corrects a notice appearing in the **Federal Register** on July 21, 2010 (75 FR 42466), that announced the availability of the Draft Environmental Impact Statement (EIS) and Public Meeting for the AREVA Enrichment Services LLC Proposed Eagle Rock Uranium Enrichment Facility. This action is necessary to correct the phone number that the public could call to: (a) Register for providing oral comments on the Draft EIS at the public meeting; and (b) request special equipment or accommodations that are needed to attend or present information at the public meeting.

FOR FURTHER INFORMATION CONTACT: Mr. Stephen Lemont, Senior Project Manager, Office of Federal and State Materials and Environmental Management Program, via telephone at (301) 415–5163, or via e-mail at *Stephen.Lemont@nrc.gov.*

SUPPLEMENTARY INFORMATION: On page 42467, in the first column, line 67, and in the second column, line 14, the phone number is corrected to read: (800) 368–5642.

Dated at Rockville, Maryland, this 22nd day of July 2010.

For the Nuclear Regulatory Commission.

David Skeen,

Acting Deputy Director, Environmental Protection and Performance Assessment Directorate, Division of Waste Management and Environmental Protection, Office of Federal and State Materials and Environmental Management Programs.

[FR Doc. 2010–18512 Filed 7–27–10; 8:45 am]

BILLING CODE 7590–01–P

NUCLEAR REGULATORY COMMISSION

[Docket Nos. 50–282 and 50–306; NRC–2010–0022; License Nos. DPR–42 and DPR–60]

Northern States Power Company; Prairie Island Nuclear Generating Plant, Units 1 and 2; Notice of Issuance of Director's Decision

Notice is hereby given that the Director, Office of Nuclear Reactor Regulation, has issued a Director's Decision with regard to a petition dated September 4, 2009, filed by Mr. David Sebastian, hereinafter referred to as the "petitioner." On September 30, 2009, the petitioner requested an opportunity to address the U.S. Nuclear Regulatory Commission (NRC) Petition Review Board (PRB) to provide any additional information to support the petition. A teleconference took place on October 13, 2009.

The petition requested that the NRC take the following actions:

(1) Order Xcel Energy Inc. (Xcel) to cease and desist from its current arbitrary and capricious practice of using the Access Authorization and Fitness-for-Duty (AA/FFD) Programs for purposes other than their original intent, as they are being applied against him.

(2) Order compliance with:

(A) The NRC's regulations at Title 10 of the Code of Federal Regulations (10 CFR) 73.56, "Personnel Access Authorization Requirements for Nuclear Power Plants";

(B) The rationale described in the final rule "Access Authorization Program for Nuclear Power Plants" (RIN 3150–AA90) published in the **Federal Register** on April 26, 1991 (56 FR 18997); and

(C) The Nuclear Energy Institute's (NEI's) implementation guidance in NEI 03–01, "Nuclear Power Plant Access Authorization Program," Revision 2, issued October 2008.

(3) Grant the petitioner access authorization without further delay to perform his accepted job tasks, with all record of said denial removed from any and all records wherever found.

(4) Issue any other order, or grant any other relief, to which the petitioner may have shown himself entitled.

As the basis for the September 4, 2009, request, the petitioner stated that Xcel is in violation of 10 CFR 73.56 in denying him access to the Prairie Island Nuclear Generating Plant using the AA/FFD Programs by basing the decision solely upon an existing tax lien. The petitioner stated that Xcel failed to base the decision to grant or deny unescorted access authorization on a review and evaluation of all pertinent information. The petitioner stated that Xcel failed to incorporate all three elements (*i.e.,* background investigation, psychological assessment, and behavioral observation) of the unescorted access authorization program when making the decision to deny unescorted access and that this is contrary to the rationale for rulemaking, as discussed in 56 FR 18997.

On October 26 and December 2, 2009, the NRC PRB convened to discuss the petition under consideration to determine whether it met the criteria established in NRC Management Directive (MD) 8.11, "Review Process for 10 CFR 2.206 Petitions," dated October 25, 2000, for acceptance into the process under 10 CFR 2.206, "Requests for Action under This Subpart." The PRB made the following final recommendations:

(1) Item 1 met the criteria established in MD 8.11 for acceptance into the 10 CFR 2.206 process for the petition under consideration.

(2) Item 2 met the criteria established in MD 8.11 for acceptance into the 10 CFR 2.206 process for the petition under consideration.

(3) Item 3 did not meet the MD 8.11 criteria for further review under the 10 CFR 2.206 process, in that the request did not specifically address an enforcement-related action.

(4) Item 4 did not meet the MD 8.11 criteria for further review under the 10 CFR 2.206 process, in that the petition provided insufficient facts to support the request.

The NRC sent a copy of the proposed Director's Decision to the petitioner and the licensee for comment on May 7, 2010. The licensee had no comments on the proposed Director's Decision. On June 4, 2010, the NRC staff received comments on the proposed Director's Decision from the petitioner. The Director's Decision includes the comments and the NRC staff's response to them.

The Director of the Office of Nuclear Reactor Regulation has determined that the request pertaining to Xcel be denied. The Director's Decision, DD–10–02, explains the reasons for this decision pursuant to 10 CFR 2.206. The complete text of the decision is available in the Agencywide Documents Access and Management System (ADAMS) Electronic Reading Room (ADAMS Accession No. ML101650032) on the NRC's Web site, *http://www.nrc.gov/reading-rm/adams.html,* and for inspection at the Commission's Public Document Room, located at One White Flint North, Room O1 F21, 11555 Rockville Pike (first floor), Rockville, Maryland.

In accordance with 10 CFR 2.206 of the Commission's regulations, the staff will file a copy of the Director's Decision with the Secretary of the Commission for the Commission's review. As provided for by this regulation, the director's decision will constitute the final action of the Commission 25 days after the date of the decision, unless the Commission, on its own motion, institutes a review of the Director's Decision within that time.

Dated at Rockville, Maryland, this 20th day of July 2010.

For the Nuclear Regulatory Commission.

Eric J. Leeds,

Director, Office of Nuclear Reactor Regulation.

[FR Doc. 2010–18515 Filed 7–27–10; 8:45 am]

BILLING CODE 7590–01–P

POSTAL REGULATORY COMMISSION

[Docket Nos. MC2010–32 and CP2010–77; Order No. 497]

New Postal Product

AGENCY: Postal Regulatory Commission.

ACTION: Notice.

SUMMARY: The Commission is noticing a recently-filed Postal Service filing to add Priority Mail Contract 27 to the competitive product list. The Postal Service has also filed a related contract. This notice addresses procedural steps associated with the filing.

DATES: Comments are due: July 30, 2010.

ADDRESSES: Submit comments electronically via the Commission's Filing Online system at *http://www.prc.gov.* Commenters who cannot submit their views electronically should contact the person identified in the **FOR FURTHER INFORMATION CONTACT** section by telephone for advice on alternatives to electronic filing.

FOR FURTHER INFORMATION CONTACT: Stephen L. Sharfman, General Counsel, *stephen.sharfman@prc.gov* or 202–789–6820.

SUPPLEMENTARY INFORMATION:

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II. Notice of Filing
III. Ordering Paragraphs

I. Introduction

Pursuant to 39 U.S.C. 3642 and 39 CFR 3020.30 *et seq.*, the Postal Service filed a formal request and associated supporting information to add Priority

Mail Contract 27 to the competitive product list.[1] The Postal Service asserts that Priority Mail Contract 27 is a competitive product "not of general applicability" within the meaning of 39 U.S.C. 3632(b)(3). *Id.* at 1. The Postal Service states that prices and classification underlying this contract are supported by Governors' Decision No. 09–6 in Docket No. MC2009–25. *Id.* The Request has been assigned Docket No. MC2010–32.

The Postal Service contemporaneously filed a contract related to the proposed new product pursuant to 39 U.S.C. 3632(b)(3) and 39 CFR 3015.5. The contract has been assigned Docket No. CP2010–77.

Request. In support of its Request, the Postal Service filed six attachments as follows:

- Attachment A—a redacted copy of the Governor's Decision No. 09–6, originally filed in Docket No. MC2009–25, authorizing certain Priority Mail contracts;
- Attachment B—a redacted copy of the contract;
- Attachment C—a proposed change in the Mail Classification Schedule competitive product list;
- Attachment D—a Statement of Supporting Justification as required by 39 CFR 3020.32;
- Attachment E—a certification of compliance with 39 U.S.C. 3633(a); and
- Attachment F—an application for non-public treatment of materials to maintain redacted portions of the contract and supporting document under seal.

In the Statement of Supporting Justification, Brian G. Denneny, Acting Manager, Sales and Communications, asserts that the service to be provided under the contract will cover its attributable costs, make a positive contribution to institutional costs, and increase contribution toward the requisite 5.5 percent of the Postal Service's total institutional costs. *Id.,* Attachment D. Thus, Mr. Denneny contends there will be no issue of subsidization of competitive products by market dominant products as a result of this contract. *Id.*

Related contract. A redacted version of the specific Priority Mail Contract 27 is included with the Request. The contract will become effective on the day that the Commission provides all necessary regulatory approvals. It is terminable upon 30 days notice by a party, but could continue for 3 years. The Postal Service represents that the contract is consistent with 39 U.S.C. 3633(a). *See id.,* Attachment D. The Postal Service will provide the shipper with Priority Mail packaging for eligible Priority Mail items mailed by the shipper.

The Postal Service filed much of the supporting materials, including the specific Priority Mail Contract 27, under seal. It maintains that the contract and related financial information, including the customer's name and the accompanying analyses that provide prices, terms, conditions, cost data, and financial projections should remain under seal. *See* Attachment F. It also requests that the Commission order that the duration of such treatment of all customer-identifying information be extended indefinitely, instead of ending after 10 years. *Id.* at 7.

II. Notice of Filings

The Commission establishes Docket Nos. MC2010–32 and CP2010–77 for consideration of the Request pertaining to the proposed Priority Mail Contract 27 product and the related contract, respectively. In keeping with practice, these dockets are addressed on a consolidated basis for purposes of this order; however, future filings should be made in the specific docket in which issues being addressed pertain.

Interested persons may submit comments on whether the Postal Service's filings in the captioned dockets are consistent with the policies of 39 U.S.C. 3632, 3633, or 3642 and 39 CFR part 3015 and 39 CFR 3020, subpart B. Comments are due no later than July 30, 2010. The public portions of these filings can be accessed via the Commission's Web site (*http://www.prc.gov*).

The Commission appoints Paul L. Harrington to serve as Public Representative in these dockets.

III. Ordering Paragraphs

It is ordered:

1. The Commission establishes Docket Nos. MC2010–32 and CP2010–77 for consideration of the matter raised in each docket.

2. Pursuant to 39 U.S.C. 505, Paul L. Harrington is appointed to serve as officer of the Commission (Public Representative) to represent the interests of the general public in these proceedings.

3. Comments by interested persons in these proceedings are due no later than July 30, 2010.

4. The Secretary shall arrange for publication of this order in the **Federal Register**.

By the Commission.

Shoshana M. Grove

Secretary.

[FR Doc. 2010–18540 Filed 7–27–10; 8:45 am]

BILLING CODE 7710–FW–S

[1] Request of the United States Postal Service to Add Priority Mail Contract 27 to Competitive Product List and Notice of Filing (Under Seal) of Contract and Supporting Data, July 21, 2010 (Request).

SECURITIES AND EXCHANGE COMMISSION

Proposed Collection; Comment Request

Upon Written Request, Copies Available From: Securities and Exchange Commission, Office of Investor Education and Advocacy, Washington, DC 20549–0213.

Extension:
Rule 17a–7; SEC File No. 270–147; OMB Control No. 3235–0131.

Notice is hereby given that pursuant to the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*), the Securities and Exchange Commission ("Commission") is soliciting comments on the collection of information summarized below. The Commission plans to submit this existing collection of information to the Office of Management and Budget for extension and approval.

Rule 17a–7 (17 CFR 240.17a–7) under the Securities Exchange Act of 1934 (15 U.S.C. 78a *et seq.*) ("Exchange Act") requires non-resident broker-dealers registered or applying for registration pursuant to Section 15 of the Exchange Act to maintain—in the United States—complete and current copies of books and records required to be maintained under any rule adopted under the Exchange Act. Alternatively, Rule 17a–7 provides non-resident broker-dealers may sign written undertakings to furnish the requisite books and records to the Commission upon demand.

There are approximately 63 non-resident brokers and dealers. Based on the Commission's experience in this area, it is estimated that the average amount of time necessary to preserve the books and records required by Rule 17a–7 is one hour per year. Accordingly, the total burden is 63 hours per year. With an average cost per hour of approximately $294, the total cost of compliance for the respondents is approximately $18,522 per year.

Written 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 Commission'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. Consideration will be given to comments and suggestions submitted in writing within 60 days of this publication.

Comments should be directed to: Charles Boucher, Director/Chief Information Officer, Securities and Exchange Commission, c/o Shirley Martinson, 6432 General Green Way, Alexandria, Virginia 22312, or send an e-mail to: *PRA_Mailbox@sec.gov.*

Dated: July 21, 2010.

Florence E. Harmon,

Deputy Secretary.

[FR Doc. 2010–18444 Filed 7–27–10; 8:45 am]

BILLING CODE 8010–01–P

SECURITIES AND EXCHANGE COMMISSION

Proposed Collection; Comment Request

Upon Written Request, Copies Available From: Securities and Exchange Commission, Office of Investor Education and Advocacy, Washington, DC 20549–0213.

Extension:

Rule 17e–1; SEC File No. 270–224; OMB Control No. 3235–0217.

Notice is hereby given that, pursuant to the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520), the Securities and Exchange Commission (the "Commission") is soliciting comments on the collections of information summarized below. The Commission plans to submit these existing collections of information to the Office of Management and Budget ("OMB") for extension and approval.

Rule 17e–1 (17 CFR 270.17e–1) under the Investment Company Act of 1940 (15 U.S.C. 80a–1) (the "Act") is entitled "Brokerage Transactions on a Securities Exchange." The rule governs the remuneration that a broker affiliated with a registered investment company ("fund") may receive in connection with securities transactions by the fund. The rule requires a fund's board of directors to establish, and review as necessary, procedures reasonably designed to provide that the remuneration to an affiliated broker is a fair amount compared to that received by other brokers in connection with transactions in similar securities during a comparable period of time. Each quarter, the board must determine that all transactions with affiliated brokers during the preceding quarter complied with the procedures established under the rule. Rule 17e–1 also requires the fund to (i) maintain permanently a written copy of the procedures adopted by the board for complying with the requirements of the rule; and (ii) maintain for a period of six years a written record of each transaction subject to the rule, setting forth: the amount and source of the commission, fee or other remuneration received; the identity of the broker; the terms of the transaction; and the materials used to determine that the transactions were effected in compliance with the procedures adopted by the board. The Commission's examination staff uses these records to evaluate transactions between funds and their affiliated brokers for compliance with the rule.

Based on an analysis of fund filings, the staff estimates that approximately 252 fund portfolios enter into subadvisory agreements each year.[1] Based on discussions with industry representatives, the staff estimates that it will require approximately 3 attorney hours to draft and execute additional clauses in new subadvisory contracts in order for funds and subadvisers to be able to rely on the exemptions in rule 17e–1. Because these additional clauses are identical to the clauses that a fund would need to insert in their subadvisory contracts to rely on rules 12d3–1, 10f–3, 17a–10, and because we believe that funds that use one such rule generally use all of these rules, we apportion this 3 hour time burden equally to all four rules. Therefore, we estimate that the burden allocated to rule 17e–1 for this contract change would be 0.75 hours.[2] Assuming that all 252 funds that enter into new subadvisory contracts each year make the modification to their contract required by the rule, we estimate that the rule's contract modification requirement will result in 189 burden hours annually, with an associated cost of approximately $59,724.[3]

Based on an analysis of fund filings, the staff estimates that approximately 1935 funds use at least one affiliated broker. Based on conversations with fund representatives, the staff estimates that rule 17e–1's exemption would free approximately 40 percent of transactions that occur under rule 17e–1 from the rule's recordkeeping and review requirements. This would leave approximately 1161 funds (1935 funds × .6 = 1161) still subject to the rule's recordkeeping and review requirements. The staff estimates that each of these funds spends approximately 59 hours per year (40 hours by accounting staff, 15 hours by an attorney, and 4 director hours) at a cost of approximately $25,500 per year to comply with rule 17e–1's requirements that (i) the fund retain records of transactions entered into pursuant to the rule, and (ii) the fund's directors review those transactions quarterly.[4] We estimate, therefore, that the total yearly hourly burden for all funds relying on this exemption is 68,499 hours,[5] with yearly costs of approximately $29,605,500.[6] Therefore, the estimated annual aggregate burden hour associated with rule 17e–1 is 68,688,[7] and the estimated annual aggregate cost associated with it is $29,665,224.[8]

The estimate of average burden hours is made solely for the purposes of the Paperwork Reduction Act, and is not derived from a comprehensive or even a representative survey or study. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.

Written comments are invited on: (a) Whether the collections of information are necessary for the proper

[1] Based on information in Commission filings, we estimate that 42.5 percent of funds are advised by subadvisers.

[2] This estimate is based on the following calculation (3 hours ÷ 4 rules = .75 hours).

[3] These estimates are based on the following calculations: (0.75 hours × 252 portfolios = 189 burden hours); ($316 per hour × 189 hours = $59,724 total cost). The Commission staff's estimates concerning the wage rates for attorney time are based on salary information for the securities industry compiled by the Securities Industry Association. The $316 per hour figure for an attorney is from the SIA Report on Management & Professional Earnings in the Securities Industry 2009, modified to account for an 1800-hour work-year and multiplied by 5.35 to account for bonuses, firm size, employee benefits and overhead.

[4] This estimate is based on the following calculations: (40 hours accounting staff × $119 per hour = $4760) (15 hours by an attorney × $316 per hour = $4740); (4 hours by directors × $4000 = $16,000) ($4760 + $4740 + $16,000 = $25,500 total cost). The Commission staff's estimates concerning the wage rate for professional time are based on salary information for the securities industry compiled by the Securities Industry Association, except for the estimate of $4000 per hour for a board of directors. The $316 per hour estimate for an attorney and the $119 per hour estimate for accountant time is from the SIA Report on Management & Professional Earnings in the Securities Industry 2009, modified to account for an 1800-hour work-year and multiplied by 5.35 to account for bonuses, firm size, employee benefits and overhead.

[5] This estimate is based on the following calculation: (1161 funds × 59 hours = 68,499).

[6] This estimate is based on the following calculation: ($25,500 × 1161 funds = $29,605,500).

[7] This estimate is based on the following calculation: (189 hours + 68,499 hours = 68,688 total hours).

[8] This estimate is based on the following calculation: ($59,724 + $29,605,500 = $29,665,224).

performance of the functions of the Commission, including whether the information has practical utility; (b) the accuracy of the Commission's estimate of the burdens of the collections of information; (c) ways to enhance the quality, utility, and clarity of the information collected; and (d) ways to minimize the burdens of the collections of information on respondents, including through the use of automated collection techniques or other forms of information technology. Consideration will be given to comments and suggestions submitted in writing within 60 days of this publication.

Please direct your written comments to Charles Boucher, Director/Chief Information Officer, Securities and Exchange Commission, C/O Shirley Martinson, 6432 General Green Way, Alexandria, VA 22312; or send an e-mail to: *PRA_Mailbox@sec.gov.*

Dated: July 21, 2010.

Florence E. Harmon,

Deputy Secretary.

[FR Doc. 2010–18445 Filed 7–27–10; 8:45 am]

BILLING CODE 8010–01–P

SECURITIES AND EXCHANGE COMMISSION

Request for Public Comment; Comment Request

Upon Written Request, Copies Available From: Securities and Exchange Commission, Office of Investor Education and Advocacy, Washington, DC 20549–0213.

Extension:

Rule 203–2 and Form ADV–W; SEC File No. 270–40; OMB Control No. 3235–0313.

Notice is hereby given that, pursuant to the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*), the Securities and Exchange Commission ("Commission") is soliciting comments on the collection of information summarized below. The Commission plans to submit this existing collection of information to the Office of Management and Budget for extension and approval.

The title for the collection of information is "Rule 203–2 (17 CFR 275.203–2) and Form ADV–W (17 CFR 279.2) under the Investment Advisers Act of 1940 (15 U.S.C. 80b)." Rule 203–2 under the Investment Advisers Act of 1940 establishes procedures for an investment adviser to withdraw its registration with the Commission. Rule 203–2 requires every person withdrawing from investment adviser registration with the Commission to file Form ADV–W electronically on the Investment Adviser Registration Depository ("IARD"). The purpose of the information collection is to notify the Commission and the public when an investment adviser withdraws its pending or approved SEC registration. Typically, an investment adviser files a Form ADV–W when it ceases doing business or when it is ineligible to remain registered with the Commission.

The respondents to the collection of information are all investment advisers that are registered with the Commission or have applications pending for registration. The Commission has estimated that compliance with the requirement to complete Form ADV–W imposes a total burden of approximately 0.75 hours (45 minutes) for an adviser filing for full withdrawal and approximately 0.25 hours (15 minutes) for an adviser filing for partial withdrawal. Based on historical filings, the Commission estimates that there are approximately 500 respondents annually filing for full withdrawal and approximately 500 respondents annually filing for partial withdrawal. Based on these estimates, the total estimated annual burden would be 500 hours ((500 respondents × .75 hours) + (500 respondents × .25 hours)).

Rule 203–2 and Form ADV–W do not require recordkeeping or records retention. The collection of information requirements under the rule and form are mandatory. The information collected pursuant to the rule and Form ADV–W are filings with the Commission. These filings are not kept confidential. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid control number.

Written comments are invited on: (a) Whether the documentation of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility; (b) the accuracy of the agency's estimate of the burden of the collection of information; (c) ways to enhance the quality, utility, and clarity of the information collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection of information on respondents, including through the use of automated collection techniques or other forms of information technology. Consideration will be given to comments and suggestions submitted in writing within 60 days of this publication.

Please direct your written comments to Charles Boucher, Director/CIO, Securities and Exchange Commission, C/O Shirley Martinson, 6432 General Green Way, Alexandria, VA 22312; or send an e-mail to: *PRA_Mailbox@sec.gov.*

Dated: July 20, 2010.

Florence E. Harmon,

Deputy Secretary.

[FR Doc. 2010–18446 Filed 7–27–10; 8:45 am]

BILLING CODE 8010–01–P

SECURITIES AND EXCHANGE COMMISSION

Proposed Collection; Comment Request

Upon Written Request, Copies Available From: Securities and Exchange Commission, Office of Investor Education and Advocacy, Washington, DC 20549–0213.

Extension:

Rule 203–3, Form ADV–H; SEC File No. 270–481; OMB Control No. 3235–0538.

Notice is hereby given that, pursuant to the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*), the Securities and Exchange Commission (the "Commission") is soliciting comments on the collection of information summarized below. The Commission plans to submit this existing collection of information to the Office of Management and Budget ("OMB") for extension and approval.

The title for the collection of information is "Rule 203–3 and Form ADV–H under the Investment Advisers Act of 1940." Rule 203–3 (17 CFR 275.203–3) under the Investment Advisers Act of 1940 (15 U.S.C. 80b) establishes procedures for an investment adviser to obtain a hardship exemption from the electronic filing requirements of the Investment Advisers Act. Rule 203–3 requires every person requesting a hardship exemption to file Form ADV–H (17 CFR 279.3) with the Commission. The purpose of this collection of information is to permit advisers to obtain a hardship exemption, on a continuing or temporary basis, to not complete an electronic filing. The temporary hardship exemption permits advisers to make late filings due to unforeseen computer or software problems, while the continuing hardship exemption permits advisers to submit all required electronic filings on hard copy for data entry by the operator of the IARD.

The respondents to the collection of information are all investment advisers that are registered with the Commission. The Commission has estimated that compliance with the requirement to complete Form ADV–H imposes a total

burden of approximately 1 hour for an adviser. Based on our experience with hardship filings, we estimate that we will receive 11 Form ADV–H filings annually. Based on the 60 minute per respondent estimate, the Commission estimates a total annual burden of 11 hours for this collection of information.

Written comments are invited on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility; (b) the accuracy of the agency's estimate of the burden of the collection of information; (c) ways to enhance the quality, utility, and clarity of the information collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology. Consideration will be given to comments and suggestions submitted in writing within 60 days of this publication.

Please direct your written comments to Charles Boucher, Director/CIO, Securities and Exchange Commission, C/O Shirley Martinson, 6432 General Green Way, Alexandria, VA 22312; or send an e-mail to: *PRA_Mailbox@sec.gov.*

Dated: July 21, 2010.

Florence E. Harmon,

Deputy Secretary.

[FR Doc. 2010–18447 Filed 7–27–10; 8:45 am]

BILLING CODE 8010–01–P

SECURITIES AND EXCHANGE COMMISSION

[Rule 15Ba2–5; SEC File No. 270–91; OMB Control No. 3235–0088]

Proposed Collection; Comment Request

Upon Written Request, Copies Available From: U.S. Securities and Exchange Commission, Office of Investor Education and Advocacy, Washington, DC 20549–0213.

Extension:

Rule 15Ba2–5, SEC File No. 270–91, OMB Control No. 3235–0088.

Notice is hereby given that pursuant to the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*), the Securities and Exchange Commission ("Commission") is soliciting comments on the collection of information provided for in Rule 15Ba2–5 (17 CFR. 240.15Ba2–5)—Registration of Fiduciaries, under the Securities Exchange Act of 1934 (15 U.S.C. 78a *et seq.*) (the "Exchange Act"). The Commission plans to submit this existing collection of information to the Office of Management and Budget for extension and approval.

On July 7, 1975, effective July 16, 1975 (*see* 41 FR 28948, July 14, 1975), the Commission adopted Rule 15Ba2–5 under the Exchange Act of 1934 to permit a duly-appointed fiduciary to assume immediate responsibility for the operation of a municipal securities dealer's business. Without the rule, the fiduciary would not be able to assume operation until it registered as a municipal securities dealer. Under the rule, the registration of a municipal securities dealer is deemed to be the registration of any executor, administrator, guardian, conservator, assignee for the benefit of creditors, receiver, trustee in insolvency or bankruptcy, or other fiduciary, appointed or qualified by order, judgment, or decree of a court of competent jurisdiction to continue the business of such municipal securities dealer, provided that such fiduciary files with the Commission, within 30 days after entering upon the performance of his duties, a statement setting forth as to such fiduciary substantially the same information required by Form MSD or Form BD. The statement is necessary to ensure that the Commission and the public have adequate information about the fiduciary.

There is approximately 1 respondent per year that requires an aggregate total of 4 hours to comply with this rule. This respondent makes an estimated 1 annual response. Each response takes approximately 4 hours to complete. Thus, the total compliance burden per year is 4 burden hours. The approximate cost per hour is $20, resulting in a total cost of compliance for the respondent of approximately $80 (*i.e.,* 4 hours × $20).

Written comments are invited on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the Commission, including whether the information shall have practical utility; (b) the accuracy of the Commission's estimates of the burden of the proposed collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology. Consideration will be given to comments and suggestions submitted in writing within 60 days of this publication.

Please direct your written comments to: Charles Boucher, Director/Chief Information Officer, Securities and Exchange Commission, c/o Shirley Martinson, 6432 General Green Way, Alexandria, Virginia 22312 or send an e-mail to: *PRA_Mailbox@sec.gov.*

Dated: July 21, 2010.

Florence E. Harmon,

Deputy Secretary.

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SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–62550; File No. SR–MSRB–2010–02]

Self-Regulatory Organizations; Municipal Securities Rulemaking Board; Notice of Filing of Amendment No. 1 to Proposed Rule Change to MSRB Rule G–34, CUSIP Numbers and New Issue Requirements, To Enhance the Interest Rate and Descriptive Information Currently Collected and Made Transparent by the MSRB on Municipal Auction Rate Securities and Variable Rate Demand Obligations

July 22, 2010.

On March 10, 2010, the Municipal Securities Rulemaking Board ("MSRB") filed with the Securities and Exchange Commission ("Commission"), pursuant to section 19(b)(1) of the Securities Exchange Act of 1934 ("Act") [1] and Rule 19b–4 thereunder,[2] a proposed rule change to enhance the interest rate and descriptive information currently collected and made transparent by the MSRB on municipal Auction Rate Securities ("ARS") and Variable Rate Demand Obligations ("VRDOs"). The proposed rule change was published for comment in the **Federal Register** on April 2, 2010.[3] The Commission received five comment letters about the proposed rule change.[4] On July 9, 2010, the MSRB filed with the Commission, pursuant to section 19(b)(1) of the Exchange Act [5] and Rule 19b–4

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] *See* Securities Exchange Act Release No. 61793 (March 26, 2010), 75 FR 16878 (April 2, 2010) (File No. SR–MSRB–2010–02).

[4] *See* letters from: Vladimir Drozdoff, Centerport, New York, dated April 4, 2010; Joseph S. Fichera, Saber Partners, LLC, New York, New York ("Saber Partners"), dated April 12, 2010; Heather Traeger, Associate Counsel, Investment Company Institute ("ICI"), dated April 23, 2010; Leslie M. Norwood, Managing Director and Associate General Counsel, Securities Industry and Financial Markets Association ("SIFMA"), dated April 23, 2010; and Robert J. Stracks, Counsel, BMO Capital Markets GKST Inc. ("BMO Capital"), dated April 23, 2010.

[5] 15 U.S.C. 78s(b)(1).

thereunder,[6] Amendment No. 1 to the proposed rule change. Amendment No. 1 is described in items I, II, and III below, which items have been prepared by the MSRB. The Commission is publishing this notice of Amendment No. 1 to solicit comments on the proposed rule change, as amended, from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The MSRB is filing with the Commission Amendment No. 1 to File No. SR–MSRB–2010–02, originally filed on March 10, 2010 (the "original proposed rule change"). Amendment No. 1 amends and restates the original proposed rule change relating to enhancements to the interest rate and descriptive information currently collected and made transparent by the MSRB on municipal Auction Rate Securities ("ARS") and Variable Rate Demand Obligations ("VRDOs") (as amended, the "proposed rule change"). The proposed rule change would: (i) amend Rules G–8, books and records, and G–34(c), variable rate security market information, to require brokers, dealers and municipal securities dealers (collectively "dealers") to (a) submit to the MSRB documents that define auction procedures and interest rate setting mechanisms for ARS and liquidity facilities for VRDOs ("short-term obligation document disclosure rule change"); (b) report to the MSRB ARS bidding information ("ARS bidding information rule change"); (c) report to the MSRB additional VRDO information ("VRDO information rule change"); and (d) communicate to an ARS Program Dealer the fact that an order submitted for inclusion in an auction is on behalf of an ARS issuer or conduit borrower ("ARS issuer bidding rule change") (collectively, the "rule change proposal"); (ii) amend the MSRB Short-term Obligation Rate Transparency ("SHORT") System Facility to collect and disseminate information identified in the ARS bidding information rule change and the VRDO information rule change and documents identified in the short-term obligation document disclosure rule change (the "SHORT System Facility amendment proposal"); and (iii) amend the MSRB EMMA Short-term Obligation Rate Transparency Service to make the documents collected in the SHORT System Facility amendment proposal available on the MSRB's Electronic Municipal Market Access (EMMA) Web site (the "EMMA Short-term Obligation Rate Transparency Service amendment").

The MSRB has requested that the proposed rule change, which may be implemented in phases, be made effective on such date or dates as would be announced by the MSRB in notices published on the MSRB Web site, which dates would be no later than nine months after Commission approval of the proposed rule change and would be announced no later than sixty (60) days prior to the effective dates.

The text of the proposed rule change is available on the MSRB's Web site (*http://www.msrb.org*), at the MSRB's principal office, and at the Commission's Public Reference Room. If approved, the rule text for the Short-term Obligation Rate Transparency System, as well as for the EMMA Short-Term Obligation Rate Transparency Service, would be available on the MSRB Web site at *http://www.msrb.org/Rules-and-Interpretations/Information-Facilities.aspx.*

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the MSRB included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The MSRB has prepared summaries, set forth in sections A, B, and C below, of the most significant aspects of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

Amendment No. 1 makes certain modifications to the original proposed rule change based on comments received on the original proposed rule change, as described below.

The proposed rule change would enhance the interest rate and descriptive information currently collected and made transparent by the MSRB on municipal Auction Rate Securities ("ARS") and Variable Rate Demand Obligations ("VRDOs"). The proposed rule change would: (i) Amend MSRB Rules G–8, books and records, and G–34(c), variable rate security market information, to require brokers, dealers and municipal securities dealers (collectively "dealers") to (a) submit to the MSRB documents that define auction procedures and interest rate setting mechanisms for ARS and liquidity facilities for VRDOs; (b) report to the MSRB ARS bidding information; (c) report to the MSRB additional VRDO information; and (d) communicate to an ARS Program Dealer the fact that an order submitted for inclusion in an auction is on behalf of an ARS issuer or conduit borrower (collectively "rule change proposal"); (ii) amend the MSRB Short-term Obligation Rate Transparency ("SHORT") System Facility to collect and disseminate the documents identified in the rule change proposal ("SHORT System Facility amendment proposal"); and (iii) amend the MSRB EMMA Short-term Obligation Rate Transparency Service to make the documents collected in the SHORT System Facility amendment proposal available on the MSRB's Electronic Municipal Market Access (EMMA) Web site (the "EMMA Short-term Obligation Rate Transparency Service amendment").

SHORT and EMMA are components of an integrated suite of programs, services and systems ("MSRB market information programs") for the collection of municipal securities market data and documents from dealers and other market participants and the dissemination of such data and documents to the public. The MSRB market information programs leverage the components of the various individual programs, services and systems to enhance the overall efficiency and effectiveness of the MSRB market information programs. In particular, processes, software, hardware or other components initially placed into service for a particular program, service or system may be utilized by other programs, services and systems within the MSRB market information programs to optimize the effectiveness of the MSRB market information programs and the individual components thereof.[7]

Background. Since January 30, 2009 for ARS and April 1, 2009 for VRDOs, MSRB Rule G–34(c), on variable rate security market information, has required dealers that act as Program Dealers[8] for ARS or Remarketing Agents for VRDOs to report (either directly or through an agent) certain information following an ARS auction or VRDO

[6] 17 CFR 240.19b–4.

[7] For example, certain elements of the SHORT System Facility amendment proposal would rely on components previously placed into service pursuant to the EMMA primary market or continuing disclosure services for purposes of processing submissions made to the MSRB.

[8] An ARS Program Dealer is defined in Rule G–34(c) as a dealer that submits an order directly to an Auction Agent for its own account or on behalf of another account to buy, hold or sell ARS through the auction process.

interest rate reset to the SHORT System.[9] Information generally is required to be reported to the SHORT System by no later than 6:30 p.m. e.t. on the day that an ARS auction or VRDO interest rate reset occurs and all collected information is made available to market participants for free in real-time on the MSRB's Electronic Municipal Market Access ("EMMA") Web site.[10] The specific items of interest rate and descriptive information about ARS and VRDOs currently required to be reported to the SHORT System are listed below.

The following is a list of the information currently required to be reported to the SHORT System by an ARS Program Dealer following an ARS auction:

- CUSIP number;
- Interest rate for the next reset period;
- Identity of Program Dealer(s);
- Number of days of the reset period;
- Minimum denomination;
- Date and time of the auction;
- Date and time of posting of auction results by an Auction Agent;
- Indication of whether the interest rate represents a "maximum rate," an "all hold rate," or a rate that was "set by auction;"
- Minimum and maximum rates, if any, applicable at the time of the auction or, if not calculable as of the time of auction, indication that such rate or rates are not calculable; [11] and
- Par amount auctioned, not including hold orders effective at any rate.

The following is a list of the information currently required to be reported to the SHORT System by a VRDO Remarketing Agent following a VRDO interest rate reset:

- CUSIP number;
- Interest rate for the next reset period;
- Identity of Remarketing Agent;
- Date of interest rate reset;
- Length of the interest rate reset period;
- Length of Notification Period;
- Indication of whether interest rate is "set by formula," "set by Remarketing Agent" or a "maximum rate;"
- Minimum and maximum rates, if any, applicable at the time of the interest rate reset or, if not calculable as of the time of the interest rate reset, indication that such rate or rates are not calculable; [12]
- Minimum denomination;
- Type of liquidity facility(ies); [13] and
- Expiration date of each liquidity facility.

Description of the Rule Change Proposal. The proposed rule change would enhance the interest rate and descriptive information currently made available to market participants about ARS and VRDOs. The proposed rule change would require dealers to report to the MSRB documents that set forth auction procedures and interest rate setting mechanisms for ARS and liquidity facilities for VRDOs, as well as ARS bidding information and additional VRDO information. All collected documents and information would be made available in real-time on EMMA.[14] The documents and information about ARS and VRDOs that would be required to be provided to the MSRB under the proposed rule change are described below.

ARS Bidding Information. As amended and restated by this amendment, the proposed rule change would require each ARS Program Dealer to report to the SHORT System "ARS bidding information," which would include information about all orders placed by an ARS Program Dealer with an ARS Auction Agent for inclusion in an auction. This information would augment the interest rate and descriptive information currently provided to market participants by also providing information that would show, for example, how the interest rate was determined for a successful auction. The specific items of ARS bidding information an ARS Program Dealer would be required to report to the SHORT System are listed below.[15] All items would be required to be reported within the same timeframe as the ARS interest rate and descriptive information currently required to be reported under Rule G–34(c). ARS bidding information would be required to be submitted to the SHORT System as data elements in the same manner as the interest rate and descriptive information currently required to be reported to the SHORT System.[16]

- Aggregate par amount of orders to sell at any interest rate and aggregate par amount of such orders that were executed;
- Interest rate(s) and aggregate par amount(s) of orders to hold at a specific interest rate and aggregate par amount of such orders that were successfully held;
- Interest rate(s) and aggregate par amount(s) of orders to buy and aggregate par amount of such orders that were executed;
- Interest rate(s), aggregate par amount(s), and type of order—either buy, sell or hold—by a Program Dealer for its own account and aggregate par amounts of such orders, by type, that were executed; and
- Interest rate(s), aggregate par amount(s), and type of order—either buy, sell or hold—by an issuer or conduit borrower for such Auction Rate Security.[17]

ARS Issuer Bidding . One of the items of ARS bidding information that would be required to be submitted to the SHORT System by ARS Program Dealers are orders by issuers or conduit borrowers for the ARS. In response to comments received on the original proposed rule change, as discussed below, this amendment adds a requirement for dealers other than ARS Program Dealers that receive orders for inclusion in an auction for ARS from an issuer or conduit borrower of such ARS to disclose this fact when submitting such order to an ARS Program Dealer. This would ensure that ARS Program

[9] *See* Securities Exchange Act Release No. 34–59212, January 7, 2009 (File No. SR–MSRB–2008–07).

[10] The 6:30 p.m. e.t. deadline only applies to those ARS auctions and VRDO interest rate resets that occur during an "RTRS Business Day," as defined in Rule G–14(d)(ii). Information about ARS auctions and VRDO interest rate resets that occur outside of the hours of an "RTRS Business Day" is required to be submitted to the SHORT System by no later than 6:30 p.m. e.t. on the next "RTRS Business Day."

[11] Some ARS and VRDOs have minimum and maximum rates that are set pursuant to formulas that are unable to be calculated at the time a submission to the SHORT System is required. In these cases, a value of "NC" is required to be included in a submission to the SHORT System to show that the minimum and maximum rates are "not calculable." This exception does not apply to minimum and maximum rates that are linked to an index or bank lending rate, such as LIBOR. Such rates are required to be computed and the resulting values included on a submission to the SHORT System.

[12] *Id.*

[13] Dealers are required to submit to the SHORT System whether each applicable liquidity facility is a letter of credit or standby bond purchase agreement.

[14] In the future, the MSRB also plans to make all information collected under the rule change proposal available on a subscription basis.

[15] In response to comments received on the original proposed rule change, as discussed below, this amendment modifies the list of specific items of ARS bidding information in the original proposed rule change. This amendment deletes the requirement to report the "interest rate(s) and aggregate par amount(s) of orders to sell at a specific interest rate and aggregate par amount of such orders that were executed."

[16] In response to comments received on the original proposed rule change, as discussed below, this amendment modifies the original proposed rule change by requiring ARS Program Dealers to report ARS bidding information as data elements. The original proposed rule change specified that ARS bidding information would be required to be reported as a word-searchable electronic document.

[17] In response to comments received on the original proposed rule change, as discussed below, this amendment modifies the original proposed rule change by deleting the requirement for ARS Program Dealers to report whether orders submitted by an issuer or conduit borrower for an ARS were executed.

Dealers are able to submit to the SHORT System orders by issuers or conduit borrowers for the ARS when such orders are not submitted directly to the ARS Program Dealer by the issuer or conduit borrower.

Additional VRDO Information. As amended and restated by this amendment, the proposed rule change would require VRDO Remarketing Agents to submit additional items of VRDO information to the SHORT System in conjunction with the VRDO interest rate and descriptive information currently required to be reported under Rule G–34(c). This information would provide additional details concerning the interest rate set for a VRDO, such as the effective date of the interest rate, and would facilitate the tendering of a position in a VRDO by investors by requiring VRDO Remarketing Agents to report the identity of the agent of the issuer of the VRDOs to which a holder may tender their security ("Tender Agent").

The additional VRDO information would also provide transparency related to the current holders of the VRDO. Information about current holders of a VRDO would indicate, for example, that the interest rate set represents an interest rate paid to holders of the VRDO instead of instances when the VRDO is held entirely by a liquidity provider (as a "Bank Bond") and that the interest rate set is therefore not set by market demand.

The proposed rule change would require a VRDO Remarketing Agent to report to the SHORT System the effective date that the interest rate reset is applicable as well as the following information available to the VRDO Remarketing Agent as of the time of the interest rate reset: [18]

- Identity of the Tender Agent;
- Identity of the liquidity provider(s) including a indication of those VRDOs for which an issuer provides "self liquidity" and the identity of the party providing such self-liquidity; [19]
- Par amount of the VRDO, if any, held as a Bank Bond; and
- Par amount of the VRDO, if any, held by parties other than a liquidity provider, which includes the par amounts held by a VRDO Remarketing Agent and by investors.

ARS and VRDO Documents. As amended and restated by this amendment, the proposed rule change would require ARS Program Dealers and VRDO Remarketing Agents to submit certain documents to the SHORT System to ensure that market participants have centralized access to critical documents about ARS programs and VRDO issues. For existing ARS programs, dealers would be required to submit the current versions of ARS documents defining current auction procedures and interest rate setting mechanisms to the SHORT System within ninety days after the effective date of the proposed rule change. For existing VRDO issues, dealers would be required to undertake and document [20] best efforts to obtain current versions of VRDO liquidity facility documents, including Letters of Credit, Stand-by Bond Purchase Agreements and any other document that establishes an obligation to provide liquidity, and submit such documents to the SHORT System within ninety days after the effective date of the proposed rule change. On an ongoing basis, dealers would be required to submit any new or amended versions of these documents within five business days of receipt.[21]

The MSRB recognizes that for some ARS programs, documents defining current auction procedures and interest rate setting mechanisms may already be available in the SHORT System. This may occur in the case of an ARS with multiple Program Dealers in which one Program Dealer has already submitted to the SHORT System the required document. In these cases, in lieu of submitting duplicate documents, dealers would be provided the capability to signify that a document required to be submitted has already been submitted to the SHORT System by identifying the relevant document.

Since January 1, 2010, all documents submitted to EMMA have been required to be word-searchable PDF files. While this same requirement would apply to the submission of ARS and VRDO documents to the SHORT System, MSRB acknowledges that some of these documents for outstanding ARS and VRDOs are likely to be older documents that may not be available in electronic format or a format that would easily permit a dealer to produce a word-searchable PDF file of the document. Accordingly, the proposed rule change would only require ARS and VRDO documents submitted to EMMA to be word-searchable for new or amended versions of documents produced after the effective date of the proposed rule change.

Description of the SHORT System Facility Amendment Proposal. The SHORT System is an MSRB Facility for the collection and public dissemination of information about ARS and VRDO. The proposed rule change would amend this facility to provide for the collection and public dissemination of documents identified in the rule change proposal.[22]

Submissions to the SHORT System. The SHORT System receives submissions of information and documents about securities bearing interest at short-term rates under MSRB Rule G–34, on CUSIP numbers, new issue and market information requirements.

Information and Documents to be Submitted. The basic items of information and documents that would be required to be submitted to the SHORT System are the same as those required to be submitted to the MSRB under MSRB Rule G–34(c). Submitters of documents would be required to provide to the SHORT System related indexing information with respect to each document submitted, including an indication of the document type, date such document became available to the dealer, and CUSIP number(s) of the municipal securities to which such document relates. A submitter required to submit a document that is already available in its entirety in the SHORT System would be permitted to, in lieu of submitting a duplicate document, identify the document already submitted and provide such items of related indexing information as are required by MSRB rules or the SHORT System input specifications and system

[18] In response to comments received on the original proposed rule change, as discussed below, this amendment modifies the original proposed rule change by clarifying that the VRDO Remarketing Agent is only required to report the identities of the Tender Agent and liquidity provider(s) reflective of information available to the VRDO Remarketing Agent as of the time of the interest rate reset.

[19] Some VRDOs have liquidity provisions under which the liquidity is provided by the issuer, conduit borrower or affiliate instead of by a third-party. Rule G–34(c) currently requires Remarketing Agents to report the type of liquidity facility applicable to a VRDO. Currently, SHORT System specifications only provide two options for this data element—letter of credit and standby bond purchase agreement—and in conjunction with proposed rule change the MSRB would revise the specifications to also capture VRDOs that have "self liquidity."

[20] For documents of existing VRDO issues that are unable to be obtained through best efforts, the proposed rule change would require dealers to keep records of all efforts undertaken for a period of three years. Such records of best efforts would include, for example, all written requests for documents to and any responses from an issuer or liquidity provider. In response to comments received on the original proposed rule change, as discussed below, this amendment modifies the original proposed rule change by clarifying that such records are only required to be kept for those documents that are unable to be obtained.

[21] In response to comments received on the original proposed rule change, as discussed below, this amendment modifies the original proposed rule change by changing the deadline to submit new or amended versions of documents from one to five business days of receipt.

[22] This amendment does not modify the provisions of the original proposed rule change relating to the SHORT System Facility.

procedures. A submitter required to submit a document that is not able to be obtained through best efforts as provided in the proposed rule change would be required to provide an affirmative indication that a document required to be submitted is not available for submission notwithstanding the submitter's best efforts to obtain such document. The complete list of data elements that would be required on a submission to the SHORT System would be available in input specifications and system procedures made available on *http://www.msrb.org.* Submitters would be responsible for the accuracy and completeness of all information submitted to the SHORT System.

Submitters. Submissions to the SHORT System may be made solely by authorized submitters using password-protected accounts in the MSRB's user authentication system, MSRB Gateway. MSRB Gateway is designed to be a single, secure access point for all MSRB applications. Submitters of information to the SHORT System are required to obtain an account in MSRB Gateway in order to submit information to the SHORT System. Through MSRB Gateway, submitters also have the ability to designate third-party agents to submit information to the SHORT System on the submitter's behalf.

Submissions may be made by the following classes of submitters:

- ARS Program Dealer;
- VRDO Remarketing Agent;
- ARS Auction Agent; and
- Designated Agent, which may submit any information otherwise permitted to be submitted by another class of submitter which has designated such agent, as provided below.

All ARS Auction Agents are allowed to submit information about an auction to the SHORT System without prior designation by an ARS Program Dealer. Dealers optionally may designate agents to submit information on their behalf, and may revoke the designation of any such agents, through MSRB Gateway. All actions taken by a Designated Agent on behalf of a dealer that has designated such agent shall be the responsibility of the dealer.

Timing of Submissions. Submitters are required to make submissions to the SHORT System within the timeframes set forth in MSRB Rule G–34(c) and related MSRB procedures. Submissions of information to the SHORT System may be made throughout any RTRS Business Day, as defined in Rule G–14 RTRS Procedures, from at least the hours of 6 a.m. to 9 p.m., e.t., subject to the right of the MSRB to make such processes unavailable at times as needed to ensure the integrity of the SHORT System and any related systems. Submissions of documents would be able to be made throughout any day, subject to the right of the MSRB to make such processes unavailable between the hours of 3 a.m. and 6 a.m. each day, e.t., for required maintenance, upgrades or other purposes, or at other times as needed to ensure the integrity of MSRB systems. The MSRB provides advance notice of any planned periods of unavailability and shall endeavor to provide information to submitters as to the status of the submission interface during unanticipated periods of unavailability, to the extent technically feasible.

Method of Submission. Information and documents may be submitted to the SHORT System through a secure, password-protected, Web-based electronic submitter interface or through a secure, authenticated computer-to-computer data connection, at the election of the submitter. When making submissions using the Web-based interface, related information is entered manually into an on-line form and documents would be required to be uploaded as portable document format (PDF) files. Computer-to-computer submissions utilize XML files for data and PDF files for documents. Appropriate schemas and procedures for Web-based and computer-to-computer submissions would be available in input specifications and system procedures made available on *http://www.msrb.org.*

Designated Electronic Format for Documents. All documents submitted to the SHORT System would be required to be in portable document format (PDF), configured to permit documents to be saved, viewed, printed and retransmitted by electronic means. If the submitted file is a reproduction of the original document, the submitted file must maintain the graphical and textual integrity of the original document. Documents submitted to the SHORT System created on or after the effective date of the proposed rule change would be required to be word-searchable (without regard to diagrams, images and other non-textual elements).

SHORT System Processing

The SHORT System provides a single portal for the submission of information and documents. The SHORT System, as well as other MSRB systems and services, performs various data checks to ensure that information and documents are submitted in the correct format. In addition, data checks are performed to monitor dealer compliance with MSRB Rule G–34(c) as well as to identify information submitted in correct formats that may contain errors due to information not falling within reasonable ranges of expected values for a given item of information. All submissions generate an acknowledgement or error message, and all dealers that have information or documents submitted on their behalf by either an ARS Auction Agent or a Designated Agent are able to monitor such submissions.

SHORT System Information and Document Dissemination. Information and documents submitted to the SHORT System that pass the format and data checks described above are processed and disseminated on a real-time basis. Any changes to submissions also are processed upon receipt and updated information and documents are disseminated in real-time. Information submitted to the SHORT System is, in general, disseminated to the EMMA short-term obligation rate transparency service within 15 minutes of acceptance, although during peak traffic periods dissemination may occur within one hour of acceptance. Submissions of documents to the SHORT System accepted during the hours of 8:30 a.m. to 6 p.m. e.t. on an MSRB business day would generally be disseminated to the EMMA short-term obligation transparency service within 15 minutes of acceptance, although during peak traffic periods posting may occur within one hour of acceptance. Submissions outside of such hours often would be posted within 15 minutes although some submissions outside of the MSRB's normal business hours may not be processed until the next business day. SHORT System information and documents, along with related indexing information, would be made available to the public through the EMMA portal for the life of the related securities.

The MSRB plans to offer subscriptions to the information and documents submitted to the SHORT System in the future.

Description of The Emma Short-Term Obligation Rate Transparency Service Amendment Proposal. The EMMA short-term obligation rate transparency service currently makes the information collected by the SHORT System available to the public, at no charge, on the EMMA portal. The proposed rule change would add the documents identified in the rule change proposal to this service so that such documents would also be available to the public, at no charge, on the EMMA portal.[23]

[23] This amendment does not modify the provisions of the original proposed rule change

2. Statutory Basis

The MSRB believes that the proposed rule change is consistent with section 15B(b)(2)(C) of the Act,[24] which requires, among other things, that MSRB rules must be designed to prevent fraudulent and manipulative acts and practices, to promote just and equitable principles of trade, to foster cooperation and coordination with persons engaged in regulating, clearing, settling, processing information with respect to, and facilitating transactions in municipal securities, to remove impediments to and perfect the mechanism of a free and open market in municipal securities, and, in general, to protect investors and the public interest.

The MSRB believes that the proposed rule change is consistent with the Act. The proposed rule change would serve as an additional mechanism by which the MSRB works toward removing impediments to and helping to perfect the mechanisms of a free and open market in municipal securities by providing a centralized venue for free public access to information about and documents relating to ARS and VRDO. The proposed rule change would provide greater access to information about and documents relating to ARS and VRDO to all participants in the municipal securities market on an equal basis thereby removing potential barriers to obtaining such information. These factors serve to promote the statutory mandate of the MSRB to protect investors and the public interest.

B. Self-Regulatory Organization's Statement on Burden on Competition

The MSRB does not believe the proposed rule change would impose any burden on competition not necessary or appropriate in furtherance of the purposes of the Act, since it would apply equally to dealers in municipal securities.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants or Others

The Commission received five[25] comment letters regarding the original proposed rule change and the Commission has requested that the MSRB respond. While all of the commentators indicated general support for the MSRB's effort to increase transparency of ARS and VRDO several compliance concerns as well as suggested improvements to the proposed rule change were noted. The provisions of the original proposed rule change, comments received and a discussion of these comments are below.

Additional VRDO Information. The original proposed rule change would increase the information that a VRDO Remarketing Agent would be required to report to the SHORT System in conjunction with the VRDO interest rate and descriptive information currently required to be reported on the day that an interest rate reset occurs. The specific items of information include:

- Effective date that the interest rate reset is applicable;
- Identity of the Tender Agent;
- Identity of the liquidity provider(s) including an indication of those VRDOs for which an issuer provides "self liquidity" and the identity of the party providing such self-liquidity;
- Information available to the VRDO Remarketing Agent as of the time of the interest rate reset of the par amount of the VRDO, if any, held as a Bank Bond; and
- Information available to the VRDO Remarketing Agent as of the time of the interest rate reset of the aggregate par amount of the VRDO, if any, held by parties other than a liquidity provider, which includes the par amounts held by a VRDO Remarketing Agent and by investors.

SIFMA stated concerns with the requirement in the proposed rule change to report the identities of the Tender Agent and liquidity providers. SIFMA noted that the identities of these parties may change and that the VRDO Remarketing Agent may not receive timely notification of such changes. Accordingly, SIFMA suggested that VRDO Remarketing Agents only be required to report such information on a "best efforts" basis. While the MSRB acknowledges that the identities of Tender Agents and liquidity providers may change, and that VRDO Remarketing Agents may not receive timely notification that such information has changed, the MSRB does not believe that it is appropriate for VRDO Remarketing Agents to be required only to exercise best efforts to report this information. However, the MSRB is sensitive to compliance concerns in the event that the identity of a Tender Agent or liquidity provider changes, unbeknownst to the VRDO Remarketing Agent, yet a report to the SHORT System has been made that includes outdated information. Under the terms of the original proposed rule change, the VRDO Remarketing Agent would be required to modify any past submissions to the SHORT System in the event updated information about the Tender Agents and liquidity providers becomes known, which could place a significant compliance burden on dealers and result in frequent corrections to reports made to the SHORT System. Accordingly, in response to this comment, the MSRB has amended the original proposed rule change to clarify that the requirement to report these identities is based upon information known to the VRDO Remarketing Agent as of the time of the interest rate reset. The MSRB believes that this clarification would alleviate concerns with respect to dealers failing to receive timely information about a change in the identity of a Tender Agent or liquidity facility provider and provide a clearer requirement that such information is anticipated to be reported than would be provided through a best efforts provision.

SIFMA also stated concerns related to reporting the par amount of Bank Bonds that are focused on whether the VRDO Remarketing Agent would be able to obtain and report accurate information. SIFMA noted that VRDO Remarketing Agents may not know the precise amount of securities held as Bank Bonds as a result of revised amortization schedules for securities held as Bank Bonds as well as instances when holders tender securities directly to a Tender Agent. The MSRB believes that the original proposed rule change already adequately addresses SIFMA's concern as it only requires VRDO Remarketing Agents to report the par amount of Bank Bonds based upon "information available to the VRDO Remarketing Agent as of the time of the interest rate."

ARS Bidding Information. The original proposed rule change identified ARS Bidding Information that an ARS Program Dealer would be required to report within the same timeframe as the ARS interest rate and descriptive information currently required to be reported. The proposed rule change identified the following items of "bidding information" that would be required to be submitted to the SHORT System as a word-searchable portable document format ("PDF") file.

- Interest rate(s) and aggregate par amount(s) of orders to sell at a specific interest rate and aggregate par amount of such orders that were executed;
- Aggregate par amount of orders to sell at any interest rate and aggregate par amount of such orders that were executed;
- Interest rate(s) and aggregate par amount(s) of orders to hold at a specific interest rate and aggregate par amount of such orders that were successfully held;

relating to the short-term obligation rate transparency service.

[24] 15 U.S.C. 78*o*–4(b)(2)(C).

[25] *See supra* note 4.

• Interest rate(s) and aggregate par amount(s) of orders to buy and aggregate par amount of such orders that were executed;

• Interest rate(s), aggregate par amount(s), and type of order—either buy, sell or hold—by a Program Dealer for its own account and aggregate par amounts of such orders, by type, that were executed; and

• Interest rate(s), aggregate par amount(s), and type of order—either buy, sell or hold—by an issuer or conduit borrower for such Auction Rate Security and aggregate par amounts of such orders, by type, that were executed.

Saber Partners and SIFMA both stated that ARS Bidding Information should be reported as individual data elements instead of as a word-searchable document. A document-based approach for collecting such information was included in the original proposed rule change based in large part upon earlier comments from SIFMA that it would be costly and time consuming to require the collection of such information as individual data elements.[26] In response to the original proposed rule change, SIFMA noted that "a data element level of submission would not only be easier but also a superior method of data management and analysis." The MSRB agrees with Saber Partners and SIFMA's comments on the original proposed rule change that having ARS bidding information collected as data elements would be a preferred method of data collection as it would facilitate data analysis and the computation of statistics, such as a bid-to-cover ratio, that would provide meaningful information about the demand for a specific ARS. Accordingly, in response to these comments, the MSRB has amended the original proposed rule change to require ARS bidding information to be reported to the SHORT System as individual data elements.

SIFMA also stated concerns with the requirement to report orders submitted by an issuer or conduit borrower. SIFMA noted that some issuers or conduit borrowers utilize the services of a third party for submitting orders to an ARS Program Dealer. In these cases, the ARS Program Dealer may not know that an order represents an order submitted by an issuer or conduit borrower and would not be able to identify these orders in reports to the SHORT System. MSRB acknowledges that issuers or conduit borrowers may not always submit orders for an ARS directly to an ARS Program Dealer. To ensure ARS Program Dealers are provided with information that an order represents an order by an issuer or conduit borrower when such orders are placed with other dealers, the MSRB has amended the original proposed rule change to include a new requirement whereby any dealer that receives an order for inclusion in an auction for ARS from an issuer or conduit borrower of such ARS to disclose this fact when submitting the order to an ARS Program Dealer. MSRB has also amended the original proposed rule change by removing the requirement to identify whether orders placed by an issuer or conduit borrower were executed. MSRB notes that ARS Program Dealers would not be able to reliably ascertain whether orders on behalf of an issuer or conduit borrower submitted by a third-party dealer were executed, particularly if the third-party dealer submits more orders than just those on behalf of the issuer or conduit borrower and only some of those orders are filled.

SIFMA also suggested that the requirement to report "hold at rate" and "sell at rate" orders is redundant. MSRB acknowledges that this requirement could be consolidated to simplify the rule language and has therefore amended the original proposed rule change to remove the requirement to report "sell at rate" orders as the remaining "hold at rate" and "sell at any interest rate" categories of orders should provide for the reporting of all sell orders.

ARS and VRDO Documents. The original proposed rule change would require ARS Program Dealers and VRDO Remarketing Agents to submit to the MSRB current and any new or amended versions of the following documents:

• ARS documents defining auction procedures and interest rate setting mechanisms;

• VRDO documents consisting of liquidity facilities, including Letter of Credit Agreements and Stand-by Bond Purchase Agreements.

For existing documents, the original proposed rule change would require VRDO Remarketing Agents to make and document best efforts to obtain existing VRDO documents and specified a timeframe of ninety days from the date of effectiveness of a rule change for dealers to submit such documents to the MSRB. For ARS documents, ARS Program Dealers would be required to submit existing documents to the MSRB no later than ninety days from the date of effectiveness of a rule change. On an ongoing basis, the original proposed rule change included a requirement to submit new or amended versions of ARS and VRDO documents no later than one business day after receipt by the dealer.

ICI stated that it "believes there is a need for timely receipt of the proposed information for outstanding ARS and VRDOs." Accordingly, ICI stated that it "supports the MSRB's original proposed submission deadline of [thirty] days from the effective date of the proposed [rule] change."[27] While MSRB agrees that it is important to have a centralized source of ARS and VRDO documents as soon as practical, given the large number of documents that would need to be submitted to the MSRB and the fact that, for outstanding issues, dealers may need time to request documents from third parties, the MSRB believes that ninety days is an appropriate timeframe for having such documents submitted to the MSRB.

ICI also stated that it "strongly supports the one-business day submission requirement for new or amendment versions of the ARS and VRDO documents." SIFMA, however, suggested that the deadline for submitting such new or amended documents be five business days after receipt. SIFMA noted the lack of a uniform manner in which dealers receive such documents from issuers and liquidity facility providers and that "it may take a couple of days internally at a broker dealer for these documents to get routed to the proper place for submission to [the MSRB]." MSRB acknowledges that it is unlikely that dealers would have an existing process in place to support submitting new or amended versions of ARS and VRDO documents within one business day of receipt. While MSRB believes that five business days is a generous amount of time, MSRB recognizes that it is consistent with the timeframe for submitting advance refunding documents to the MSRB and would be an appropriate timeframe, at least initially, for such new or amended versions of ARS and VRDO documents to be submitted to the MSRB. Accordingly, in response to this comment, MSRB has amended the original proposed rule change to provide a five business day deadline for submitting new or amended versions of ARS and VRDO documents to the MSRB.

SIFMA also requested clarification of the recordkeeping requirement for VRDO Remarketing Agents to document best efforts to obtain existing VRDO documents and whether such documents would be required to contain

[26] *See* Securities Exchange Act Release No. 34–61793, March 26, 2010 (File No. SR–MSRB–2010–02).

[27] *See* MSRB Notice 2009–43 (July 13, 2009).

signatures. MSRB, in response to this comment, amended the original proposed rule change to clarify that such records are only required to be kept for those documents that are unable to be obtained. MSRB also notes that all documents would be required to be final, operative versions of such documents. While this requirement does not necessarily require that the document be signed, MSRB notes that signatures would provide a clear indication that the document reflects a final version.

Other Comments. ICI recommended that the proposed rule change include a "catch-all" category to require dealers to report information "about new products that fall outside of the scope of the ARS and VRDO disclosure requirements." MSRB agrees that new products may benefit from the transparency offered for ARS and VRDO by the SHORT System, yet technically fall outside of the definitions of such products, and plans to review in the future whether changes to the SHORT System and associated rules could accommodate future products without subsequent system and rule modifications.

ICI also suggested that VRDO "credit enhancement" data and documentation be required to be reported. MSRB believes that such information should not be limited to VRDOs and notes a separate MSRB initiative to display on EMMA information offered by credit ratings agencies would provide additional access to credit enhancement features associated with municipal securities on a market-wide basis.[28]

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

Within 35 days of the date of publication of this notice in the **Federal Register** or within such longer period: (i) As the Commission may designate up to 90 days of such date if it finds such longer period to be appropriate and publishes its reasons for so finding or (ii) as to which the self-regulatory organization consents, the Commission will:

(A) By order approve such proposed rule change, or

(B) Institute proceedings to determine whether the proposed rule change should be disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change, as amended by Amendment No. 1, is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's Internet comment form (*http://www.sec.gov/rules/sro.shtml*); or
- Send an e-mail to *rule-comments@sec.gov.* Please include File Number SR–MSRB–2010–02 on the subject line.

Paper Comments

- Send paper comments in triplicate to Elizabeth M. Murphy, Secretary, Securities and Exchange Commission, 100 F Street, NE., Washington, DC 20549–1090.

All submissions should refer to File Number SR–MSRB–2010–02. This file number should be included on the subject line if e-mail is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's Internet Web site (*http://www.sec.gov/rules/sro.shtml*). Copies of the submission,[29] all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for Web site viewing and printing in the Commission's Public Reference Room, 100 F Street, NE., Washington, DC 20549, on official business days between the hours of 10 a.m. and 3 p.m. Copies of the filing also will be available for inspection and copying at the principal office of the MSRB. All comments received will be posted without change; the Commission does not edit personal identifying information from submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR–MSRB–2010–02 and should be submitted on or before August 18, 2010.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[30]

Florence E. Harmon,

Deputy Secretary.

[FR Doc. 2010–18442 Filed 7–27–10; 8:45 am]

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[28] *See* MSRB Notice 2010–13 (May 20, 2010).

[29] The text of Amendment No. 1 to the proposed rule change is available on the Commission's Web site at *http://www.sec.gov/.*

[30] 17 CFR 200.30–3(a)(12).

DEPARTMENT OF TRANSPORTATION

Office of the Secretary of Transportation

[DOT Docket No. DOT–OST–2010–0074]

The Future of Aviation Advisory Committee (FAAC) Environment Subcommittee; Notice of Meeting

AGENCY: U.S. Department of Transportation, Office of the Secretary of Transportation.

ACTION: The Future of Aviation Advisory Committee (FAAC) Environment Subcommittee; Notice of Federal Advisory Committee Meeting.

SUMMARY: The Department of Transportation (DOT), Office of the Secretary of Transportation, announces a meeting of the FAAC Environment Subcommittee, which will be held at Jeppesen Corporate World Headquarters in Englewood, Colorado. This notice announces the date, time, and location of the meeting, which will be open to the public. The purpose of the FAAC is to provide advice and recommendations to the Secretary of Transportation to ensure the competitiveness of the U.S. aviation industry and its capability to manage effectively the evolving transportation needs, challenges, and opportunities of the global economy. The Environment Subcommittee is charged with examining steps and strategies that can be taken by aviation-sector stakeholders and the Federal Government to reduce aviation's environmental footprint and foster sustainability gains in cost-effective ways. This includes consideration of potential approaches to promote effective international actions through the International Civil Aviation Organization.

DATES: The meeting will be held on August 10, 2010, from 10:30 a.m. to 3 p.m., Mountain Daylight Time.

ADDRESSES: The meeting will be held at Jeppesen Corporate World Headquarters, 2nd floor board room, 55 Inverness Drive East, Englewood, Colorado 80112. Englewood is located in the Denver, Colorado, metropolitan area.

Public Access: The meeting is open to the public. (*See* below for registration instructions.)

Public Comments: Persons wishing to offer written comments and suggestions concerning the activities of the advisory committee or Environment Subcommittee should file comments in the Public Docket (Docket Number DOT–OST–2010–0074 at *http://www.regulations.gov*) or alternatively through the *FAAC@dot.gov* e-mail. If comments and suggestions are intended specifically for the Environment Subcommittee, the term "Environment"should be listed in the subject line of the message. To ensure such comments can be considered by the subcommittee before its August 10, 2010, meeting, public comments must be filed by 5 p.m., Eastern Daylight Time on Monday, August 2, 2010.

SUPPLEMENTARY INFORMATION:

Background

Under section 10(a)(2) of the Federal Advisory Committee Act (5 U.S.C. App. 2), we are giving notice of a meeting of the Environment Subcommittee of the Future of Aviation Advisory Committee taking place on August 10, 2010, from 10:30 a.m. to 3 p.m. Mountain Daylight Time, at Jeppesen Corporate World Headquarters, 2nd floor board room, 55 Inverness Drive East, Englewood, Colorado 80112. The agenda includes—

1. Presentations and discussion of operational and technology improvements, sustainable alternative fuels, and harmonized domestic and global efforts that can contribute to reducing aviation carbon emissions.
2. Consideration of public comments.
3. Identification of environmental presentations for the next meeting of the full committee.

Registration

The meeting room can accommodate up to 18 members of the public. Persons desiring to attend must pre-register through e-mail to *FAAC@dot.gov.* The term "Registration: Environment"should be listed in the subject line of the message and admission will be limited to the first 18 persons to pre-register and receive a confirmation of their pre-registration. All foreign visitors must provide their nationality when registering.

Arrangements to attend by teleconference can be made by contacting the person listed in the **FOR FURTHER INFORMATION CONTACT** section by 5 p.m. Monday, August 5, 2010. Minutes of the meeting will be taken and will be made available to the public.

Requests for Special Accommodation

The DOT is committed to providing equal access to this meeting for all participants. If you need alternative formats or services because of a disability, please send a request to *FAAC@dot.gov* with the term "Special Accommodations" listed in the subject line of the message by close of business Monday, August 5, 2010.

FOR FURTHER INFORMATION CONTACT: Lynne Pickard, Deputy Director, Office of Environment and Energy, Federal Aviation Administration, 800 Independence Avenue, SW., Washington DC 20591; telephone (202) 267–3577; fax (202) 267–5594; *Lynne.Pickard@faa.gov.*

Issued in Washington, DC, on July 23, 2010.

Pamela Hamilton-Powell,

Designated Federal Official, Future of Aviation Advisory Committee.

[FR Doc. 2010–18514 Filed 7–27–10; 8:45 am]

BILLING CODE P

DEPARTMENT OF TRANSPORTATION

Noise Exposure Map Notice, Portland International Airport, Portland, OR

AGENCY: Federal Aviation Administration, DOT.

ACTION: Notice.

SUMMARY: The Federal Aviation Administration (FAA) announces its determination that the noise exposure maps submitted by Port of Portland for Portland International Airport under the provisions of 49 U.S.C. 47501 *et seq.* (Aviation Safety and Noise Abatement Act) and 14 CFR part 150 are in compliance with applicable requirements.

DATES: *Effective Date:* The effective date of the FAA's determination on the noise exposure maps is July 21, 2010.

FOR FURTHER INFORMATION CONTACT: Cayla Morgan, Federal Aviation Administration, Airports Division, 1601 Lind Avenue, SW., Renton, WA 98057–3356, telephone (425) 227–2653.

SUPPLEMENTARY INFORMATION: This notice announces that the FAA finds that the noise exposure maps submitted for Portland International Airport are in compliance with the applicable requirements of part 150, effective July 20, 2010. Under 49 U.S.C. section 47503 of the Aviation Safety and Noise Abatement Act (hereinafter referred to as "the Act"), an airport operator may submit to the FAA noise exposure maps which meet applicable regulations and which depict non-compatible land uses as of the date of submission of such maps, a description of projected aircraft operations and the ways in which such operations will affect such maps. The Act requires such maps to be developed in consultation with interested parties in the local community, government agencies, and persons using the airport. An airport operator who has submitted noise exposure maps that are found by the FAA to be in compliance with the requirements of Federal Aviation Regulations (FAR) part 150, promulgated pursuant to the Act, may submit a noise compatibility program for the FAA approval which sets forth the measures the operator has taken or proposes to take to reduce the existing non-compatible uses and prevent the introduction of additional non-compatible uses.

The FAA has completed its review of the noise exposure maps and accompanying documentation submitted by Port of Portland for Portland International Airport. The documentation that constitutes the "noise exposure maps" as defined in section 150.7 of Part 150 includes the following from the July, 2010, FAR Part 150 Noise Exposure Map Update, Portland International Airport:

- Existing 2008 Noise Exposure Map
- Future 2017 Noise Exposure Map
- Table 2–1, Average Daily Aircraft Operations by Type, Time of Day, and Stage Length, 2008
- Table 2–2, Average Daily Aircraft Operations by Type, Time of Day, and Stage Length, 2017
- Table 2–3, Runway Use Summary—2008
- Table 2–4, Runway Use Summary—2017
- Figure 2–1, Noise Exposure Map depicting estimated population, residential units and acres within DNL 65, 70 and 75 noise contours, 2008
- Figure 2–2, Noise Exposure Map depicting estimated population, residential units and acres within DNL 65,70 and 75 noise contours, 2017
- There are no properties on or eligible for inclusion in the National Register of Historic Places within the 65 DNL contour
- Appendix B—Evidence of Public and Stakeholder Involvement
- Appendix C—Flight Track Data

The FAA has determined that these noise exposure maps and accompanying documentation are in compliance with the applicable requirements. This determination is effective July 21, 2010.

FAA's determination of an airport operator's noise exposure maps is limited to a finding that the maps were developed in accordance with the procedures contained in appendix A of FAR Part 150. Such determination does

not constitute approval of the applicant's data, information or plans, or a commitment to approve a noise compatibility program or to fund the implementation of that program. If questions arise concerning the precise relationship of specific properties to noise exposure contours depicted on a noise exposure map submitted under section 47503 of the Act, it should be noted that the FAA is not involved in any way in determining the relative locations of specific properties should be covered by the provisions of section 47506 of the Act. These functions are inseparable from the ultimate land use control and planning responsibilities of local government. These local responsibilities are not changed in any way under Part 150 or through FAA's review of noise exposure maps. Therefore, the responsibility for detailed overlaying of the noise exposure contours onto the map depicting properties on the surface rests exclusively with the airport operator that submitted those maps, or with those public agencies and planning agencies with which consultation is required under section 47503 of the Act. The FAA has relied on the certification by the airport operator, under section 150.21 of FAR Part 150, that the statutorily required consultation has been accomplished.

Copies of the full noise exposure map documentation and of the FAA's evaluation of the maps are available for examination at the following locations:

Federal Aviation Administration, Seattle Airports District Office, 1601 Lind Avenue, SW., Renton, Washington.

Port of Portland, Portland International Airport, 7200 N.E. Airport Way, Portland, Oregon 97218.

Questions may be directed to the individual names above under the heading **FOR FURTHER INFORMATION CONTACT**.

Issued in Renton, Washington, July 21, 2010.

Carolyn T. Read,

Acting Manager, Airports Division, Northwest Mountain Region.

[FR Doc. 2010–18478 Filed 7–27–10; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Surface Transportation Board

[Docket No. AB 1053X]

Michigan Air-Line Railway Co.—Abandonment Exemption—in Oakland County, MI

Michigan Air-Line Railway Co. (MAL Railway), filed a verified notice of exemption under 49 CFR pt. 1152 subpart F–*Exempt Abandonments* to abandon approximately 2.37 miles of its line of railroad extending westerly from Engineer's Profile Station 2250+20 at the west line of Arrowhead Road to Engineer's Profile Station 2389+72 at the west line of Haggerty Road, in West Bloomfield Township, Oakland County, Mich.[1] The line traverses United States Postal Service Zip Codes 48322 and 48323.

MAL Railway has certified that: (1) No local traffic has moved over the line for at least 2 years; (2) there is no overhead traffic on the line that has been or would need to be rerouted; (3) no formal complaint filed by a user of rail service on the line (or by a state or local government entity acting on behalf of such user) regarding cessation of service over the line either is pending with the Surface Transportation Board (Board) or with any U.S. District Court or has been decided in favor of complainant within the 2-year period; and (4) the requirements at 49 CFR 1105.7 (environmental report), 49 CFR 1105.8 (historic report), 49 CFR 1105.11 (transmittal letter), 49 CFR 1105.12 (newspaper publication), and 49 CFR 1152.50(d)(1) (notice to governmental agencies) have been met.

As a condition to this exemption, any employee adversely affected by the abandonment shall be protected under *Oregon Short Line Railroad—Abandonment Portion Goshen Branch Between Firth & Ammon, in Bingham & Bonneville Counties, Idaho,* 360 I.C.C. 91 (1979). To address whether this condition adequately protects affected employees, a petition for partial revocation under 49 U.S.C. 10502(d) must be filed.

Provided no formal expression of intent to file an offer of financial assistance (OFA) has been received, this exemption will be effective on August 27, 2010, unless stayed pending reconsideration. Petitions to stay that do not involve environmental issues,[2] formal expressions of intent to file an OFA under 49 CFR 1152.27(c)(2),[3] and trail use/rail banking requests under 49 CFR 1152.29 must be filed by August 9, 2010.[4] Petitions to reopen or requests for public use conditions under 49 CFR 1152.28 must be filed by August 17, 2010, with the Surface Transportation Board, 395 E Street, SW., Washington, DC 20423–0001.

A copy of any petition filed with the Board should be sent to MAL Railway's representative: W. Robert Alderson, Alderson, Alderson, Weiler, Conklin, Burghart & Crow, L.L.C., 2101 SW., 21st Street, Topeka, KS 66604.

If the verified notice contains false or misleading information, the exemption is void *ab initio.*

MAL Railway has filed a combined environmental and historic report which addresses the effects, if any, of the abandonment on the environment and historic resources. SEA will issue an environmental assessment (EA) by August 2, 2010. Interested persons may obtain a copy of the EA by writing to SEA (Room 1100, Surface Transportation Board, Washington, DC 20423–0001) or by calling SEA, at (202) 245–0305. Assistance for the hearing impaired is available through the Federal Information Relay Service (FIRS) at 1–800–877–8339. Comments on environmental and historic preservation matters must be filed within 15 days after the EA becomes available to the public.

Environmental, historic preservation, public use, or trail use/rail banking conditions will be imposed, where appropriate, in a subsequent decision.

Pursuant to the provisions of 49 CFR 1152.29(e)(2), MAL Railway shall file a notice of consummation with the Board to signify that it has exercised the authority granted and fully abandoned the line. If consummation has not been effected by MAL Railway's filing of a notice of consummation by July 28, 2011, and there are no legal or regulatory barriers to consummation, the authority to abandon will automatically expire.

[1] On July 14, 2010, MAL Railway amended its notice of exemption.

[2] The Board will grant a stay if an informed decision on environmental issues (whether raised by a party or by the Board's Section of Environmental Analysis (SEA) in its independent investigation) cannot be made before the exemption's effective date. *See Exemption of Out-of-Serv. Rail Lines,* 5 I.C.C.2d 377 (1989). Any request for a stay should be filed as soon as possible so that the Board may take appropriate action before the exemption's effective date.

[3] Each OFA must be accompanied by the filing fee, which is currently set at $1,500. *See* 49 CFR 1002.2(f)(25).

[4] MAL Railway states that, upon abandonment of the line, it proposes to effectuate an agreement with the Parks & Recreation Commission of West Bloomfield Township (WBPRC) whereby WBPRC has agreed to purchase the right-of-way for use as a recreational trail.

Board decisions and notices are available on our Web site at *www.stb.dot.gov.*

Decided: July 20, 2010.

By the Board, Joseph H. Dettmar Acting Director, Office of Proceedings.

Jeffrey Herzig,

Clearance Clerk.

[FR Doc. 2010–18228 Filed 7–27–10; 8:45 am]

BILLING CODE 4915–01–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

Eleventh Meeting: Joint RTCA Special Committee 213: EUROCAE WG–79: Enhanced Flight Vision Systems/ Synthetic Vision Systems (EFVS/SVS)

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

ACTION: Notice of Joint RTCA Special Committee 213: EUROCAE WG–79: Enhanced Flight Vision Systems/ Synthetic Vision Systems (EFVS/SVS).

SUMMARY: The FAA is issuing this notice to advise the public of a meeting of Joint RTCA Special Committee 213: EUROCAE WG–79: Enhanced Flight Vision Systems/Synthetic Vision Systems (EFVS/SVS).

DATES: The meeting will be held September 21–23, 2010 from 8:30 a.m.—5 p.m. (0830–1700).

ADDRESSES: The meeting will be held at the London Gatwick Airport, UK CAA Aviation House, 3rd floor, Conf Room #1, Gatwick Airport South West Sussex, RH6 0YR, United Kingdom, Phone: +44 (0) 1293 768821.

Logistics: If attending, please inform Terry Neale no later than 16 August of name and company. (If driving, you will need your car registration).

Objectives: Plenary approval DO–315B (MASPS for SVS approach). Discussion on DO–315C performance objectives.

FOR FURTHER INFORMATION CONTACT: (1) RTCA Secretariat, 1828 L Street, NW., Suite 805, Washington, DC 20036; telephone (202) 833–9339; fax (202) 833–9434; Web site *http://www.rtca.org.*

SUPPLEMENTARY INFORMATION: Pursuant to section 10(a) (2) of the Federal Advisory Committee Act (Pub. L. 92–463, 5 U.S.C., Appendix 2), notice is hereby given for a Joint RTCA Special Committee 213: EUROCAE WG–79: Enhanced Flight Vision Systems/ Synthetic Vision Systems (EFVS/SVS) meeting. The agenda will include:

Tuesday, 21 September

Morning

- Plenary discussion (sign-in at 0830).
- Introductions and administrative items.
- Review and approve minutes from last full plenary meeting.

Afternoon

- Work Group 1 (SVS) Discussion: Resolve DO–315B FRAC comment list.
- Work Group 2 (EFVS) Discussion: Begin discussion of DO–315C performance objectives for landing in reported visibilities < 1000 ft RVR.

Wednesday, 22 September

- Plenary Discussion of DO–315B FRAC disposition (0830–1700, including breaks and lunch).

Thursday, 23 September

- Plenary discussion (0830–1500, including breaks and lunch).
- Approve DO–315B draft.
- Administrative items (meeting schedule).

Attendance is open to the interested public but limited to space availability. With the approval of the chairmen, members of the public may present oral statements at the meeting. Persons wishing to present statements or obtain information should contact the person listed in the **FOR FURTHER INFORMATION CONTACT** section. Members of the public may present a written statement to the committee at any time.

Issued in Washington, DC, on July 21, 2010.

Francisco Estrada C.,

RTCA Advisory Committee.

[FR Doc. 2010–18472 Filed 7–27–10; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

Fifth Meeting: RTCA Special Committee 223: Airport Surface Wireless Communications

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

ACTION: Notice of RTCA Special Committee 223: Airport Surface Wireless Communications meeting.

SUMMARY: The FAA is issuing this notice to advise the public of a meeting of RTCA Special Committee 223: Airport Surface Wireless Communications.

DATES: The meeting will be held August 17–18, 2010 from 9 a.m.–5 p.m.

ADDRESSES: The meeting will be held at the NASA Glenn Research Center, 21000 Brookpark Road, Cleveland, OH 44135, Host: Jim Budinger—(Office) 216–443–3496: (Mobile) 440–289–0424, *james.m.budinger@nasa.gov.*

Notes

- Please confirm attendance via SC–223 Workspace link by COB Friday 13 August 2010. If you receive an Outlook Meeting Invitation, please reply to that as well. The list of acceptances will be used to generate the Official NASA Visitors Request Form for preparation of badges. Your access to the meeting location will be delayed significantly if your visit is not pre-authorized.
- If you would like to attend but are *not* a U.S. citizen and have *not* already provided your personal information to NASA, please contact Jim Budinger.
- Please *See SC–223 Workspace for lodging options and detailed directions around the NASA main gate during construction.*
- *Please allow up to 20 minutes for badging and driving to the meeting locations on both days. No escort will be needed for U.S. citizens.*

FOR FURTHER INFORMATION CONTACT: RTCA Secretariat, 1828 L Street, NW., Suite 805, Washington, DC 20036; telephone (202) 833–9339; fax (202) 833–9434; Web site *http://www.rtca.org.*

SUPPLEMENTARY INFORMATION: Pursuant to section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92–463, 5 U.S.C., Appendix 2), notice is hereby given for a RTCA Special Committee 223: Airport Surface Wireless Communications meeting. The agenda will include:

Tuesday, August 17, 2010—Building 54 Room 101

- 0900 a.m.—Opening Plenary.
- Welcome, Introductions, Administrative Remarks, Approve/ Review Meeting #4 Summary, RTCA Paper No. 099–10/SC223–009).
- Welcome from NASA Glenn Research Center Management: Dr. Gary Seng.
- Special Committee Leadership.
- Designated Federal Official (DFO): Mr. Brent Phillips.
- Co-Chair: Mr. Aloke Roy, Honeywell International.
- Co-Chair: Mr. Ward Hall, ITT Corporation.
- 0915 a.m.—Agenda Overview.
- Fill out lunch orders.
- 0930 a.m.—AeroMACS Profile Working Group Status (Mr. Art Ahrens).
- 0940 a.m.—AeroMACS User Services & Applications Ad-Hoc Working Group Status (Mr. Chris Wargo).
- 0950 a.m.—4th Plenary meeting action item status.

• 1010 a.m.—Break.
• 1020 a.m.—Status of AeroMACS planning within FAA—Mr. Brent Phillips.
• 1030 a.m.—EUROCONTROL/EUROCAE WG–82 status and inputs—Mr. Luc Lommaert.
• 1100 a.m.—NASA GRC C-band interference modeling and simulation results—Dr. Jeffrey Wilson.
• 1115 a.m.—Ohio University grant findings and recommendations—Dr. David Matolak.
• 1135 a.m.—Proposed additional topics.
• *Lunch* 1200 p.m.—(brought in to B54–R101).

Profiles WG Breakout Session

• 1230 p.m.—Technical work on AeroMACS Profile (Mr. Art Ahrens).
• 1300 p.m.—WiMAX Forum perspective and guidance (Mr. Edward Agis, Certification Working Group Chair, WiMAX Forum).

User Services & Applications (USAS) Breakout Session

• 1330 p.m.—User services and applications definition (Mr. Chris Wargo).
• 1700 p.m.—Adjourn.

Wednesday, August 18, 2010—(*Note:* Different Location)

AeroMACS Testing and Demonstrations—Building 110 Room 313

• Fill out lunch orders.
• 0900 a.m.—Overview of AeroMACS test and evaluation results summary—Mr. Ward Hall.
• 0930 a.m.—Selected AeroMACS fixed and mobile services presentations/demonstrations.
• *Lunch* 1230 p.m. (brought in to Building 54–Room 101).

Reconvene Plenary—Building 54 Room 101

• 1300 p.m.—Profiles WG Status Report and Plenary Guidance.
• 1330 p.m.—USAS WG Status Report and Plenary Guidance.
• 1400 p.m.—Establish Agenda for joint plenary meeting in Brussels Belgium 28–30 September 2010.
• 1410 p.m.—Establish Agenda for joint plenary meeting for AeroMACS MOPS in Washington DC.
• 1420 p.m.—Review of Meeting summary report.
• 1500 p.m.—Adjourn.

Attendance is open to the interested public but limited to space availability. With the approval of the chairmen, members of the public may present oral statements at the meeting. Persons wishing to present statements or obtain information should contact the person listed in the **FOR FURTHER INFORMATION CONTACT** section. Members of the public may present a written statement to the committee at any time.

Issued in Washington, DC, on July 21, 2010.

Francisco Estrada C.,

RTCA Advisory Committee.

[FR Doc. 2010–18477 Filed 7–27–10; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

[Summary Notice No. PE–2010–32]

Petition for Exemption; Summary of Petition Received

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of petition for exemption received.

SUMMARY: This notice contains a summary of a petition seeking relief from specified requirements of 14 CFR 21.151 and 21.153. The purpose of this notice is to improve the public's awareness of, and participation in, this aspect of FAA's regulatory activities. Neither publication of this notice nor the inclusion or omission of information in the summary is intended to affect the legal status of the petition or its final disposition.

DATES: Comments on this petition must identify the petition docket number involved and must be received on or before August 17, 2010.

ADDRESSES: You may send comments identified by Docket Number FAA–2009–1174 using any of the following methods:

• *Government-wide rulemaking Web site:* Go to *http://www.regulations.gov* and follow the instructions for sending your comments electronically.
• *Mail:* Send comments to the Docket Management Facility; U.S. Department of Transportation, 1200 New Jersey Avenue, SE., West Building Ground Floor, Room W12–140, Washington, DC 20590.
• *Fax:* Fax comments to the Docket Management Facility at 202–493–2251.
• *Hand Delivery:* Bring comments to the Docket Management Facility in Room W12–140 of the West Building Ground Floor at 1200 New Jersey Avenue, SE., Washington, DC, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

Privacy: We will post all comments we receive, without change, to *http://www.regulations.gov*, including any personal information you provide. Using the search function of our docket Web site, anyone can find and read the comments received into any of our dockets, including the name of the individual sending the comment (or signing the comment for an association, business, labor union, etc.). You may review DOT's complete Privacy Act Statement in the **Federal Register** published on April 11, 2000 (65 FR 19477–78).

Docket: To read background documents or comments received, go to *http://www.regulations.gov* at any time or to the Docket Management Facility in Room W12–140 of the West Building Ground Floor at 1200 New Jersey Avenue, SE., Washington, DC, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

FOR FURTHER INFORMATION CONTACT: John Linsenmeyer, Aircraft Certification Service—Production Certification Branch, AIR–220, Federal Aviation Administration, 950 L'Enfant Plaza, SW., Room 514B, Washington, DC 20024; telephone (202) 385–6364, facsimile (202) 267–5580; e-mail *john.linsenmeyer@faa.gov.*

This notice is published pursuant to 14 CFR 11.85.

Issued in Washington, DC, on July 23, 2010.

Pamela Hamilton-Powell,

Director, Office of Rulemaking.

Petition for Exemption

Docket No.: FAA–2009–1174.

Petitioner: Pratt & Whitney (P&W).

Sections of 14 CFR Affected: §§ 21.151 and 21.153.

Description of Relief Sought: Pratt & Whitney seeks relief to enable it, under its production certificate No. 2, to install parts or kits certificated under 14 CFR parts 23, 25, 27, or 29 as part of its production limitation record.

[FR Doc. 2010–18545 Filed 7–27–10; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF THE TREASURY

Submission for OMB Review; Comment Request

July 23, 2010.

The Department of Treasury will submit the following public information collection requirement to OMB for review and clearance under the Paperwork Reduction Act of 1995, Public Law 104–13 on or after the publication date of this notice. A copy of the submission may be obtained by calling the Treasury Departmental Office Clearance Officer listed.

Comments regarding this information collection should be addressed to the OMB reviewer listed and to the Treasury PRA Clearance Officer, Department of the Treasury, 1750 Pennsylvania Avenue, NW., Suite 11010, Washington, DC 20220.

Dates: Written comments should be received on or before August 27, 2010 to be assured of consideration.

Community Development Financial Institutions (CDFI) Fund

OMB Number: 1559–0027.

Type of Review: Revision of a currently approved information collection.

Title: CDFI Program and NMTC Program Annual Report including CIIS.

Description: The mission is to expand the capacity of financial institutions to provide credit, capital and financial services to underserved populations and communities in the United States. The CDFI Fund's strategic goal is to improve the economic conditions of underserved communities by providing capital and technical assistance to CDFIs, capital to insured depository institutions, and NMTC allocations to Community Development Entities (CDEs), which provide credit, capital, financial services, and development services to these markets. The CDFI Fund certifies entities as CDFIs and/or CDEs.

Estimated Total Burden Hours: 38,073 hours.

CDFI Fund Clearance Officer: Ashanti McCallum, Community Development Financial Institutions Fund, Department of the Treasury, 601 13th Street, NW., Suite 200 South, Washington, DC 20005; (202) 622–9018.

OMB Reviewer: Shagufta Ahmed, Office of Management and Budget, New Executive Office Building, Room 10235, Washington, DC 20503; (202) 395–7873.

Dawn D. Wolfgang,

Treasury PRA Clearance Officer.

[FR Doc. 2010–18517 Filed 7–27–10; 8:45 am]

BILLING CODE 4810–70–P

DEPARTMENT OF THE TREASURY

Submission for OMB Review; Comment Request

July 23, 2010.

The Department of the Treasury will submit the following public information collection requirements to OMB for review and clearance under the Paperwork Reduction Act of 1995, Public Law 104–13 on or after the date of publication of this notice. A copy of the submissions may be obtained by calling the Treasury Bureau Clearance Officer listed. Comments regarding these information collections should be addressed to the OMB reviewer listed and to the Treasury PRA Clearance Officer, Department of the Treasury, 1750 Pennsylvania Avenue, NW., Suite 11010, Washington, DC 20220.

Dates: Written comments should be received on or before August 27, 2010 to be assured of consideration.

Internal Revenue Service (IRS)

OMB Number: 1545–0004.

Type of Review: Extension without change to a currently approved collection.

Title: Determination of Worker Status for Purposes of Federal Employment Taxes and Income Tax Withholding.

Form: SS–8.

Abstract: Form SS–8 is used by employers and workers to furnish information to IRS in order to obtain a determination as to whether a worker is an employee for purposes of Federal employment taxes and income tax withholding. IRS uses this information to make the determination.

Respondents: Private Sector: Businesses or other for-profits.

Estimated Total Burden Hours: 101,464 hours.

OMB Number: 1545–0008.

Type of Review: Extension without change to a currently approved collection.

Title: Wage and Tax Statements W–2/W–3 series.

Forms: W–2, W–2C, W–2AS, W–2GU, W–2VI, W–3, W–3C, W–3CPR, W–3PR, W–3SS.

Abstract: Section 6051 of the Internal Revenue Code requires employers to furnish income and withholding statements to employees and to the IRS. Employers report income and withholding information on Form W–2. Forms W–2AS, W–2GU, and W–2VI are variations of the W–2 for use in U.S. possessions. The W–3 series forms transmit W–2 series forms to SSA for processing. The W–2c and W–3c series are used to correct previously filed forms.

Respondents: Private Sector: Businesses or other for-profits.

Estimated Total Burden Hours: 1 hour.

OMB Number: 1545–0047.

Type of Review: Extension without change to a currently approved collection.

Title: Return of Organization Exempt From Income Tax Under Section 501(c), 527, or 4947(a)(1) of the Internal Revenue Code (except black lung benefit trust or private foundation).

Forms: 990 and 990–EZ and related schedules A–M and R.

Abstract: Form 990 is needed to determine that IRC section 501(a) tax-exempt organizations fulfill the operating conditions within the limitations of their tax exemption.

Respondents: Private Sector: Not-for-profits institutions.

Estimated Total Burden Hours: 4,126,068 hours.

OMB Number: 1545–0092.

Type of Review: Extension without change to a currently approved collection.

Title: U.S. Income Tax Return for Estates and Trusts.

Form: 1041 and related Schedules D, I, J, and K–1.

Abstract: IRC section 6012 requires that an annual income tax return be filed for estates and trusts. Data is used to determine that the estates, trusts, and beneficiaries filed the proper returns and paid the correct tax. IRC section 59 requires the fiduciary to recompute the distributable net income on a minimum tax basis.

Respondents: Private Sector: Businesses or other for-profits.

Estimated Total Burden Hours: 27,478,960 hours.

OMB Number: 1545–0134.

Type of Review: Extension without change of a currently approved collection.

Title: Application to Adopt, Change, or Retain a Tax Year.

Form: 1128.

Abstract: Form 1128 is needed in order to process taxpayers' request to change their tax year. All information requested is used to determine whether the application should be approved. Respondents are taxable and nontaxable entities including individuals, partnerships, corporations, estates, tax-exempt organizations and cooperatives.

Respondents: Private Sector: Businesses or other for-profits.

Estimated Total Burden Hours: 232,066 hours.

OMB Number: 1545–0367.

Type of Review: Extension without change of a currently approved collection.

Title: Transmittal of Information Returns Reported Magnetically.

Form: 4804.

Abstract: 26 U.S.C. 6041 and 6042 require all persons engaged in a trade or business and making payments of taxable income to file reports of this income with the IRS. In certain cases, this information must be filed on magnetic media. Form 4804 is used to provide signature and balancing totals for magnetic media filers of information returns.

Respondents: Private Sector: Businesses or other for-profits.

Estimated Total Burden Hours: 20,902 hours.

OMB Number: 1545–0582.

Type of Review: Extension without change of a currently approved collection.

Title: Form 1139; Corporation Application for Tentative Refund.

Form: 1139.

Abstract: Form 1139 is filed by corporations that expect to have a net operating loss, net capital loss, or unused general business credits carried back to a prior tax year. IRS uses Form 1139 to determine if the amount of the loss or unused credits is proper.

Respondents: Private Sector: Businesses or other for-profits.

Estimated Total Burden Hours: 165,938 hours.

OMB Number: 1545–0720.

Type of Review: Revision of a currently approved collection.

Title: Form 8038, Information Return for Tax-Exempt Private Activity Bond Issues, Form 8038–G, Information Return for Tax-Exempt Governmental Obligation, and Form 8038–GC, Information Return for Small Tax-Exempt Governmental Bond Issues, Leases, and Installment Sales.

Form: 8038, 8038–G, and 8038–GC.

Abstract: Issuers of state or local bonds must comply with certain information reporting requirements contained in Internal Revenue Code section 149 to qualify for tax exemption. The information must be reported by the issuers about bonds issued by them during each preceding calendar quarter. Forms 8038, 8038–G, and 8038–GC are used to provide the IRS with the information required by Code section 149 and to monitor the requirements of Code sections 141 through 150.

Respondents: State, Local, and Tribal Governments; Private Sector: Businesses or other for-profits.

Estimated Total Burden Hours: 845,394 hours.

OMB Number: 1545–0732.

Type of Review: Extension without change of a currently approved collection.

Title: LR–236–81 Final (TD 8251) Credit for Increasing Research Activity.

Abstract: This regulation provides rules for the credit for increasing research activities. Internal Revenue Code section 41(f) provides that commonly controlled groups of taxpayers shall compute the credit as if they are single taxpayer. The credit allowed to a member of the group is a portion of the group's credit. Section 1.41–8(d) of the regulation permits a corporation that is a member of more than one group to designate which controlled group they will be aggr egated with for the purposes of Code section 41(f).

Respondents: Private Sector: Businesses or other for-profits.

Estimated Total Burden Hours: 63 hours.

OMB Number: 1545–0763.

Type of Review: Extension without change of a currently approved collection.

Title: LR–200–76 (Final) Qualified Conservation Contributions.

Abstract: The information is necessary to comply with various substantive requirements of section 170(h), which describes situations in which a taxpayer is entitled to an income tax deduction for a charitable contribution for conservation purposes of a partial interest in real property.

Respondents: Private Sector: Businesses or other for-profits.

Estimated Total Burden Hours: 1,250 hours.

OMB Number: 1545–0908.

Type of Review: Extension without change of a currently approved collection.

Title: Form 8282, Donee Information Return (Sale, Exchange or Other Disposition of Donated Property); Form 8283, Noncash Charitable Contributions.

Forms: 8282 and 8283.

Abstract: Internal Revenue Code section 170(a)(1) and regulation section 1.170A–13(c) require donors of property valued over $5,000 to file certain information with their tax return in order to receive the charitable contribution deduction. Form 8283 is used to report the required information. Code section 6050L requires donee organizations to file an information return with the IRS if they dispose of the property received within two years. Form 8282 is used for this purpose.

Respondents: Individuals or Households.

Estimated Total Burden Hours: 7,805,692 hours.

OMB Number: 1545–0990.

Type of Review: Extension without change of a currently approved collection.

Title: Form 8610, Annual Low-Income Housing Credit Agencies Report, and Schedule A (Form 8610), Carryover Allocation of Low-Income Housing Credit.

Form: 8610 and Schedule A (8610).

Abstract: State housing credit agencies (Agencies) are required by Code section 42(l)(3) to report annually the amount of low-income housing credits that they allocated to qualified buildings during the year. Agencies report the amount allocated to the building owners and to the IRS in Part I of Form 8609. Carryover allocations are reported to the Agencies in carryover allocation documents. The Agencies report the carryover allocations to the IRS on Schedule A (Form 8610). Form 8610 is a transmittal and reconciliation document for Forms 8609, Schedule A (Form 8610), binding agreements, and election statements.

Respondents: State, Local and Tribal Governments.

Estimated Total Burden Hours: 6,529 hours.

OMB Number: 1545–1036.

Type of Review: Extension without change of a currently approved collection.

Title: Election to Have a Tax Year Other Than a Required Tax Year.

Form: 8716.

Abstract: Form 8716 is filed by partnerships, S Corporations, and personal service corporations, under section 444(a), to elect to retain or to adopt a tax year that is not a required tax year. The form provides the IRS with information to determine that the section 444(a) election is properly made and identifies the tax year to be retained, changed, or adopted.

Respondents: Private Sector: Businesses or other for-profits.

Estimated Total Burden Hours: 204,400 hours.

OMB Number: 1545–1117.

Type of Review: Extension without change of a currently approved collection.

Title: Notice 89–61, Imported Substances; Rules for Filing a Petition.

Abstract: Section 4671 of the Internal Revenue Code imposes a tax on the sale or use of certain imported taxable substances by the importer. Code section 4672 provides an initial list of taxable substances and provides that importers and exporters may petition the Secretary of the Treasury to modify the list. Notice 89–61 sets forth the procedures to be followed in petitioning the Secretary.

Respondents: Private Sector: Businesses or other for-profits.

Estimated Total Burden Hours: 100 hours.

OMB Number: 1545–1212.

Type of Review: Extension without change of a currently approved collection.

Title: U.S. Estate Tax Return for Qualified Domestic Trusts.

Form: 706–QDT.

Abstract: Form 706–QDT is used by the trustee or the designated filer to compute and report the Federal estate tax imposed on qualified domestic trusts by C section 2056A. IRS uses the

information to enforce this tax and to verify that the tax has been properly computed.

Respondents: Individuals or Households.

Estimated Total Burden Hours: 357 hours.

OMB Number: 1545–1226.

Type of Review: Extension without change of a currently approved collection.

Title: FI–59–89 (Final) Proceeds of Bonds used for Reimbursement.

Abstract: This regulation clarifies when the allocation of bond proceeds to reimburse expenditures previously made by an issuer of the bond is treated as an expenditure of the bond proceeds. The issuer must express a reasonable official intent, on or prior to the date of payment, to reimburse the expenditure in order to assure that the reimbursement is not a device to evade requirements imposed by the Internal Revenue Code with respect to tax exempt bonds.

Respondents: State, Local, and Tribal Governments.

Estimated Total Burden Hours: 6,000 hours.

OMB Number: 1545–1296.

Type of Review: Extension without change of a currently approved collection.

Title: PS–27–91 (Final) Procedural Rules for Excise Taxes Currently Reportable on Form 720, PS–8–95 (Final) Deposits of Excise Taxes.

Abstract: Internal Revenue Code section 6302(c) authorizes the use of Government depositaries for the receipt of taxes imposed under the internal revenue laws. These regulations provide reporting and recordkeeping requirements related to return, payments, and deposits of tax for excise taxes currently reportable on Form 720.

Respondents: Private Sector: Businesses or other for-profits.

Estimated Total Burden Hours: 242,350 hours.

OMB Number: 1545–1461.

Type of Review: Extension without change of a currently approved collection.

Title: INTL–24–94 (Final) Taxpayer Identifying Numbers (TINs).

Abstract: This regulation relates to requirements for furnishing a taxpayer identifying number on returns, statements, or other documents. Procedures are provided for requesting a taxpayer identifying number for certain alien individuals for whom a social security number is not available. The regulation also requires foreign persons to furnish a taxpayer identifying number on their tax returns.

Respondents: Individuals or Households.

Estimated Total Burden Hours: 1 hour.

OMB Number: 1545–1668.

Type of Review: Extension without change of a currently approved collection.

Title: Return of U.S. Persons With Respect to Certain Foreign Partnerships.

Form: 8865.

Abstract: The Taxpayer Relief Act of 1997 significantly modified the information reporting requirements with respect to foreign partnerships. The Act made the following three changes: (1) Expanded section 6038B to require U.S. persons transferring property to foreign partnerships in certain transactions to report those transfers; (2) expanded section 6038 to require certain U.S. Partners of controlled foreign partnerships to report information about the partnerships; and (3) modified the reporting required under section 6046A with respect to acquisitions and dispositions of foreign partnership interests.

Respondents: Private sector: Businesses or other for-profits.

Estimated Total Burden Hours: 296,124 hours.

OMB Number: 1545–1703.

Type of Review: Extension without change of a currently approved collection.

Title: Return Post Card for the Community Based Outlet Participants.

Form: 12815.

Abstract: This post card is used by the Community Based Outlet Program (CBOP) participants (*i.e.* grocery stores/pharmacies, copy centers, corporations, credit unions, city/county governments) to order products. The post card will be returned to the Western Area Distribution Center for processing.

Respondents: Private Sector: Businesses or other for-profits.

Estimated Total Burden Hours: 834 hours.

OMB Number: 1545–1708.

Type of Review: Extension without change of a currently approved collection.

Title: Publication 1345, Handbook for Authorized IRS e-file Providers.

Abstract: This publication provides important information for Authorized IRS e-file Providers of Individual Income Tax Returns, including information regarding return submission, record keeping requirements, payment options, and refunds.

Respondents: Private Sector: Businesses or other for-profits.

Estimated Total Burden Hours: 6,023,762 hours.

OMB Number: 1545–1730.

Type of Review: Extension without change of a currently approved collection.

Title: REG–114998–99 (TD 8941—Final) Obligations of States and Political Subdivisions.

Abstract: Section 142(f)(4) of the Internal Revenue Code of 1986 permits a person engaged in the local furnishing of electric energy or gas that uses facilities financed with exempt facility bonds under section 142(a)(8) and that expands its service area in a manner inconsistent with the requirements of sections 142(a)(8) and 142(f) to make an election to ensure that those bonds will continue to be treated as tax-exempt bonds. The final regulations (1.142(f)–1) set forth the required time and manner of making this statutory election.

Respondents: Private Sector: Businesses or other for-profits.

Estimated Total Burden Hours: 15 hours.

OMB Number: 1545–1733.

Type of Review: Extension without change of a currently approved collection.

Title: Carrier Summary Report.

Form: 720–CS.

Abstract: Representatives of the motor fuel industry, state governments, and the Federal government are working to ensure compliance with excise taxes on motor fuels. This joint effort has resulted in a system to track the movement of all products to and from terminals. Form 720–CS is an information return that will be used by carriers to report their monthly deliveries and receipts of products to and from terminals.

Respondents: Private Sector: Businesses or other for-profits.

Estimated Total Burden Hours: 183,027 hours.

OMB Number: 1545–1734.

Type of Review: Extension without change of a currently approved collection.

Title: Terminal Operator Report.

Form: 720–TO.

Abstract: Representatives of the motor fuel industry, state governments, and the Federal government are working to ensure compliance with excise taxes on motor fuels. This joint effort has resulted in a system to track the movement of all products to and from terminals. Form 720–TO is an information return that will be used by terminal operators to report their monthly receipts and disbursements of products.

Respondents: Private Sector: Businesses or other for-profits.

Estimated Total Burden Hours: 2,347,020 hours.

OMB Number: 1545–1862.

Type of Review: Extension without change of a currently approved collection.

Title: Information Regarding Request for Refund of Social Security Tax Erroneously Withheld on Wages Received by a Nonresident Alien on an F, J, or M Type Visa.

Form: 8316.

Abstract: Certain foreign students and other nonresident visitors are exempt from FICA tax for services performed as specified in the Immigration and Naturalization Act. Applicants for refund of this FICA tax withheld by their employer must complete Form 8316 to verify that they are entitled to a refund of the FICA, that the employer has not paid back any part of the tax withheld and that the taxpayer has attempted to secure a refund from his/her employer.

Respondents: Individuals or Households.

Estimated Total Burden Hours: 5,500 hours.

OMB Number: 1545–1872.

Type of Review: Extension without change of a currently approved collection.

Title: Request for Transcript of Tax Return.

Form: 4506–T.

Abstract: Internal Revenue Code section 7513 allows taxpayers to request a copy of a tax return or related products. Form 4506–T is used to request all products except copies of returns. The information provided will be used to search the taxpayers account and provide the requested information and to ensure that the requestor is the taxpayer or someone authorized by the taxpayer to obtain the documents requested.

Respondents: Individuals or Households.

Estimated Total Burden Hours: 555,600 hours.

OMB Number: 1545–2042.

Type of Review: Extension without change of a currently approved collection.

Title: IRS e-file Signature Authorization for Form 1065.

Form: 8879–PE.

Abstract: Form 8879–PE, IRS e-file Signature Authorization for Form 1065, was developed for modernized e-file for partnerships under Internal Revenue Code sections 6109 and 6103.

Respondents: Private sector: Businesses or other for-profits.

Estimated Total Burden Hours: 2,025 hours.

OMB Number: 1545–2044.

Type of Review: Extension without change of a currently approved collection.

Title: RP–104401–05 (Rev Proc 2006–54), Procedures for Requesting Competent Authority Assistance Under Tax Treaties.

Abstract: Taxpayers who believe that the actions of the United States, a treaty country, or both, result or will result in taxation that is contrary to the provisions of an applicable tax treaty are required to submit the requested information in order to receive assistance from the IRS official acting as the U.S. competent authority. The information is used to assist the taxpayer in reaching a mutual agreement with the IRS and the appropriate foreign competent authority.

Respondents: Individuals or Households.

Estimated Total Burden Hours: 9,000 hours.

OMB Number: 1545–2050.

Type of Review: Extension without change of a currently approved collection.

Title: Notice 2006–109—Interim Guidance Regarding Supporting Organizations and Donor Advised Funds.

Abstract: Notice 2006–109 provides interim guidance regarding application of new or revised requirements under sections 1231 and 1241–1244 of the Pension Protection Act of 2006. It also provides interim relief from application of new excise taxes on private foundation grants to supporting organizations and on sponsoring organizations of donor advised funds.

Respondents: Private Sector: Not-for-profit institutions.

Estimated Total Burden Hours: 612,294 hours.

Bureau Clearance Officer: R. Joseph Durbala, Internal Revenue Service, 1111 Constitution Avenue, NW., Room 6129, Washington, DC 20224; (202) 622–3634.

OMB Reviewer: Shagufta Ahmed, Office of Management and Budget, New Executive Office Building, Room 10235, Washington, DC 20503; (202) 395–7873.

Dawn D. Wolfgang,

Treasury PRA Clearance Officer.

[FR Doc. 2010–18522 Filed 7–27–10; 8:45 am]

BILLING CODE 4830–01–P

DEPARTMENT OF THE TREASURY

Office of Foreign Assets Control

Additional Designations, Foreign Narcotics Kingpin Designation Act

AGENCY: Office of Foreign Assets Control, Treasury.

ACTION: Notice.

SUMMARY: The Treasury Department's Office of Foreign Assets Control ("OFAC") is publishing the names of two entities whose property and interests in property have been blocked pursuant to the Foreign Narcotics Kingpin Designation Act ("Kingpin Act") (21 U.S.C. 1901–1908, 8 U.S.C. 1182).

DATES: The designation by the Director of OFAC of the two entities identified in this notice pursuant to section 805(b) of the Kingpin Act is effective on July 22, 2010.

FOR FURTHER INFORMATION CONTACT: Assistant Director, Compliance Outreach & Implementation, Office of Foreign Assets Control, Department of the Treasury, Washington, DC 20220, *tel.:* 202/622–2490.

SUPPLEMENTARY INFORMATION:

Electronic and Facsimile Availability

This document and additional information concerning OFAC are available on OFAC's Web site *(http://www.treas.gov/ofac)* or via facsimile through a 24-hour fax-on-demand service, *tel.:* (202) 622–0077.

Background

The Kingpin Act became law on December 3, 1999. The Kingpin Act establishes a program targeting the activities of significant foreign narcotics traffickers and their organizations on a worldwide basis. It provides a statutory framework for the President to impose sanctions against significant foreign narcotics traffickers and their organizations on a worldwide basis, with the objective of denying their businesses and agents access to the U.S. financial system and the benefits of trade and transactions involving U.S. companies and individuals.

The Kingpin Act blocks all property and interests in property, subject to U.S. jurisdiction, owned or controlled by significant foreign narcotics traffickers as identified by the President. In addition, the Secretary of the Treasury consults with the Attorney General, the Director of the Central Intelligence Agency, the Director of the Federal Bureau of Investigation, the Administrator of the Drug Enforcement Administration, the Secretary of Defense, the Secretary of State, and the

Secretary of Homeland Security when designating and blocking the property and interests in property, subject to U.S. jurisdiction, of persons who are found to be: (1) Materially assisting in, or providing financial or technological support for or to, or providing goods or services in support of, the international narcotics trafficking activities of a person designated pursuant to the Kingpin Act; (2) owned, controlled, or directed by, or acting for or on behalf of, a person designated pursuant to the Kingpin Act; or (3) playing a significant role in international narcotics trafficking.

On July 22, 2010, the Director of OFAC designated two entities whose property and interests in property are blocked pursuant to section 805(b) of the Foreign Narcotics Kingpin Designation Act.

The list of designees is as follows:

Entities:

1. ARTE Y DISENO DE CULIACAN S.A. DE C.V., Calle Rio Santa Maria, No. 1252, Colonia Los Pinos, Culiacan, Sinaloa, Mexico; R.F.C. ADC–000927–SY9 (Mexico); (ENTITY) [SDNTK]

2. AUTOTRANSPORTES JYM S.A. DE C.V., Calle Primera S/N 820, Poste No. 1504, Colonia Piggy Back, Poblado Campo El Diez, Culiacan, Sinaloa, Mexico; R.F.C. AJY–960612–HPO (Mexico); (ENTITY) [SDNTK]

Dated: July 22, 2010.

Adam J. Szubin,

Director, Office of Foreign Assets Control.

[FR Doc. 2010–18502 Filed 7–27–10; 8:45 am]

BILLING CODE 4810–AL–P

DEPARTMENT OF THE TREASURY

Office of Foreign Assets Control

Designation of Three Individuals Pursuant to Executive Order 13224

AGENCY: Office of Foreign Assets Control, Treasury.

ACTION: Notice.

SUMMARY: The Treasury Department's Office of Foreign Assets Control ("OFAC") is publishing the names of three newly-designated individuals whose property and interests in property are blocked pursuant to Executive Order 13224 of September 23, 2001, "Blocking Property and Prohibiting Transactions With Persons Who Commit, Threaten To Commit, or Support Terrorism."

DATES: The designation by the Director of OFAC of the individual identified in this notice, pursuant to Executive Order 13224, is effective on July 22, 2010.

FOR FURTHER INFORMATION CONTACT: Assistant Director, Compliance Outreach & Implementation Office of Foreign Assets Control, Department of the Treasury, Washington, DC 20220, tel.: (202) 622–2490.

SUPPLEMENTARY INFORMATION:

Electronic and Facsimile Availability

This document and additional information concerning OFAC are available from OFAC's Web site (*http://www.treas.gov/ofac*) or via facsimile through a 24-hour fax-on-demand service, tel.: (202) 622–0077.

Background

On September 23, 2001, the President issued Executive Order 13224 (the "Order") pursuant to the International Emergency Economic Powers Act, 50 U.S.C. 1701–1706, and the United Nations Participation Act of 1945, 22 U.S.C. 287c. In the Order, the President declared a national emergency to address grave acts of terrorism and threats of terrorism committed by foreign terrorists, including the September 11, 2001, terrorist attacks in New York, Pennsylvania, and at the Pentagon. The Order imposes economic sanctions on persons who have committed, pose a significant risk of committing, or support acts of terrorism. The President identified in the Annex to the Order, as amended by Executive Order 13268 of July 2, 2002, 13 individuals and 16 entities as subject to the economic sanctions. The Order was further amended by Executive Order 13284 of January 23, 2003, to reflect the creation of the Department of Homeland Security.

Section 1 of the Order blocks, with certain exceptions, all property and interests in property that are in or hereafter come within the United States or the possession or control of United States persons, of: (1) Foreign persons listed in the Annex to the Order; (2) foreign persons determined by the Secretary of State, in consultation with the Secretary of the Treasury, the Secretary of the Department of Homeland Security and the Attorney General, to have committed, or to pose a significant risk of committing, acts of terrorism that threaten the security of U.S. nationals or the national security, foreign policy, or economy of the United States; (3) persons determined by the Director of OFAC, in consultation with the Departments of State, Homeland Security and Justice, to be owned or controlled by, or to act for or on behalf of those persons listed in the Annex to the Order or those persons determined to be subject to subsection 1(b), 1(c), or 1(d)(i) of the Order; and (4) except as provided in section 5 of the Order and after such consultation, if any, with foreign authorities as the Secretary of State, in consultation with the Secretary of the Treasury, the Secretary of the Department of Homeland Security and the Attorney General, deems appropriate in the exercise of his discretion, persons determined by the Director of OFAC, in consultation with the Departments of State, Homeland Security and Justice, to assist in, sponsor, or provide financial, material, or technological support for, or financial or other services to or in support of, such acts of terrorism or those persons listed in the Annex to the Order or determined to be subject to the Order or to be otherwise associated with those persons listed in the Annex to the Order or those persons determined to be subject to subsection 1(b), 1(c), or 1(d)(i) of the Order.

On July 22, 2010 the Director of OFAC, in consultation with the Departments of State, Homeland Security, Justice and other relevant agencies, designated, pursuant to one or more of the criteria set forth in subsections 1(b), 1(c) or 1(d) of the Order, three individual whose property and interests in property are blocked pursuant to Executive Order 13224.

The designees are as follows:

1. ABDULLAH, Amir (a.k.a. ABDULLAH SAHIB, Amir); DOB 1972; POB Paktika Province, Afghanistan (individual) [SDGT]

2. HAQQANI, Nasiruddin (a.k.a. GHAIR, Dr. Alim; a.k.a. HAQQANI, Dr. Naseer; a.k.a. HAQQANI, Naseer; a.k.a. HAQQANI, Nashir; a.k.a. HAQQANI, Nassir; a.k.a. "NASERUDDIN"); DOB 1972; POB Afghanistan (individual) [SDGT]

3. ISHAKZAI, Gul Agha (a.k.a. MULLAH GUL AGHA; a.k.a. MULLAH GUL AGHA AKHUND; a.k.a. "HAJI HIDAYATULLAH"; a.k.a. "HAYADATULLAH"; a.k.a. "HIDAYATULLAH"); DOB 1972; POB Band-e-Timor, Kandahar, Afghanistan (individual) [SDGT]

Dated: July 22, 2010.

Adam J. Szubin,

Director, Office of Foreign Assets Control.

[FR Doc. 2010–18421 Filed 7–27–10; 8:45 am]

BILLING CODE 4810–AL–P

Federal Register

Wednesday,
July 28, 2010

Part II

Department of Health and Human Services

Centers for Medicare & Medicaid Services

42 CFR Parts 412, 413, 422 et al.
Medicare and Medicaid Programs; Electronic Health Record Incentive Program; Final Rule

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Parts 412, 413, 422, and 495

[CMS–0033–F]

RIN 0938–AP78

Medicare and Medicaid Programs; Electronic Health Record Incentive Program

AGENCY: Centers for Medicare & Medicaid Services (CMS), HHS.

ACTION: Final rule.

SUMMARY: This final rule implements the provisions of the American Recovery and Reinvestment Act of 2009 (ARRA) (Pub. L. 111–5) that provide incentive payments to eligible professionals (EPs), eligible hospitals and critical access hospitals (CAHs) participating in Medicare and Medicaid programs that adopt and successfully demonstrate meaningful use of certified electronic health record (EHR) technology. This final rule specifies—the initial criteria EPs, eligible hospitals, and CAHs must meet in order to qualify for an incentive payment; calculation of the incentive payment amounts; payment adjustments under Medicare for covered professional services and inpatient hospital services provided by EPs, eligible hospitals and CAHs failing to demonstrate meaningful use of certified EHR technology; and other program participation requirements. Also, the Office of the National Coordinator for Health Information Technology (ONC) will be issuing a closely related final rule that specifies the Secretary's adoption of an initial set of standards, implementation, specifications, and certification criteria for electronic health records. ONC has also issued a separate final rule on the establishment of certification programs for health information technology.

DATES: *Effective Date:* These regulations are effective on September 27, 2010.

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.

Bob Kuhl or Susan Burris, (410) 786–5594, Medicare CAH payment and charity care issues.

Frank Szeflinski, (303) 844–7119, Medicare Advantage issues.

SUPPLEMENTARY INFORMATION:

Acronyms

ARRA American Recovery and Reinvestment Act of 2009
AAC Average Allowable Cost (of certified EHR technology)
AIU Adopt, Implement, Upgrade (certified EHR technology)
CAH Critical Access Hospital
CAHPS Consumer Assessment of Healthcare Providers and Systems
CCN CMS Certification Number
CFR Code of Federal Regulations
CHIP Children's Health Insurance Program
CHIPRA Children's Health Insurance Program Reauthorization Act of 2009
CMS Centers for Medicare & Medicaid Services
CPOE Computerized Physician Order Entry
CY Calendar Year
EHR Electronic Health Record
EP Eligible Professional
EPO Exclusive Provider Organization
FACA Federal Advisory Committee Act
FFP Federal Financial Participation
FFY Federal Fiscal Year
FFS Fee-For-Service
FQHC Federally Qualified Health Center
FTE Full-Time Equivalent
FY Fiscal Year
HEDIS Healthcare Effectiveness Data and Information Set
HHS Department of Health and Human Services
HIE Health Information Exchange
HIT Health Information Technology
HIPAA Health Insurance Portability and Accountability Act of 1996
HITECH Health Information Technology for Economic and Clinical Health Act
HMO Health Maintenance Organization
HOS Health Outcomes Survey
HPSA Health Professional Shortage Area
HRSA Health Resource and Services Administration
IAPD Implementation Advance Planning Document
ICR Information Collection Requirement
IHS Indian Health Service
IPA Independent Practice Association
IT Information Technology
MA Medicare Advantage
MAC Medicare Administrative Contractor
MAO Medicare Advantage Organization
MCO Managed Care Organization
MITA Medicaid Information Technology Architecture
MMIS Medicaid Management Information Systems
MSA Medical Savings Account
NAAC Net Average Allowable Cost (of certified EHR technology)
NCQA National Committee for Quality Assurance
NCVHS National Committee on Vital and Health Statistics
NPI National Provider Identifier
NPRM Notice of Proposed Rulemaking
ONC Office of the National Coordinator for Health Information Technology
PAHP Prepaid Ambulatory Health Plan
PAPD Planning Advance Planning Document
PFFS Private Fee-For-Service
PHO Physician Hospital Organization
PHS Public Health Service
PHSA Public Health Service Act
PIHP Prepaid Inpatient Health Plan
POS Place of Service
PPO Preferred Provider Organization
PQRI Physician Quality Reporting Initiative
PSO Provider Sponsored Organization
RHC Rural Health Clinic
RHQDAPU Reporting Hospital Quality Data for Annual Payment Update
RPPO Regional Preferred Provider Organization
SMHP State Medicaid Health Information Technology Plan
TIN Tax Identification Number

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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. 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), eligible hospitals, and critical access hospitals (CAHs), and Medicare Advantage Organizations to promote the adoption and meaningful use of interoperable health information technology (HIT) and qualified electronic health records (EHRs). 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." These incentive payments are part of a broader effort under the HITECH Act to accelerate the adoption of HIT and utilization of qualified EHRs.

On January 13, 2010 we published a proposed rule (75 FR 1844), entitled "Medicare and Medicaid Programs; Electronic Health Record Incentive Program" to implement the provisions of ARRA that provide incentive payments to EPs, eligible hospitals, and CAHs participating in Medicare and Medicaid programs that adopt and successfully demonstrate meaningful use of "certified EHR technology," and incentive payments to certain Medicare Advantage Organizations for their affiliated EPs and eligible hospitals that meaningfully use certified EHR technology. Through this final rule, we are developing the incentive programs which are outlined in Division B, Title IV of the HITECH Act. This final rule sets forth the 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. In the interim final rule published on January 13, 2010 (75 FR 2014) entitled "Health Information Technology: Initial Set of Standards, Implementation Specifications, and Certification Criteria for Electronic Health Record Technology," ONC defined the term "certified EHR technology," identified the initial set of standards and implementation specifications that such EHR technology would need to support the achievement of the proposed meaningful use Stage 1, as well as the certification criteria that will be used to certify EHR technology. ONC is also issuing a final rule on the standards, implementation specifications, and certification criteria elsewhere in this issue of the **Federal Register**.

In a related proposed rule published on March 10, 2010, (75 FR 11328) entitled "Proposed Establishment of Certification Programs for Health Information Technology" ONC proposed the establishment of two certification programs for purpose of testing and certifying health information technology. In the June 24, 2010 **Federal Register** (75 FR 36157), ONC published a final rule to establish a temporary certification program whereby the National Coordinator would authorize organizations to test and certify complete EHRs and EHR Modules, and plans to issue a separate final rule to establish a permanent certification program to replace the temporary certification program. Specifically, this final rule will ensure that the definition of meaningful use of certified EHR technology does not require EPs, eligible hospitals, and CAHs to perform functions 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 final rule to also review the ONC interim final rule on standards and implementation specifications for certified EHR technology and the related final rule as well as the final rule on the establishment of a temporary certification program. Readers may also 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 demonstration of meaningful use of certified EHR technology by EPs participating in the original Medicare program (hereinafter referred to as the 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 do not demonstrate that they are meaningful users of certified EHR technology will receive an adjustment to their fee schedule for their professional services of 99 percent for 2015 (or, in the case of an eligible professional who was subject to the application of the payment adjustment under section 1848(a)(5) of the Act, 98 percent for 2014), 98 percent for 2016, and 97 percent for 2017 and each subsequent year. Section 4101(c) of the HITECH Act adds a new subsection (l) to section 1853 of the Act to provide incentive payments to certain Medicare Advantage (MA) organizations for their affiliated EPs who meaningfully use certified EHR technology and meet certain other requirements, and requires a downward adjustment to Medicare payments to certain MA organizations for professional services provided by any of their affiliated EPs who are not meaningful users of certified EHR technology, beginning in 2015. Section 1853(l) of the Act also requires us to establish a process that ensures that there are no duplicate payments made to MA organizations under section 1853(l) of the Act and to their affiliated EPs under the FFS EHR incentive program established under section 1848(o)(1)(A) of the Act.

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 incentives payments for demonstration of meaningful use of certified EHR technology by subsection (d) hospitals, as defined under section 1886(d)(1)(B) of the Act, participating in the Medicare FFS program beginning in Federal fiscal year (FFY) 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 for their inpatient hospital services. Section 4102(a)(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 costs for the purchase of certified EHR technology beginning in FY 2011. In addition, section 4102(b)(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 qualifying MA organizations for certain affiliated hospitals that meaningfully

use certified EHR technology to make a downward adjustment to payments to certain 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 1853(m) of the Act also requires us to establish a process that ensures that there are no duplicate payments made to MA organizations under section 1853(m) of the Act and to their affiliated hospitals under the FFS EHR incentive program established under section 1886(n) of the Act.

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, operate (including support services and training for staff) and meaningfully use 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 Rule and Analysis of and Responses to Public Comments

We proposed to add a new part 495 to title 42 of the Code of Federal Regulations to implement the provisions of Title IV of Division B of ARRA providing for incentive payments to EPs, eligible hospitals, CAHs and certain Medicare Advantage organizations for the adoption and demonstration of meaningful use of certified EHR technology under the Medicare program or the Medicaid program.

The HITECH Act creates incentives under the Medicare Fee-for-Service (FFS), Medicare Advantage (MA), and Medicaid programs for EPs, eligible hospitals and CAHs to adopt and demonstrate meaningful use of certified EHR technology, and payment adjustments under the Medicare FFS and MA programs for EPs, eligible hospitals, and CAHs who fail to adopt and demonstrate meaningful use of certified EHR technology. 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 demonstration of meaningful use of certified EHR technology. Eligible hospitals and CAHs may participate in both the Medicare program and the Medicaid program, assuming they meet each program's eligibility requirements, which vary across the two 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." For these reasons, we seek to create as much commonality between the three programs as possible and have structured this final rule, as we did the proposed rule, based on the 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, MA, and Medicaid Programs

Title IV, Division B of ARRA establishes incentive payments under the Medicare and Medicaid programs for certain professionals and hospitals that meaningfully use certified EHR technology, and for certain MA organizations whose affiliated EPs and hospitals meaningfully use certified EHR technology. We refer to the incentive payments made under the original Medicare program to EPs, eligible hospitals, and CAHs as the Medicare FFS EHR incentive program, the incentive payments made to qualifying MA organizations as the MA EHR incentive program, and the incentive payments made under Medicaid to eligible professionals and eligible hospitals as the Medicaid EHR incentive program. When referring to the Medicare EHR incentive program, we are generally referring to both the Medicare FFS EHR and the MA EHR incentive programs.

1. Definitions

Sections 4101, 4102, and 4201 of the HITECH Act use many identical or similar terms. In this section of the preamble, we discuss terms for which we are finalizing uniform definitions for the Medicare FFS, MA, and Medicaid EHR incentive programs. These definitions are set forth 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.

The incentive payments are available to EPs which are 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 which are 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.

a. Certified Electronic Health Record (EHR) Technology

Under all three EHR incentive programs, EPs, eligible hospitals, and CAHs 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, and for eligible hospitals and CAHs in section 1886(n)(3)(A)(i) of the Act. In the MA EHR incentive program this requirement for EPs is found in section 1853(l)(1) of the Act, and for eligible hospitals and CAHs, in section 1853(m)(1) of the 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. Certified EHR technology is a critical component of the EHR incentive programs, and the Secretary has charged ONC, under the authority given to her in the HITECH Act, with developing the criteria and mechanisms for certification of EHR technology. Therefore, we finalize our proposal to use the definition of certified EHR technology adopted by ONC. ONC issued an interim final rule with comment for the standards and certification criteria for certified EHR technology at the same time our proposed rule was issued. After reviewing the comments they received and to address changes made in this final rule, ONC will be issuing a final rule in conjunction with this final rule. When we refer to the ONC final rule, we are referring to this final rule titled

"Health Information Technology: Initial Set of Standards, Implementation Specifications, and Certification Criteria for Electronic Health Record Technology. When we refer to the ONC IFR, we are referring to the interim final rule with comment period published in the **Federal Register** on January 13, 2010.

Comment: Several commenters asked for clarification on the definition of certified EHR technology. Currently, hospitals utilize multiple systems to operate electronically. For example, some electronic operating systems feed EHR data and some systems pull EHR data. Data from the two systems are then extracted and manipulated to create a quality measure calculation. The commenters' inquired as to how these systems can continue to be utilized even though, independently, these systems will not meet all certification standards. Some commenters expressed concern the ONC IFR did not include generation of the data needed to demonstrate meaningful use as a certification requirement and that certified EHR technology requirements should also include compliance with HIPAA standards as well as all relevant state statutes for the state or states where it is installed. Commenters recommended various approaches to defining certified technology especially in the early stages of the program. Some suggestions included, grandfathering existing systems for a period of three years as long as the provider could meet specific meaningful use objectives while requiring all upgrades to existing systems to be certified, allowing all EHR products certified by the Certification Commission for Health Information Technology (CCHIT) at the criteria established for 2008 or later be deemed as meeting Stage 1 certification requirements or alternatively CMS provide a process that can verify compliance of required features at no cost to providers or vendors as is done now with Enterprise Data Interchange (EDI) claims processing. Some commenters also offered other thoughts on potential unintended consequences of defining the EHR certification software process to include certifying agencies that charge for the process. The commenters believed this could result in continued new and revised requirements to justify the certifying entities' existence and increase its revenue.

Response: We have referred those comments to ONC who addresses them in their final rule.

We are adopting the ONC definition of certified EHR technology at 45 CFR 170.102 in this final rule.

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 was defined by ONC in its in its IFR and finalized by ONC in their final rule, and we are finalizing our proposal to use the definition of qualified electronic health record adopted by ONC in their final rule to be published concurrently with this rule.

Comment: We received a few comments on the definition of qualified EHR technology. Commenters expressed concerns regarding perceived gaps in defining an EHR as qualified such as a lack of the requirement for a narrative text for physicians (also known as progress note). Another comment requested further clarification regarding the requirement for a qualified EHR to "capture and query information relevant to health care quality" and "exchange electronic health information with and integrate such information from other sources." For example, some might believe that these requirements apply strictly to information contained within the EHR or closed proprietary hospital systems and not to information that would have to be obtained from outside the four walls of the practice or the extended (but closed) system.

Response: We have referred those comments to ONC who addresses them in their final rule.

We are adopting the ONC definition of Qualified Electronic Health Record at 45 CFR 170.102.

c. Payment Year

As discussed in the proposed rule, under section 1848(o)(1)(A)(i) of the 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 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 in the Medicare and Medicaid EHR incentive programs, we are proposing a common definition for both "payment year" and "year of payment," as "any calendar year beginning with 2011" at § 495.4. In the proposed rule, we explained that this definition, which is consistent with the statutory definition of "payment year" under Medicare FFS, would simplify the EHR incentive programs for EPs. As discussed later in this preamble, EPs will have the opportunity to participate in either the Medicare or Medicaid incentive programs, and once an EP has selected 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 incentive programs, and inform their decisions regarding participation in either program.

Under section 1886(n)(1) of the 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 beginning in 2011. As hospitals are paid based on the 12-month Federal fiscal year, we interpret the reference to a "fiscal year" means the fiscal year beginning on October 1 of the prior calendar 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 in the proposed rule and summarized above for proposing a common definition of "payment year" 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 and CAHs under the Medicare FFS, MA and Medicaid EHR incentive programs, we proposed to define payment year and year of payment at § 495.4, consistent with the statutory definition, as "any fiscal year beginning with 2011."

Comment: A commenter asked CMS to identify the first possible payment year for EPs, and hospitals and CAHs.

Response: The first payment year for EPs is any calendar year (CY) beginning with CY 2011 and for eligible hospitals and CAHs is any fiscal year (FY) beginning with 2011.

Comment: The majority of commenters favored our definition of "payment year" based on the different existing fiscal periods for eligible professionals and hospitals. Additional support was received from some commenters whom explained that they participated in performance-based initiatives, which define a payment year the same as the proposed rule.

Response: After consideration of the public comments received, we are adopting our proposed definition of "payment year" in the Medicare and

Medicaid EHR incentive programs as described above.

Comment: The majority of comments received regarding the definition of a payment year asked whether payment years must be consecutive for an EP or eligible hospital to receive all years of incentive payments.

Response: In the proposed rule, we defined 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." However, section 1848(o)(1)(E) of Act defines the second through fifth payment years for an EP as each successive year immediately following the first payment year for such professional for the Medicare FFS and MA EHR incentive programs. Similarly, section 1886(n)(2)(G)(ii) of the Act defines the second through fourth payment years for an eligible hospital or CAH as requiring the years to be "successive" and "immediately following" the prior year. This requirement, that each payment year "immediately follow" the prior year, means that every year subsequent to the first payment year is a payment year regardless of whether an incentive payment is received by the EP, eligible hospital or CAH. For example, if a Medicare EP receives an incentive in CY 2011, but does not successfully demonstrate meaningful use or otherwise fails to qualify for the incentive in CY 2012, CY 2012 still counts as one of the EP's five payment years and they would only be able to receive an incentive under the Medicare EHR incentive program for three more years as CY 2013 would be there third payment year. In this example, the maximum incentive payment that would apply for this Medicare EP not practicing predominately in a health professional shortage area (HPSA) would be $18,000 in 2011, and $8,000 in 2013 as outlined in section 1848(o)(1)(B) of the Act. The EP would have qualified for a maximum incentive payment of $12,000 in 2012, but did not qualify as a meaningful user for this year. No incentives may be made under the Medicare EHR incentive program after 2016.

The same rule, however, does not apply to the Medicaid EHR incentive program. For that program, payments may generally be non-consecutive. If an EP or eligible hospital does not receive an incentive payment for a given CY or FY then that year would not constitute a payment year. For example, if a Medicaid EP receives incentives in CY 2011 and CY 2012, but fails to qualify for an incentive in CY 2013, they would still be eligible to receive incentives for an additional four payment years. For hospitals, however, starting with FY 2017 payments must be consecutive. This rule is required by section 1903(t)(5)(D) of the Act, which states that after 2016, no Medicaid incentive payment may be made to an eligible hospital unless "the provider has been provided payment * * * for the previous year." As a result, Medicaid eligible hospitals must receive an incentive in FY 2016 to receive an incentive in FY 2017 and later years. Starting in FY 2016, incentive payments must be made every year in order to continue participation in the program. In no case may any Medicaid EP or eligible hospital receive an incentive after 2021. We have revised our regulations at § 495.4 to incorporate these statutory requirements.

Comment: Some commenters requested that CMS clarify the impact on EPs when they change practices in the middle of the incentive payment program; in other words, if an EP leaves a practice in year two of the incentive payment program and goes to another practice, does that EP forfeit the ability to continue collecting incentive payments for years 3 through 5?

Response: A qualifying EP that leaves one practice for another may still be eligible to receive subsequent incentive payments if the EP is a meaningful EHR user in the new practice. The incentive payment is tied to the individual EP, and not to his or her place of practice.

d. First, Second, Third, Fourth, Fifth, and Sixth Payment Year

In accordance with sections 1848(o)(1)(A)(ii), 1886(n)(2)(E), 1814(l)(3)(A), 1903(t)(4)(B), and 1903(t)(5)(A) of the Act, for EPs, eligible hospitals, and CAHs that qualify for EHR incentive payments in a payment year, the amount of the payment will depend in part on whether the EP or hospital previously received an incentive payment and, if so (for the Medicare EHR incentive program) when the EP or hospital received his or her first payment. We proposed to define the first payment year to mean the first CY or Federal fiscal year (FY) for which an EP, eligible hospital, or CAH receives an incentive payment. Likewise, we proposed to define the second, third, fourth, fifth, and sixth payment year, respectively, to mean the second, third, fourth, fifth, and sixth CY or FY, respectively, for which an EP, eligible hospital, or CAH receives an incentive payment.

Comment: As stated above, many commenters requested clarification on non-consecutive payment.

Response: This comment is addressed above.

Comment: A commenter requested CMS to clarify the consequences for a hospital that originally qualified and received incentive payments the first year, but in a subsequent year failed to qualify as a meaningful user of certified EHR technology.

Response: Meaningful use will be assessed on a year-by-year basis as we establish different Stages of meaningful use criteria for different years. If an EP or an eligible hospital including a CAH has failed to demonstrate meaningful use of certified EHR technology for a certain payment year, the EP, eligible hospital, or CAH will not be qualified for incentive payments for that payment year. However, upon successful demonstration as a meaningful EHR user in subsequent years, an EP, eligible hospital or CAH may be eligible to receive an incentive payment. As discussed above, however, for the Medicare program, the failure of the eligible hospital or CAH to demonstrate meaningful use in the subsequent year, will affect the total payments that hospital is eligible to receive, as, pursuant to the statute, the hospital is treated as skipping a payment year. Payment adjustments apply to Medicare providers who are unable to demonstrate meaningful use starting in 2015.

Comment: One commenter asked if CMS could apply the same Medicaid EP's first year incentive eligibility requirements of adopting, implementing or upgrading to certified EHR technology to Medicare physicians instead of demonstration of meaningful use.

Response: The HITECH Act allows Medicaid EPs and eligible hospitals to receive an incentive for the adoption, implementation, or upgrade of certified EHR technology in their first participation year. In subsequent years, these EPs and eligible hospitals must demonstrate that they are meaningful users. There are no parallel provisions under the Medicare EHR incentive program that would authorize us to make payments to Medicare EPs, eligible hospitals, and CAHs for the adoption, implementation or upgrade of certified EHR technology. Rather, in accordance with sections 1848(o)(2), 1886(n)(3)(A), and 1814(l)(3)(A) of the Act, Medicare incentive payments are only made to EPs, eligible hospitals, and CAHs for the demonstration of meaningful use of certified EHR technology.

After consideration of the public comments received, we are finalizing the definitions of First payment year as proposed. For the Medicare EHR incentive programs, we are modifying the definitions of second, third, fourth, fifth payment year to make clear that these years are "each successive year following the first payment year." For the Medicaid EHR incentive program, we included definitions of first, second, third, fourth, fifth and sixth payment year that make clear that these are the years for which payment is received. The regulations can now be found at § 495.4 of our regulations.

e. EHR Reporting Period

In the proposed rule, we proposed 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, we proposed that the EHR reporting period would be any continuous 90-day period within the first payment year and the entire payment year for all subsequent payment years. In our proposed rule, we did not make any proposals regarding the reporting period that will be used for purposes of the payment adjustments that begin in 2015. We intend to address this issue in future rulemaking, 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.

For the first payment year only, we proposed to define the term EHR reporting period at § 495.4 of our regulations to mean any continuous 90-day period within a payment year in which an EP, eligible hospital or CAH 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. Starting with the second payment year and any subsequent payment years for a given EP, eligible hospital or CAH, we proposed to define the term EHR reporting period at § 495.4 to mean the entire payment year. In our discussion of considerations in defining meaningful use later in this section we discuss how this policy may be affected by subsequent revisions to the definition of meaningful use.

For the first payment year, we stated in the proposed rule our belief that giving EPs, eligible hospitals and CAHs flexibility as to the start date of the EHR reporting period is important, as unforeseen circumstances, such as delays in implementation, higher than expected training needs and other unexpected hindrances, may cause an EP, eligible hospital, or CAH to potentially miss a target start date.

Comment: Some commenters supported the 90-day reporting period proposed for the first payment year. One commenter requested that exceptions, per the provider request, be considered individually in cases of compliance for less than the 90 days (for example, 85 days). Commenters preferred the 90-day reporting period overall and many suggested it be used for subsequent years as well. We also received comments questioning why Medicaid providers would need to conform to the 90-day reporting period in order to adopt, implement or upgrade certified EHR technology.

Response: We do believe that for program integrity it is crucial to maintain a consistent reporting period. Basing the incentive payments on meaningful use implies a minimum level of use in order to receive the incentive payment. The timeframe is part of the determination of whether use is meaningful and therefore requires a minimum as well. Given the short time period as compared to the entire year, we do not believe an exception process is needed. However, we agree with commenters that an EHR reporting period for demonstrating adoption, implementation or upgrading certified EHR technology by Medicaid EPs and eligible hospitals is unnecessary and are removing it for the final rule in this instance. Similarly, Medicaid EPs and eligible hospitals who are demonstrating meaningful use for the first time in their second payment year, will have a 90-day reporting period to maintain parity with Medicare providers' first meaningful use payment year. We do not believe that after successfully demonstrating meaningful use, a 90-day period is appropriate for subsequent years. The reasons for using the 90-day period instead of the full year are based on potential delays in implementing certifying EHR technology. Once certified EHR technology is implemented these are no longer applicable.

After consideration of the public comments received and with the clarification described above for adopting, implementing or upgrading, we are finalizing the 90-day reporting period for the first payment year based on meaningful use as proposed for Medicare EPs, eligible hospitals and CAHs and full year EHR reporting periods for subsequent payment years. For Medicaid EPs and eligible hospitals, the EHR reporting period will be a 90-day period for the first year a Medicaid EP or eligible hospital demonstrates meaningful use and full year EHR reporting periods for subsequent payment years.

f. Meaningful EHR User

Section 1848(o)(1)(A)(i) of the Act, limits incentive payments under the Medicare FFS EHR incentive program to an EP who is a "meaningful EHR user." Similarly, section 1886(n)(1) and 1814(l) of the Act, limits incentive payments under the Medicare FFS EHR incentive program to an eligible hospital or CAH, respectively, who is a "meaningful EHR user." Section 1903(t)(6)(C)(i)(II) of the Act limits incentive payments for payment years other than the first payment year to a Medicaid EP or eligible hospital who "demonstrates meaningful use of certified EHR technology." We proposed to define at § 495.4 the term "meaningful EHR user" as an EP, eligible hospital, or CAH 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).

Comment: Several commenters indicated there is a need to align measures and programs, to avoid having to report similar measure standards to different Federal, State and other entities.

Response: We concur with the goal of alignment to avoid redundant and duplicative reporting and seek to accomplish this to the extent possible now and in future rulemaking.

Comment: Several commenters suggested that CMS considers EPs, eligible hospitals, and CAHs who are participating in certain existing programs as meaningful EHR users. The commenters contended that the standards followed by participants in these programs are equivalent to those we proposed to adopt for purposes of demonstrating meaningful use. The programs recommended by commenters are—

- Qualified Health Information Exchange Networks; and
- Medicare Electronic Health Record Demonstration Program.

Response: We do not agree that participation in these programs would be the equivalent to demonstrating meaningful use in accordance with the criteria under the EHR incentive programs. Most of these programs place a heavy focus on one of the five priorities of meaningful use discussed in the next section such as reporting clinical quality measures or the exchange of health information, tailored to the individual program's goals. For example, the goal of the Medicare

Electronic Health Record Demonstration Program, for example, which was started in 2009 and pre-dates passage of the HITECH Act, is to reward delivery of high-quality care supported by the adoption and use of electronic health records in physician small to medium-size primary care practices. The purpose of this program is to encourage adoption and increasingly sophisticated use of EHRs by small to medium-sized primary care practices. While this goal is similar to the overall objective of the HITECH Act, the requirements for the demonstration are not as broad-based as that of the HITECH Act, and payment incentives are based on the level of use over the duration of the program, which will vary by practice. Therefore, it is not appropriate to deem practices participating in the EHR Demonstration as meaningful users for purposes of the HITECH Act. The HITECH Act also requires use certified EHR technology as defined by ONC to qualify for incentive payments. While CCHIT has certified EHR technology in the past, the ONC regulation "Establishment of the Temporary Certification Program for Health Information Technology; Final Rule" (see 75 FR 36157) which establishes a temporary certifying body has yet to be established. Where possible, we have aligned the criteria required to demonstrate meaningful use with existing programs like PQRI and RHQDAPU as discussed in section II.A.3 of this final rule. After consideration of the public comments received, we are finalizing our definition of a meaningful EHR user as proposed.

2. Definition of Meaningful Use

a. Considerations in Defining Meaningful Use

In sections 1848(o)(2)(A) and 1886(n)(3)(A) of the Act, the Congress identified the broad goal of expanding the use of EHRs through the term meaningful use. In section 1903(t)(6)(C) of the Act, Congress applies the definition of meaningful use to Medicaid eligible professionals and eligible hospitals as well. Certified EHR technology used in a meaningful way is one piece of a broader HIT infrastructure needed to reform the health care system and improve health care quality, efficiency, and patient safety. HHS believes this ultimate vision of reforming the health care system and improving health care quality, efficiency and patient safety should drive the definition of meaningful use consistent with the applicable provisions of Medicare and Medicaid law.

In the proposed rule we explained that in defining meaningful use we sought to balance the sometimes competing considerations of improving health care quality, encouraging widespread EHR adoption, promoting innovation, and avoiding imposing excessive or unnecessary burdens on health care providers, while at the same time recognizing the short timeframe available under the HITECH Act for providers to begin using certified EHR technology.

Based on public and stakeholder input received prior to publishing the proposed rule, 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 expect to update the meaningful use criteria on a biennial basis, with the Stage 2 criteria by the end of 2011 and the Stage 3 criteria by the end of 2013. The stages represent an initial graduated approach to arriving at the ultimate goal.

- *Stage 1:* The Stage 1 meaningful use criteria, consistent with other provisions of Medicare and Medicaid law, focuses on electronically capturing health information in a structured format; using that information to track key clinical conditions and communicating that information for care coordination purposes (whether that information is structured or unstructured, but in structured format whenever feasible); implementing clinical decision support tools to facilitate disease and medication management; using EHRs to engage patients and families and reporting clinical quality measures and public health information. Stage 1 focuses heavily on establishing the functionalities in certified EHR technology that will allow for continuous quality improvement and ease of information exchange. By having these functionalities in certified EHR technology at the onset of the program and requiring that the EP, eligible hospital or CAH become familiar with them through the varying levels of engagement required by Stage 1, we believe we will create a strong foundation to build on in later years. Though some functionalities are optional in Stage 1, as outlined in discussions later in this rule, all of the functionalities are considered crucial to maximize the value to the health care system provided by certified EHR technology. We encourage all EPs, eligible hospitals and CAHs to be proactive in implementing all of the functionalities of Stage 1 in order to prepare for later stages of meaningful use, particularly functionalities that improve patient care, the efficiency of the health care system and public and population health. The specific criteria for Stage 1 of meaningful use are discussed at section II.2.c of this final rule.
- *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, genetic tests, genomic tests and other such data needed to diagnose and treat disease). For the final rule, we elaborate on our plans for Stage 2. We expect that stage two meaningful use requirements will include rigorous expectations for health information exchange, including more demanding requirements for e-prescribing and incorporating structured laboratory results and the expectation that providers will electronically transmit patient care summaries to support transitions in care across unaffiliated providers, settings and EHR systems. Increasingly robust expectations for health information exchange in stage two and stage three will support and make real the goal that information follows the patient. We expect that Stage 2 will build upon Stage 1 by both altering the expectations of the functionalities in Stage 1 and likely adding new functionalities which

are not yet ready for inclusion in Stage 1, but whose provision is necessary to maximize the potential of EHR technology. As discussed later in this final rule, we are making some objectives of the Stage 1 of meaningful use optional and other required. We will consider every objective that is optional for Stage 1 to be required in Stage 2 as well as revaluate the thresholds and exclusions of all the measures both percentage based and those currently a yes/no attestation. Additionally, we may consider applying the criteria more broadly to all outpatient hospital settings (not just the emergency department).

• *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 leading to improved health outcomes, focusing on decision support for national high priority conditions, patient access to self management tools, access to comprehensive patient data through robust, patient-centered health information exchange and improving population health.

We did not include regulatory provisions for Stage 2 or Stage 3 in our proposal and with one exception discussed under the CPOE objective, we are not finalizing Stage 2 or Stage 3 requirements at this time. However, we plan to build upon Stage 1 by increasing the expectations of the functionalities in Stage 1 and adding new objectives for Stage 2. In our next rulemaking, we currently intend to propose that every objective in the menu set for Stage 1 (as described later in this section) be included in Stage 2 as part of the core set. While allowing providers flexibility in setting priorities for EHR implementation takes into account their unique circumstances, we maintain that all the objectives are crucial to building a strong foundation for health IT and to meeting the statutory objectives of the Act. In addition, as indicated in our proposed rule, we anticipate raising the threshold for these objectives in both Stage 2 and 3 as the capabilities of HIT infrastructure increases. For Stage 2, we intend to review the thresholds and measures associated with all Stage 1 objectives considering advances in technology, changes in standard practice, and changes in the marketplace (for example, wider adoption of information technology by pharmacies) and propose, as appropriate, increases in these requirements.

We recognize that the thresholds included in the final regulation are ambitious for the current state of technology and standards of care. However, we expect the delivery of health care to evolve through the inception of the HITECH incentive programs and implementation of the Affordable Care Act prior to finalizing Stage 2. Furthermore, data collected from the initial attestations of meaningful use will be used to ensure that the thresholds of the measures that accompany the objectives in Stage 2 are continue to aggressively advance the use of certified EHR technology. Finally, we continue to 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. As appropriate, we intend to propose the addition of new objectives to capture new functions that are necessary to maximize the potential of EHR technology, but were not ready for Stage 1. For instance, we would consider adding measures related to CPOE orders for services beyond medication orders. The intent and policy goal for raising these thresholds and expectations is to ensure that meaningful use encourages patient-centric, interoperable health information exchange across provider organizations.

We will continue to evaluate the progression of the meaningful use definition for consistency with the HITECH ACT and any future statutory requirements relating to quality measurement and administrative simplification. 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, eligible hospital or CAH 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, such considerations are dependent on future rulemaking, so for this final rule Stage 1 criteria for meaningful use are valid for all payments years until updated by future rulemaking.

We proposed that Medicare EPs, eligible hospitals, and CAHs 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, eligible hospital, or CAH whose first payment year is 2011 would have to satisfy the Stage 2 criteria of meaningful use to receive the incentive payments. We proposed that Medicare EPs, eligible hospitals, and CAHs 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, eligible hospital, or CAH whose first payment year is 2012 would have to satisfy the Stage 2 criteria of meaningful use to receive the incentive payments. We discussed in the proposed rule that Medicare EPs, eligible hospitals, and CAHs 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, eligible hospital, or CAH whose first payment year is 2013 would have to satisfy the Stage 2 criteria of meaningful use to receive the incentive payments. We discussed in the proposed rule that Medicare EPs, eligible hospitals, and CAHs 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. In the proposed rule, we discussed the idea that alignment of stage of meaningful use and payment year should synchronize for all providers in 2015, and requested comment on the need to create such alignment. After reviewing public comment on this issue, our goal remains to align the stages of meaningful use across all providers in 2015. However, we acknowledge the concerns regarding the different Medicare and Medicaid incentive timelines, as well as concerns about whether Stage 3 would be appropriate for an EP's, eligible hospital's or CAH's first payment year at any point in the future and believe the issue needs additional review and discussion before we lay out a clear path forward for 2015 and beyond. Therefore, we have decided to remove language in the final rule discussing our possible directions for any year beyond 2014. We will address the years beyond 2014 in later rulemaking. Table 1 outlines how we anticipate applying the respective criteria of meaningful use in the first years of the program, and how we anticipate applying such criteria for

subsequent payment years, through 2014. Please note that nothing in this discussion restricts us from requiring additional stages of meaningful use (beyond stage 3) through future rulemaking. In addition, as we expect to engage in rulemaking to adopt the criteria that will accompany Stages 2 and 3 of meaningful use, stakeholders should wait for those rulemakings to determine what will be required for those Stages and should not view the discussions in this preamble or final rule as binding the agency to any specific definition for those future stages.

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	TBD
2012		Stage 1	Stage 1	Stage 2	TBD
2013			Stage 1	Stage 1	TBD
2014				Stage 1	TBD

Please note that each of the EHR incentive programs has different rules regarding the number of payment years available, the last year for which incentives may be received, and the last payment year that can be the first payment year for an EP, eligible hospital, or CAH. The applicable payment years and the incentive payments available for each program are also discussed in section II.C. of this final rule for the Medicare FFS EHR incentive program, in section II.D. of this final rule for the MA EHR incentive program, and in section II.E. of this final rule for the Medicaid EHR incentive program.

Comment: Numerous commenters noted that it is inappropriate to align the Medicaid EHR incentive payment program with the Medicare program due to the lack of penalties in the Medicaid program and due to the option for Medicaid providers to participate in their first year by adopting, implementing, or upgrading certified EHR technology.

Response: This was not the only reason for having all EPs, eligible hospitals, and CAHs align by 2015. However, as we are not addressing stages of meaningful use beyond 2014 in this final rule, potential alignment is not discussed. We will reconsider this comment in future rulemaking.

The stages of criteria of meaningful use and how they are demonstrated are described further in this final rule and will be updated in subsequent rulemaking to reflect advances in HIT products and infrastructure. We note that such future rulemaking might also include updates to the Stage 1 criteria.

We invited comment on our alignment between payment year and the criteria of meaningful use particularly in regards to the need to create alignment across all EPs, eligible hospitals, and CAHs in all EHR incentive programs in 2015.

Comment: Many commenters requested that if there continued to be a year where all EPs, eligible hospitals and CAHs must meet the same stage of meaningful use that that year be 2017, rather than 2015 as we had discussed in the proposed rule. These commenters asserted that EPs, eligible hospitals, and CAHs whose first payment year is after 2011 might not have sufficient time to reach the Stage 3 of meaningful use criteria by 2015. Some commenters pointed out that while the HITECH Act states that 2015 is the first year of payment adjustments, it provides for escalation of the payment adjustments so that they do not reach their full levels until 2017.

Response: As we explained in the proposed rule, equity in the level of meaningful use across all EPs, eligible hospitals, and CAHs subject to the payment adjustment was not the only reason for our plan that all EPs, eligible hospitals, and CAHs satisfy the Stage 3 criteria for either the Medicare or Medicaid EHR incentive programs. The achievement of many of the ultimate goals of meaningful use of certified EHR technology are dependent on a critical mass of EPs, eligible hospitals, and CAHs all being meaningful EHR users. Exchange of health information is most valuable when it is so robust that it can be relied upon to provide a complete or nearly complete picture of a patient's health. For example, robust Stage 3 meaningful use by an EP does not assist that EP in avoiding ordering a duplicative test, if the EP with information on the original test is only a Stage 1 meaningful EHR user and is not yet exchanging that information. This dependency is key to the need to get to Stage 3 for all providers. Another reason for alignment at Stage 3 in 2015 is that many of the barriers to functionalities of EHRs that exist today as may no longer exist in 2015. The existence of these barriers today is one of the primary reasons for having a staged approach as opposed to requiring more robust meaningful use at the beginning of the program. Providers, developers of EHRs, government and non-governmental organizations are all working to remove these barriers. We believe it is likely there will be success in removing many of these barriers, which would make many of the compromises made in Stage 1 no longer necessary by 2015. However, due to the many comments on alignment starting in 2015 and our plan to engage in additional more rounds of rulemaking, we are removing discussion of actual alignment between the first payment year of an EP, eligible hospital, or CAH and the Stage of meaningful use they will be expected to meet for all years after 2014. Our policies for 2015 and subsequent years will be determined through future rulemaking.

Comment: Several commenters requested that CMS base the payment adjustments on Stage 1 of meaningful use regardless of the EP, eligible hospital, or CAH's prior participation in the incentive program.

Response: We thank commenters for the thoughtful comments received, and will take their input into consideration when in future rulemaking when we consider whether to require that EPs, eligible hospitals, and CAHs satisfy the stage 3 definition of meaningful use in order to avoid reduced payments under Medicare for their professional services and inpatient hospital services beginning 2015. We reiterate, however, that in this final rule we are only adopting criteria that we expect will

apply in 2011 and 2012. We have also outlined the expected progression of stages of meaningful use criteria until 2014. However, we are not in this rule finalizing regulations that address the meaningful use standards that apply in 2015 and thereafter.

Comment: Numerous commenters requested that we specifically propose objectives and measures for Stage 2 and 3. We also received recommendations on what those objectives and, in rare cases, measures should be. We discussed some of these objectives in the proposed rule and discuss them again in this final rule in section II.d. Others are highly related to existing objectives, while still others were not discussed in any way in the proposed rule. The suggested objectives and measures for Stages 2 and 3 include the following:

- Use of evidence-based order sets.
- Electronic medication administration record (eMAR).
- Bedside medication administration support (barcode/RFID).
- Record nursing assessment in EHR.
- Record nursing plan of care in EHR.
- Record physician assessment in EHR.
- Record physician notes in EHR.
- Multimedia/Imaging integration.
- Generate permissible discharge prescriptions electronically.
- Contribute data to a PHR.
- Record patient preferences (language, etc).
- Provide electronic access to patient-specific educational resources.
- Asking patients about their experience of care.

Response: With one exception discussed under the CPOE objective, we continue to believe that finalizing specific objectives and measures for later stages is inappropriate. One of the greatest benefits of the phased stage approach is the ability to consider the impact and lessons of the prior stage when formulating a new stage. Many commenters supported our discussion of later stages for this very reason. In addition, we do not believe it is appropriate to finalize objectives for any stage of meaningful use that were not specifically discussed in the proposed rule, as doing so would deprive the public the opportunity to comment on the objective in question. Nevertheless, we thank commenters for the thoughtful comments received, and expect to take their input into consideration when in future rulemaking we consider additional or revised criteria and measures to adopt for the stage 2 and stage 3 definitions of meaningful use.

Comment: A commenter indicated that attestation is an insufficient means to hold providers accountable for the expenditure of public funds and to protect against fraud and abuse.

Response: We likewise are concerned with the potential fraud and abuse. However, Congress for the HITECH Act specifically authorized submission of information as to meaningful use through attestation. CMS is developing an audit strategy to ameliorate and address the risk of fraud and abuse.

b. Common Definition of Meaningful Use Under Medicare and Medicaid

Under sections 1848(o)(1)(A)(i), 1814(l)(3)(A), and 1886(n)(1) of the Act, an EP, eligible hospital or CAH must be a meaningful EHR user for the relevant EHR reporting period in order to qualify for the incentive payment for a payment year in the Medicare FFS EHR incentive program. 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 in section II.D.7.b.2 of this final 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, 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 EHR incentive programs for EPs and eligible hospitals/CAHs 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 stated in the proposed rule that 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 declared in the proposed rule that we had 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 proposed to offer EPs an opportunity to switch between the Medicare and Medicaid EHR incentive programs. Therefore, we proposed to create a common definition of meaningful use that would serve as the definition for EPs, eligible hospitals and CAHs 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 clarified that under Medicaid this proposed common definition would be the minimum standard. We proposed to 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 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.8. of this final rule for further details.

For hospitals, we proposed to exercise the option granted under section 1903(t)(8) of the Act and deem any Medicare eligible hospital or CAH 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 and CAHs, as EPs cannot simultaneously receive an incentive payment under both Medicare and Medicaid.

We solicited comments as to whether there are compelling reasons to give the States additional flexibility in creating disparate definitions beyond what was proposed. In addition, if commenting in favor of such disparate definitions, we also asked interested parties to comment on whether the proposal of deeming meeting the Medicare definition as sufficient for meeting the Medicaid definition 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.

Comment: Most commenters believe that States should not be allowed the option to add to or change the meaningful use requirements for the Medicaid EHR incentive program. The commenters' main reason for standardizing the meaningful use requirements for both Medicare and Medicaid is to eliminate administrative burden on both providers and EHR vendors to accommodate programming and reporting using different technical specifications for the same or similar measures.

Response: After consideration of the comments received, we are finalizing the provisions regarding possible differences in the definition of meaningful use between Medicare and Medicaid with the following revisions. We believe that over time the option to add to or change the floor definition of meaningful use might represent an important policy tool for States and therefore CMS plans to review and adjudicate these requests over the duration of the program. For Stage 1 of meaningful use, we have revised the definition of meaningful use in response to the many comments and are requiring an overall lower bar and an approach that is more flexible. On the other hand, we wish to support the ability for States to reinforce their public health priorities and goals based upon their existing public health infrastructure and maturity. For that reason, we, for Stage 1, will only entertain States' requests to tailor the Stage 1 meaningful use definition as it pertains specifically to public health objectives and data registries. For purposes of the Medicaid EHR incentive program during Stage 1 of meaningful use, these are limited to:

Objective: Generate lists of patients by specific conditions to use for quality improvement, reduction of disparities, research, or outreach.

Measure: Generate at least one report listing patients of the EP or eligible hospital with a specific condition.

Example: Generate lists of patients with the following conditions: depression, diabetes, obesity, etc. This would not be for reporting to the State but to draw EPs' or eligible hospitals' attention in order to better manage their patient population. States would also be permitted to request CMS approval to include this in the core set for all EPs and/or eligible hospitals.

Objective: Capability to submit electronic data to immunization registries of Immunization Information Systems and actual submission in accordance with applicable law and practice.

Measure: Performed at least one test of certified EHR technology's capacity to submit electronic data to immunization registries and follow up submission if the test is successful (unless none of the immunization registries to which the EP or eligible hospital submits such information have the capacity to received the information electronically).

Example: State could point to a specific immunization registry that supports standards-based transmission of data and dictate how that information is transmitted. States would also be permitted to request CMS approval to include this objective in the core list for all EPs and eligible hospitals. The justification for this request in their State Medicaid HIT Plan, should address any potential barriers for providers in achieving this objective.

Objective: Capability to submit electronic data on reportable (as required by state or local law) lab results to public health agencies and actual submission in accordance with applicable law and practice.

Measure: Performed at least one test of certified EHR technology's capacity to submit electronic data on reportable lab results to public health agencies and follow-up submission if the test is successful (unless none of the public health agencies to which an eligible hospital submits such information have the capacity to receive the information electronically).

Example: State could specify the standards-based means of transmission and/or the destination of this data. States would also be permitted to request CMS approval to include this objective in the core list for all and eligible hospitals. The justification for this request in their State Medicaid HIT Plan, should address any potential barriers for providers in achieving this objective.

Objective: Capability to submit electronic syndromic surveillance data to public health agencies and actual transmission according to applicable law and practice.

Measure: Performed at least one test of certified EHR technology's capacity to submit electronic syndromic surveillance data to public health agencies and follow-up submission if the test is successful (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).

Example: State could specify the standards-based means of transmission and/or the destination of this data. States would also be permitted to request CMS approval to include this objective in the core list for all EPs and eligible hospitals. The justification for this request in their State Medicaid HIT Plan, should address any potential barriers for providers in achieving this objective.

We reiterate that we will not approve any requests that would require EHR functionality above and beyond that included in the ONC EHR certification criteria as finalized for Stage 1 of meaningful use.

Comment: Several commenters requested that CMS affirm the ability of States to require additional meaningful use criteria for all eligible professionals and hospitals (pursuant to §§ 495.316(a), 495.316(d)(2)), regardless of whether those entities were deemed eligible through Medicare.

Response: Section 1903(t)(8) provides authority for the Secretary to "deem satisfaction of requirements for * * * meaningful use for a payment year under title XVIII to be sufficient to qualify as meaningful use under [1903(t)]." We continue to believe that allowing deeming ensures that hospitals eligible for both programs are able to focus on only one set of measures, without requiring duplication of effort or confusion regarding meaningful use standards. Thus, hospitals eligible for both Medicare and Medicaid incentive payments will be deemed for Medicaid if they have met the meaningful use definition through Medicare, even if a State has an approved State-specific definition of meaningful use. States cannot withhold a Medicaid EHR incentive payment from dually eligible hospitals if they have met all the eligibility criteria for Medicaid, and have met the Medicare definition for meaningful use.

Because of this comment, we are revising section § 495.4 of our regulations to indicate that eligible hospitals who are meaningful users under the Medicare EHR incentive payment program are deemed as meaningful users under the Medicaid EHR incentive payment program, and need not meet additional criteria imposed by the State. While this is not a new requirement, it was not previously listed in regulations.

Comment: A commenter asked that CMS adopt and affirm the deeming approach in its final rule and ensure that the regulatory language reflects this approach.

Response: We agree and have included in the final rule regulation language that hospitals that are meaningful users under the Medicare EHR Incentive Program are deemed meaningful users under the Medicaid EHR Program.

Comment: Several commenters requested that CMS not deem hospitals having met the meaningful use requirements for the Medicare EHR Incentive Payment, as having fulfilled the meaningful use requirements for the State's Medicaid EHR Incentive Payment. The commenters noted that if a State sought for acute care hospitals to participate in their statewide health information exchange and yet those hospitals did not have to do so in order to qualify for both the Medicare and Medicaid EHR Incentive Payments, then they would have no motivation to do so. The commenters would like acute care hospitals eligible for both the Medicare and Medicaid EHR Incentive Program to have to comply with any State-specific meaningful use requirements, in addition to the Medicare floor definition.

Response: In consideration of the comments received, CMS adopts its proposed preamble language about deeming hospitals and adds the corresponding regulation text. This is necessary for Stage 1 of meaningful use in particular, where we believe it is crucial to prevent additional burden on providers and foster eligible hospitals' path to successful EHR adoption and meaningful use. In addition, as already noted, for Stage 1, we will not entertain States' requests to alter the floor definition of meaningful use as codified in this final rule except for specific public health objectives. That thereby reduces the possible differences between the Medicare and Medicaid definitions of meaningful use. As part of Stage 2 of meaningful use, CMS might consider States requests to tailor meaningful use as it pertains to health information exchange, for example. Further details about this policy option will be included in future rulemaking and subject to public comment.

c. Stage 1 Criteria for Meaningful Use

In the proposed rule we proposed that to qualify as a meaningful EHR user for 2011, EPs, eligible hospitals or CAHs must demonstrate that they meet all of the objectives and their associated measures as set forth in proposed § 495.6. We further proposed and finalize in this final rule that except where otherwise indicated, each objective and its associated measure 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).

Discussion of Whether an EP, Eligible Hospital or CAH Must Meet All Stage 1 Meaningful Use Objectives and Their Associated Measures

Comment: Commenters almost unanimously said that requiring an EP, eligible hospital or CAH to meet all of the objectives and their associated measures in order to qualify as a meaningful EHR user was too ambitious given the current state of EHR technology, adoption levels, the timeline for certification of EHR technologies, the realities of implementing EHR technology and the timeline proposed for Stage 1 of meaningful use in our proposed rule.

Most of the commenters suggested alternatives that they believed would support the health care policy priorities of Stage 1. Several different alternatives were proposed. The first alternative would be to require a specified percentage of the Stage 1 meaningful use objectives and associated measures, with an EP, eligible hospital or CAH free to select which of the objectives and associated measures it would satisfy. For example under our proposed objectives and associated measures, if an EP were required to meet 20 percent, then an EP would be considered a meaningful EHR user if he or she satisfied any five of the proposed twenty–five objectives and associated measures. Most commenters suggesting this alternative envisioned that later stages of meaningful use would require that EPs, eligible hospitals, and CAHs satisfy a higher of the percentage of the objectives and associated measures. For example if 20 percent of the objectives and associated measures were required for Stage 1, then 50 percent might be required in Stage 2.

After a fixed percentage, the suggestion next favored by commenters, including the HIT Policy Committee and MedPAC, was to divide the meaningful use objectives into two categories, a "core set" of objectives and "menu set" of objectives. To be a considered a meaningful user under this approach, an EP, eligible hospital, or CAH would be required to satisfy (1) all core set of objectives, and (2) a specified percentage of the menu set of objectives, with the EP, eligible hospital, or CAH free to select which of the menu set of objectives it would satisfy. For example, if five objectives were in the core set all EPs, eligible hospitals, and CAHs would have to meet those objectives. If twenty objectives were in the menu set, then EPs, eligible hospitals, and CAHs would not have to meet one or more of those objectives. Commenters varied widely as to which objectives should be included in the core set of objectives, as well as the percentage of menu set objectives an EP, eligible hospital, or CAH must satisfy.

Some commenters suggested that we simply reduce the number of objectives required for Stage 1 of meaningful use. Recommendations in this regard varied from reducing the required objectives to only just a few (the lowest number being three), limiting the required objectives to only to those objectives that affect health outcomes of individual patients, to targeted elimination of a few objectives.

Finally, some commenters suggested that we eliminate all of the measures associated with the Stage 1 meaningful use objectives and only require that EPs, eligible hospitals, and CAHs attest that they have attempted to meet each of the objectives.

Response: After reviewing the comments, we agree that requiring that EPs, eligible hospitals, and CAHs satisfy all of the objectives and their associated measures in order to be considered a meaningful EHR user would impose too great a burden and would result in an unacceptably low number of EPs, eligible hospitals, and CAHs being able to qualify as meaningful EHR users in the first two years of the program. In considering an alternative approach, we have sought to develop an alternative that is responsive to some degree to all the concerns raised by the commenters. We have tried to reduce the requirements both in number required and in the thresholds of the associated measures and provide some flexibility as well. At the same time, however, we must be mindful of the relevant statutory requirements. Sections 1848 (o)(2)(A) and 1886(n)(3) of the Act, specify three 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. We believe that each EP, eligible hospital, and CAH must meet at least one objective within each of the three requirements for meaningful use. We are concerned that if we were to give EPs, eligible hospitals, and CAHs full discretion to select which meaningful use objectives they will satisfy, some providers would not choose one or more objectives within each of the three statutory requirements for meaningful use. Furthermore, we are concerned that affording EPs, eligible hospitals, and CAHs such flexibility as to which meaningful use objectives to meet would delay many of the goals outlined for meaningful use in section II.a.2. of this final rule. If in choosing what objectives to defer, one provider chooses to focus on improving processes to improve healthcare quality, another chooses to focus on being able to exchange health information and yet another on engaging patients and families it is possible that we would fail to accomplish any of these goals at a population level. For these reasons, we do not believe it would be appropriate to afford providers the unlimited flexibility to select which of the meaningful use objectives they will meet. Rather, as explained below, we believe providers at a minimum should have to satisfy a core set of objectives in order to qualify as meaningful EHR users.

Similarly, while we agree that merely reducing the number of objectives would make meaningful use easier to achieve for most providers, we believe that this reduction does not afford the same flexibility to all providers to account for their individual difficulties in meeting meaningful use that some of the other alternatives do as allowing a provider to choose certain objectives to defer. Due to any number of circumstances such as EHR adoption level, availability of health information exchange network, size of practice or hospital, etc., an objective that is easy for one EP to achieve might be very difficult for another EP. Under this alternative, no allowance is made for those differences. Finally, we disagree that meaningful use should be limited to improving the health outcomes of individual patients. There are significant gains that meaningful use can achieve in the areas of public health, privacy and security, engagement of patients and their families and efficiency of care that may not improve health outcomes, but have significant other benefits such as engaging patients more fully in decisions affecting their health and reducing costs through increased efficiency of care. We believe that all of these have a significant impact on health outcome priorities. Therefore, we do not categorically reduce the number of objectives for Stage 1 definition of meaningful use. We consider requests to defer an objective to later stages of the meaningful use criteria or eliminate a specific objective below in our discussion of each objective.

Comment: Another alternative that was recommended by a significant number of commenters was that we base the incentive payment amount on the number of stage 1 meaningful use objectives satisfied by an EP or eligible hospital, with those satisfying more objectives eligible for a higher incentive payment amount. While some commenters varied in the specifics or did not provide specifics, generally we take this to mean that if an EP, eligible hospital, or CAH met half of the objectives then they would receive half of the incentive payment they would have received had they met all the objectives.

Response: The HITECH Act does not give us the authority to award partial payments. As discussed elsewhere in this final rule, sections 1848(o)(1)(A) of the Act specifies the payment incentive amount to which an EP who is a meaningful EHR user is entitled. Similarly, section 1886(n)(2) of the Act sets forth a formula for calculation of incentive payment amount to which an eligible hospital that is a meaningful EHR user is entitled. Similarly, section 1814(l)(3)(A) of the Act sets forth a formula for calculation of incentive payment amount to which an eligible hospital that is a meaningful EHR user is entitled. Similarly, section 1903(t)(4)(B) of the Act sets parameters for determining the Medicaid EHR incentive for Medicaid EP. None of these parameters are related to meaningful use. Similarly, section 1903(t)(5)(A) of the Act sets forth a formula for calculation of the incentive payment amount to which a Medicaid eligible hospital is entitled. As we do not have the authority to alter these statutory formulas for calculating the incentive payment amounts under Medicare and Medicaid, we cannot pro rate the incentive payment amount based on the number of meaningful use objectives satisfied by an EP, eligible hospital, or CAH.

After consideration of the public comments received, we are establishing a core set of objectives with associated measures and a menu set of objectives with associated measures. In order to qualify as a meaningful EHR user, an EP, eligible hospital, or CAH must successfully meet the measure for each objective in the core set and all but five of the objectives in the menu set. With one limitation, an EP, eligible hospital, or CAH may select any five objectives from the menu set to be removed from consideration for the determination of qualifying as a meaningful EHR user. Further discussion of the objectives, including additional details about their inclusion in the core set, can be found at each objective.

We believe that establishing both a core and a menu set adds flexibility and allows the minimum statutory set to be met. In determining the objectives to include in the core set, we looked at all comments, especially those of the HIT Policy Committee and other commenters who recommended some required and optional elements. The HITECH Act requires the use of health information technology in improving the quality of health care, reducing medical errors, reducing health disparities, increasing prevention and improving the continuity of care among health care settings. In defining the core set of meaningful use objective, we believe the most crucial aspect to consider is meeting the three statutory guidelines provided in the HITECH Act and discussed in section II.A.2.a of this final rule. Second is to identify those objectives that are most crucial to laying the foundation for obtaining value from meaningful use of certified EHR technology. Third, we believe that meaningful use should be patient-centered so we focus on getting the most value to the patient. We believe the recommendation of the HIT Policy Committee accomplishes third criteria, but falls short of the first and second. To accomplish the first criteria, we add the objective of submitting clinical quality measures to CMS or the States and the objective of exchanging key clinical information among providers of care and patient authorized entities. To accomplish the second, we add several additional objectives to the core set of measures as critical elements pertinent to the management of patients. We have received a number of comments in support of these particular measures as critical to the management of patients (maintaining an up-to-date problem list, active medication list, active allergy list, smoking history and incorporate clinical

lab tests into EHR as structured data) in comparison to other requirements. The addition of two other functional objectives (drug-drug and drug-allergy features) as core measures are for improved patient-safety. All of the listed elements are integral to the initial or on-going management of a patient's current or future healthcare. While each element is important in the management of patients in and of itself, the aggregate of the elements elevates the importance of clinical information to not only the primary provider but for all members of the interdisciplinary team involved in the patient's care. The HITECH Act statutorily requires the use of health information technology in improving the quality of health care, reducing medical errors, reducing health disparities, increasing prevention, and improving the continuity of care among health care settings. These core set of measures are also foundational and aligned with each other. For example, electronic copies of health information given to patient will be useless if it does not contain basic information such as a problem list, medication list or allergy list. Exchange of information to other members of the health care team across settings will depend on having structured data of these elements. Therefore, in support of the HITECH Act in meeting the statutory requirements, we have expanded the core set of measures to include these fundamental elements to improve patient care. Below we list the objectives included in the core set of meaningful use objectives.

—Use CPOE
—Implement drug to drug and drug allergy interaction checks
—E-Prescribing (EP only)
—Record demographics
—Maintain an up-to-date problem list
—Maintain active medication list
—Maintain active medication allergy list
—Record and chart changes in vital signs
—Record smoking status
—Implement one clinical decision support rule
—Report CQM as specified by the Secretary
—Electronically exchange key clinical information
—Provide patients with an electronic copy of their health information
—Provide patients with an electronic copy of their discharge instructions (Eligible Hospital/CAH Only)
—Provide clinical summaries for patients for each office visit (EP Only)
—Protect electronic health information created or maintained by certified EHR

In addition, achieving Stage 1 meaningful use means demonstration of progress in each of the five healthcare outcome priorities outlined in the proposed rule and discussed again later in this section. Only one of these priorities is not represented in the core set, population and public health. As we have discussed in this section we do not want any priority to be overlooked due to the flexibility we have added to Stage 1 of meaningful use; therefore, all EPs and hospitals must choose at least one of the population and public health measures to demonstrate as part of the menu set. This is the only limitation placed on which five objectives can be deferred from the menu set.

Discussion on Whether Certain EP, Eligible Hospital or CAH Can Meet all Stage 1 Meaningful Use Objectives Given Established Scopes of Practice

In the proposed rule, we specifically encouraged comments on whether certain providers may have difficulty meeting one or more of the objectives due to their provider type or chosen specialties

Comment: We received many comments, both general and specific, that certain providers or specialists may not be able to comply with certain objectives because they are beyond the scope of their licensing authority or because they are outside the scope of their standard of practice. For example, chiropractors do not have prescribing authority and thus may not make use of an EHR technology's e-prescribing function and rheumatologists may not require information on vital signs. While comments on this potential non-applicability primarily focused on EPs, we did receive comments that some objectives may not be relevant to smaller or specialized eligible hospitals as well.

Response: We believe the division of the meaningful use objectives into a core set and a menu set may minimize the impact of including among the meaningful use objectives one or more objectives that certain providers or specialists may be unable to satisfy as the EP, eligible hospital, or CAH can defer five objectives from the menu set. However, if the EP, eligible hospital or CAH has an insurmountable barrier to meeting an objective in the core set or a significant number in the menu set then the problem remains. For example, without any consideration on an EP, eligible hospital or CAH's capability to meet the measure associated with a core objective any EP that could not order medications requiring a prescription would not be able to become a meaningful EHR user as e-prescribing is a core set objective. Similarly, any eligible hospital or CAH that did not have any requests for electronic copy of discharge instructions would not be able to become a meaningful EHR user. In addition, if this were to occur for a significant number of menu set objectives, the flexibility for the EP, eligible hospital, or CAH to use the five objectives to account for other concerns such as implementation struggles or workflow process redesign would be curtailed. To account for this possibility, we have modified each objective and measure to indicate when there is an option for an EP, eligible hospital, or CAH to report that the objective/measure is inapplicable to them, because they have no patients or no or insufficient number of actions that would allow calculation of the meaningful use measure. This will allow an EP, eligible hospital, or CAH to qualify as a meaningful EHR user without being required to meet objectives we have specified as potentially inapplicable. We note that the exclusions to meaningful use objectives/measures are specific to each objective/measure. In our discussion of each specific objective/measure (which occurs later in this preamble), we have identified specific exclusions where they exist. Providers wishing to claim that an objective/measure is inapplicable to them would need to meet the criteria of such an exception.

After consideration of the public comments received, we have identified, for each meaningful use objective, whether the EP, eligible hospital, or CAH may attest that they did not have any patients or insufficient actions on which to base a measurement of a meaningful use for the EHR reporting period. For objectives in the core set, such an attestation would remove the objective from consideration when determining whether an EP, eligible hospital, or CAH is a meaningful EHR user. In other words, the EP, eligible hospital, or CAH could satisfy the core set objectives by satisfying all remaining objectives included in the core set. For objectives in the menu set, such an attestation would also remove the objective from consideration when determining whether an EP, eligible hospital, or CAH is a meaningful EHR user. For example, if for one objective included in the menu set an EP attests that he or she did not have any patients or insufficient actions during the EHR reporting period on which to base a measurement of a meaningful use objective, rather than satisfy 5 of the 10 meaningful use objectives included in the menu set for EPs, the EP need only

satisfy 4 of the 9 remaining meaningful use objectives included in the menu set for EPs

EPs Practicing in Multiple Practices

Another situation where flexibility may be needed in order for an EP to become a meaningful EHR user is the situation where an EP may provide care in multiple practices or multiple locations. We proposed a policy to account for EPs practicing in multiple practices and settings. We discussed in the proposed rule that we believe it is unlikely for an EP to use one record keeping system for one patient population and another system for another patient population at one location. We are concerned about the application of the measures associated with the meaningful use objectives 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 for the EP to successfully become a meaningful EHR user based on the measures associated with the meaningful use 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 proposed that 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 geographic location. Equipped does not mean the certified EHR technology is functioning on any given day during the EHR reporting period. Allowances for downtime and other technical issues with certified EHR technology are made on an objective-by-objective basis as discussed later in this section. 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 of different 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 proposed 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 equipped with certified EHR technology. For example, if the EP practices at both a Federally Qualified Health Center (FQHC) and within his or her individual practice, we would include in our review both of these locations and certified EHR technology would have to be available at the location where the EP has at least 50 percent of their patient encounters.

Comment: Some commenters recommended that 50 percent or more of the patient encounters must occur at the practice location that receives the incentive payment.

Response: As discussed in section II.A.4 of this final rule, an EP may assign their incentive payment to other practices. We do not believe that limiting practices and EPs to only considering the location that receives an incentive payment provides advantages to the program. The requirement suggested by commenters would potentially cause some EPs not to meet the 50 percent threshold even if through a combination of practices they may use certified EHR technology for far more than 50 percent of their patient encounters.

Comment: Some commenters requested clarification of our proposed statement "Therefore, we proposed that all measures be limited to actions taken at practices/locations equipped with certified EHR technology"

Response: We mean this statement to be that as long as an EP has certified EHR technology available for 50 percent or more of their patient encounters during the EHR reporting period they only have to include those encounters where certified EHR technology is available at the start of the EHR reporting period. We discuss the measures later in this section of the final rule, but an illustrative example would be the objective of maintain an up-to-date problem list. The measure associated with this objective is "More than 80% of all unique patients seen by the EP or admitted to the eligible hospital's or CAH's inpatient or emergency department (POS 21 or 23) have at least one entry or an indication that no problems are known for the patient recorded as structured data." Therefore, if an EP only practices at one location or has certified EHR technology available at all practice locations then the denominator would be all unique patients seen during the EHR reporting period. However, if an EP practices at multiple locations and only has certified EHR technology for 80 percent of their patient encounters, then the denominator is only those unique patients seen at locations where certified EHR technology is available. We reiterate that this is not to account for certified EHR technology downtime, Certified EHR technology is available at a location if it is available at the start of the EHR reporting period regardless of its actual availability for any given day during the EHR reporting period.

After consideration of the comments received, we are finalizing this requirement as proposed.

Discussion of the Burden Created by the Measures Associated With the Stage 1 Meaningful Use Objectives

Comment: Many commenters expressed concerns about the difficulties of capturing the denominators for the measures that are expressed as percentages. They pointed out that the formulas in the proposed rule would require providers to conduct labor-intensive counts of paper documents such as prescriptions or laboratory results in order to compute the denominators of the percentage based measures. Some commenters suggested that we adopt alternative measurement mechanisms, for example establishing simple counts of electronic occurrences, while others proposed that denominators be computed utilizing only data collected in the certified EHR technology.

Response: We acknowledge that the percentage-based measures, as expressed in the proposed rule, would create a reporting burden for EPs, eligible hospitals, and CAHs, and we examined a number of alternatives that potentially reduce the burden of reporting.

In the proposed rule, we discussed the option of counts instead of percentages and due to comments received have reassessed this option in the final rule. This approach clearly has the advantage of simplifying the process. For example, rather than counting the number of prescriptions transmitted electronically and then dividing by the total number of prescriptions, the EP would simply need to count the number of electronically transmitted prescriptions until a benchmark number is passed. If the benchmark number is exceeded, then the provider meets the measure. However, there are several shortcomings to this approach. First, we received little input from commenters as to where the benchmark numbers for the various objectives should be set and any benchmark set now would not benefit

from public comment without significantly delaying the Medicare and Medicaid EHR incentive programs. (One exception was that a number of commenters suggested using the PQRI measure for e-prescribing, which is the generation of at least one eRx associated with a patient visit on 25 or more unique events during the reporting period.) Setting the limit too high would disadvantage small providers, since they would have smaller patient populations, while setting the limit too low would create requirements for larger providers that would be so limited as to be meaningless. A larger provider could implement the functionality for a much shorter period than the EHR reporting period and meet the count. In either case, it would be difficult to establish a trajectory in later stages that would result in meaningful progress being made by both small and large providers.

We then assessed the option of limiting the occurrences counted in the denominator to those included in the provider's certified EHR technology. As an example, if an EP captures 1,000 prescriptions as structured data in certified EHR technology, and electronically transmits 500 of these prescriptions, the EP's certified EHR technology generated score would be 50 percent. This approach does simplify the computation process, since this approach does not have to take into account whether some prescriptions were not included or included as unstructured data in the certified EHR technology. However, it does not demonstrate the extent to which the provider has used the certified EHR technology. For example, a provider that has captured only 10 prescriptions in the certified EHR technology as structured data, but writes 1,000 prescriptions because the provider achieved only a limited use of their certified EHR technology would also score 50 percent by electronically transmitting only 5 prescriptions according to an automatic report from the certified EHR technology. Again, this methodology does not lead providers toward an upward trajectory of both certified EHR technology deployment and accomplishment of meaningful use.

We selected a third option, which we believe addresses the shortcomings of the second option while still preserving much of the simplicity of that approach. In our approach, we focus on those measures whose denominator is not based on all patients, but rather a subset of patients or actions such as the ordering of a lab test or the recording of a patient's request for an electronic copy of their discharge instructions. We believe that it is reasonable to require an EP, eligible hospital, or CAH to know how many unique patients they care for in the EHR reporting period and therefore maintain that denominator where it applies. The maintenance of measures using the patient as the denominator as encompassing all patients ensures a certain level of utilization of certified EHR technology by the EP, eligible hospital, or CAH. If a measure encompassing all patients has a threshold of 80 percent, then at least 80 percent of the patients' records must be maintained using certified EHR technology otherwise the EP, eligible hospital or CAH could not possibly meet the threshold. We note a number of measures included in the core set (such as "Record Demographics" and "Maintain an Up-to-Date Problem List") require an analysis of all unique patients, and not just patients whose records are maintained in certified EHR technology As discussed later the thresholds for maintaining an up-to-date problem list, medication list and medication allergy list are set at 80 percent. We believe these thresholds will create a baseline that ensures that EPs, eligible hospitals and CAHS are maintain a minimum percentage of patient records in certified EHR technology, and allows the provider community to advance toward the longer-term objective of capturing all patient data in certified EHR technology. For those measures that focus on the recording of actions or subset of patients to generate the denominator, we limit the measures to the information for patients whose records are maintained in certified EHR technology. We offer the following examples that relate to the e-prescribing and the provision of electronic copy of a patient's health information:

E-Prescribing Example: An EP orders 1,000 prescriptions for patients whose records are maintained in their certified EHR technology and 500 of those are transmitted electronically. The EP's denominator is 1,000 prescriptions, the numerator is 500 prescriptions, and their score is 50 percent. If the EP captures all 1,000 prescriptions as structured data the calculation could be automated by the certified EHR technology. If the EP does not capture all 1,000 prescriptions as structured data than more manual review may be required. We would define "records maintained in the certified EHR technology" to include any patient for which sufficient data was entered in the certified EHR technology to allow the record to be saved, and not rejected due to incomplete data. This may be a more limited set of data, but an EP, eligible hospital, or CAH would still have to have sufficient information in certified EHR technology to meet the measures associated with Stage 1 of meaningful use. For example, an EP might be able to save a record with just a patient's name, but as the record would lack any information this patient would count in the denominator, but not the numerator for many objectives. *Electronic Copy of a Patient's Health Information Provided upon Request Example:* An EP maintains 1,000 patient records in their certified EHR technology. Of those patients, fifty make requests for electronic copies of their health information. The EP provides all of the electronic copies within three business days. The denominator is 50, the numerator is 50, and the EP's percentage is 100 percent. If the EP captures requests for information as structured data, the calculation could be automated by the certified EHR technology. If the EP does not capture all the requests as structured data then more manual review may be required. We will likely revisit the methodology in Stage 2, where we would expect that at least basic EHR functionality has been implemented throughout the provider enterprise.

After consideration of public comments, we are limiting the following objectives and their associated measures to patients whose records are maintained using certified EHR technology. Specific information on how to determine inclusion in the denominator and numerator is discussed in the full discussion of each objective later in this final rule.

- Use CPOE
- Generate and transmit permissible prescriptions electronically (eRx)
- Record and chart changes in vital signs
- Record smoking status for patients 13 years old or older
- Record advance directives for patients 65 years old or older
- Incorporate clinical lab-test results into certified EHR technology as structured data
- Provide patients with an electronic copy of their health information (including diagnostic test results, problem list, medication lists, medication allergies), upon request
- Provide patients with an electronic copy of their discharge instructions at time of discharge, upon request
- Provide clinical summaries for patients for each office visit
- Send reminders to patients per patient preference for preventive/follow-up care

• Perform medication reconciliation at relevant encounters and each transition of care

• Provide summary care record for each transition of care and referral

Discussion on Meaningful Use Relationship to Certified EHR Technology

Comment: We received several comments requesting more specific information of how certified EHR technology will accomplish meaningful use. Some commenters expressed concern that patient clinical outcome measurement and improvement was not addressed explicitly in the requirements of certified EHR technology, but rather the requirements focused data entry and provision of data electronically.

Response: One of the main purposes of certifying EHR technology is to provide the EP, eligible hospital, or CAH with confidence that the technology will not be the limiting factor in the achievement of meaningful use. As such, all questions of how or will certified EHR technology be able to accomplish meaningful use broadly or at a specific objective level are best answered by ONC. CMS and ONC have worked closely since the enactment of the HITECH Act to ensure certification fully supports meaningful use. We explicitly link each meaningful use objective to certification criteria for certified EHR technology. The capabilities and standards that are certified are those that are used to meet the Stage 1 objectives of meaningful use. This way we ensure that certified EHR technology can accomplish meaningful use and meaningful use has the intended consequences of improving the healthcare priorities that make up meaningful use.

Discussion on the Relationship Between a Stage 1 Meaningful Use Objective and Its Associated Measure

Comment: Many commenters pointed out gaps between what they believed were the anticipated results from an objective and the results that are measured by the associated measure. A particular concern of some of these commenters is cases where the certification criteria supports the measure, but in their view fell short of supporting the objective.

Response: In the proposed rule, we attempted to draw a clear distinction between the objective and the associated measure. The objectives represent a wide range of activities some of which are commonplace for EPs, eligible hospitals, and CAHs using EHRs today, while others are ambitious goals even for the most sophisticated EHR user of today. For some objectives, all aspects of the objective are within the control of the EP, eligible hospital, or CAH. Other objectives rely on electronic exchange with partners or external infrastructure over which EPs, eligible hospitals and CAHs may have little influence and no control. We have attempted to accommodate these differences when we select the Stage 1 measure for a given objective. The measure more accurately reflects our view of what is feasible for Stage 1 than the objective itself. The certification criteria necessarily reflect more on the measure than the objective, as full compliance with an objective is beyond the scope of what can be accomplished for a significant number of EPs, eligible hospitals or CAHs in our timeframe for Stage 1. This rationale was our assertion in the proposed rule as the justification for measures that represent less than full achievement of their objective. This is further supported by some of the comments received although for any given objective the comments addressing that objective were a small fraction of the total number of comments received and views on how much a measure should allow for less than full achievement varied widely among those commenting. Although we received over 2,000 public comments, the number of specific comments addressing an individual objective were relatively small ranging from 40 to 200. We reviewed those comments and made specific changes to measures in the discussion of each objective. We reiterate that achievement of the measure always equates to achievement of the objective for Stage 1 of meaningful use. We also reiterate that certified EHR technology will always be able to support achievement of the measure by including the necessary functionalities. However, as with any technology, certified EHR technology is only as good as the information it contains and getting information into certified EHR technology is heavily dependent on processes developed by the EP, eligible hospital, or CAH. It is for this reason that all measures, even those for objective whose aspects are fully under the control of the EP, eligible hospital, or CAH, represent less than full fulfillment of the objective to varying degrees. As stated, for demonstrating meaningful use and any follow up review by CMS or the States, successfully meeting the associated measure always equates to successfully meeting the objective. Updated information on the associated measures including the numerator, denominator, thresholds and exclusions are as discussed in the following section. More detailed specifications and guidance on calculating the measures will be issued soon after the publication of this final rule.

As we described in the proposed rule, 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.

We will now review the comments for each objective and measure and make changes to our original proposal or finalize as proposed.

(1) Objectives and Their Associated Measures

The HIT Policy Committee identified as its first health outcomes policy priority improving quality, safety, efficiency and reducing health disparities. The HIT Policy Committee also 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 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.

As we explained in the proposed rule, for the last care goal, the HIT Policy Committee proposed the goal as "Report to patient registries for quality improvement, public reporting, etc." We have modified 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.

NPRM EP Objective: Use CPOE.

NPRM Eligible Hospital Objective: Use CPOE for orders (any type) directly

entered by the authorizing provider (for example, MD, DO, RN, PA, NP).

In the proposed rule, we described 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. We said that for Stage 1 criteria, it will not include the electronic transmittal of that order to the pharmacy, laboratory, or diagnostic imaging center.

Comment: A majority of commenters recommended that EPs, eligible hospitals, and CAHs be allowed to defer CPOE for varying lengths of time ranging from 2012 to 2017. The commenters cited various reasons for deferment including that CPOE is an advanced clinical function that typically is the last process to be implemented due to the need to build the entire infrastructure to support the CPOE process. Other commenters noted an increased burden as if the orders cannot be transmitted, then duplicate paper orders will have to be produced which can lead to patient safety risks. Commenters also noted that CPOE appears in the latter stages of the Certification Commission for Healthcare Information Technology (CCHIT) EHR implementation process. A minority, but significant number of comments encouraged CMS to maintain CPOE for 2011. Those commenters in favor of retaining CPOE in 2011 believed that CPOE is a basic EHR feature that should be a standard offering of a certified EHR technology and is critical to improving quality of care through audit trails and alerting of delinquent order and/or delinquent deferred orders.

Response: We have determined that CPOE should be included in the core set of measures for Stage 1 in order to advance meaningful use. CPOE is a foundational element to many of the other objectives of meaningful use including exchange of information and clinical decision support. Many commenters, including several physician associations, the HIT Policy Committee and members of Congress through their endorsement of the HIT Policy Committee's recommendation, recommended that CPOE be required in Stage 1. CPOE has been a major initiative of US hospitals for over a decade and is a foundational functionality to many of the activities that further the health care policy priorities of meaningful use. For example, entering a medication order using CPOE allows the EHR to provide feedback on whether the medication may have adverse reactions with other medications the patient is taking. Another benefit of CPOE is that greatly simplifies the workflow process of inputting information into certified EHR technology in a structured way to populate the patient record.

Comment: Several commenters asked that we further specify who could enter the order using CPOE. Some commenters stated that only the ordering provider should be permitted to enter the order. These commenters stated that the ordering professional needs to be presented with clinical decision support at the time of entry and that the relay of an order to another individual is a source of potential error. Other commenters recommended that any licensed healthcare professional or indeed any individual (licensed or not) who receives the order from the ordering provider be permitted to perform the CPOE. The most common argument presented by these commenters is that this is currently how CPOE is handled in practice and a shift to entry by only the ordering provider would be too disruptive to workflow.

Response: We agree with those commenters who recommend allowing any licensed healthcare professional to enter orders using CPOE. We further refine this recommendation to be that any licensed healthcare professional can enter orders into the medical record per state, local and professional guidelines. While we understand that this policy may decrease opportunities for clinical decision support and adverse interaction, we believe it balances the potential workflow implications of requiring the ordering provider to enter every order directly, especially in the hospital setting. We disagree with commenters that anyone should be allowed to enter orders using CPOE. This potentially removes the possibility of clinical decision support and advance interaction alerts being presented to someone with clinical judgment, which negates many of the benefits of CPOE.

Comment: We received requests for clarification of this objective and what types of orders would meet this requirement.

Response: Our intent in the proposed rule was to capture orders for medications, laboratory or diagnostic imaging.

However, after careful consideration of the comments, we are adopting an incremental approach by only requiring medication orders for Stage 1. First, this supports the objectives of e-prescribing, drug-drug and drug-allergy checks. Second, this requirement will improve patient-safety because of the alignment of ordering medications in a structured data format will enable providers to create registries of patients for potential medical recalls, participate in surveillance for potential sentinel events and life-threatening side effects of new medications. Third, other measures involving transitions of care documents and summary of care document will require the entry of an active medication list. After consideration of the public comments received, we are finalizing the meaningful use objective for EPs at 495.6(d)(1)(i) and for eligible hospitals, and CAHs at 495.6(f)(1)(i) as "Use CPOE for medication orders directly entered by any licensed healthcare professional who can enter orders into the medical record per state, local and professional guidelines".

NPRM EP Measure: CPOE is used for at least 80 percent of all orders.

NPRM Eligible Hospital or CAH Measure: For eligible hospitals, CPOE is used for 10 percent of all orders.

In the proposed rule under CPOE, we discussed several concepts related to any associated measure of any objective that relies on a percentage calculation. These are the use of a percentage versus a count; setting a threshold for measures not requiring the electronic exchange of information; EPs practicing in multiple locations, some of which may not have certified EHR technology available, and the patient population to which the measure would apply. All except the last of these received extensive comments and are addressed in comment and response sections earlier in this section. In the proposed rule, we said that we would base the measures associated with the objectives on both the Medicare/Medicaid patient population and all other patients as well. We said that 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 and that requiring reporting differences based on payers would actually increase the burden of meeting meaningful use. We received very few comments on this aspect of our proposed rule and those that were received were generally supportive of this proposal. Therefore, we are finalizing the policy that all meaningful use measures be calculated based on the eligible provider's entire patient population (except where otherwise noted).

Comment: Nearly every commenter who commented on CPOE objected to our proposal to limit this measure to the

inpatient department (Place of Service Code 21) for the eligible hospital or CAH. Commenters stated that this limitation was inappropriate given the manner in which hospitals use EHR technology. To account for current practice, the commenters recommended the measures be expanded to include the emergency department (ED) (POS 23). Other reasons cited by commenters were that orders begin in the ED and remain open as the patient transitions to inpatient (for example, infusions), transitioning from paper documentation in the ED to electronic for subsequent care is unsafe as it can result in missed information, and/or transcription errors as the initial allergies and medications are entered into the system, significant data collection occurs in the ED that would not be included in the system, the exclusion of the ED creates disincentives to adoption and that the ED is a hybrid of temporal and functional services that are neither purely ambulatory nor inpatient.

Response: We agree with the commenters, and therefore are expanding this objective and its associated measure to the emergency room (POS 23). More information on place of service codes is available at *http://www.cms.gov/PlaceofServiceCodes/*. Furthermore, given the revision to the HITECH Act that changed hospital based eligible professionals to include only the setting of inpatient and emergency departments and all of the benefits of integration of these two departments spelled out by commenters we will adopt both departments when considering the measure of eligible hospitals or CAHs unless we find there are unique circumstances of an objective and its associated measure that would preclude the inclusion of the emergency department for meaningful use. This change does not affect the incentive payment calculation described in section II.B. of this final rule

Comment: We received several recommendations from commenters that the requirement of a percentage measurement for determining whether an EP, eligible hospital or CAH meets this objective should be replaced with a numerical count for CPOE and many other measures associated with percentage thresholds. The two main reasons given for switching to numerical counts are the burden of calculating the percentage if it cannot be done automatically using certified EHR technology and the assertion that if an EP, eligible hospital, or CAH does something a specific number of times it can be assumed that it is done often enough to constitute meeting the objective for Stage 1 of meaningful use.

Response: We have previously discussed the merits of a percentage based measure over a count based measure earlier in this section under the discussion of the burden created by the measures associated with the Stage 1 meaningful use objectives. However, we do try to seek a balance reducing the burden on providers while still ensuring the progression of meaningful use of certified EHR technology. In the next comment/response, we discuss changes to this measure that respond to concerns regarding burden.

Comment: Many commenters representing EPs as well as other commenters recommended lowering the CPOE threshold for EPs. Those commenters representing EPs generally recommended parity with eligible hospitals at 10 percent, while other commenters recommending a reduction generally recommended 50 percent.

Response: With CPOE, we had a unique situation of disparate thresholds between EPs and hospitals. This was due to recommendations prior to the proposed rule by the HIT Policy Committee. Eligible hospitals were granted an even lower threshold for this particular requirement. The reason given for this recommendation was that CPOE is one of the last functionalities to be implemented in the hospital setting. Commenters point out that holds true for EPs as well. As discussed above, given the limitations we are placing on the numerator and denominator for calculating the CPOE percentage, we no longer see a compelling reason to maintain disparate thresholds for the EPs and the eligible hospital/CAH.

Comment: Commenters have suggested that our proposal to count an action per unique patients could be applied to the measure for CPOE as well through a revised measure of "[a]t least 10% of unique patients seen by the EP or admitted to the eligible hospital or CAH have at least one order entered using CPOE." Commenters also pointed to CPOE as an example of a case where adequate lead time is necessary to implement certified EHR technology.

Response: At the heart of this new basis for this measure is the assumption that every patient would have at least one order that could be entered using CPOE. We believe this is a reasonable assumption for EPs, eligible hospitals and CAHs. According to analysis of 25,665 office-based visits in the 2005 National Ambulatory Medical Care Survey, 31 percent of visits included a new medication order, and 44 percent included at least one refill; 66 percent had any type of medication order. However, whether a medication order is appropriate for every practice could vary significantly by scope of practice; therefore, for the final rule, we are further limiting the denominator to patients with at least one medication listed in their medication list. We believe that this limitation will reduce providers' burden as compared to accounting for all orders. To further reduce the burden on providers, we also will limit the numerator to unique patients with at least one medication order entered using CPOE. Because we have reduced provider burden by limiting the denominator and numerator as discussed above, we believe that a corresponding increase in the CPOE threshold is appropriate for hospitals and CAHs. For stage 1, we are finalizing a threshold for CPOE of 30 percent for EPs, eligible hospitals, and CAHS. We believe this relatively low threshold, in combination with the limitation to only medication orders, will allow hospitals and EPs to gain experience with CPOE. However, as providers gain greater experience with CPOE, we believe it is reasonable to expect greater use of the function. As explained above, we also believe CPOE is foundational to many other objectives of meaningful use. For these reasons, we believe it is reasonable to expect providers to move to a 60 percent threshold at Stage 2 of meaningful use. Thus, for this measure, we are finalizing, for Stage 2 of meaningful use, that EPs, eligible hospitals and CAHs must meet a 60 percent threshold for CPOE. Therefore, we are finalizing a Stage 2 measure for CPOE at § 495.6(h) for EPs and § 495.6(i) for eligible hospitals and CAHs as "More than 60 percent of all unique patients with at least one medication in their medication list seen by the EP or admitted to the eligible hospital's or CAH's inpatient or emergency department (POS 21 or 23) during the EHR reporting period have at least medication one order entered using CPOE".

Comment: We received several comments asking for clarification of the term unique patient in response to various objectives.

Response: In the proposed rule, we state, "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." To further describe the concept of "unique patient" we mean that if a patient is seen by an EP or admitted to an eligible hospital's or CAH's inpatient or emergency department (POS 21 or 23) more than once during the EHR reporting period

then for purposes of measurement they only count once in the denominator for the measure. All the measures relying on the term "unique patient" relate to what is contained in the patient's medical record. Not all of this information will need to be updated or even be needed by the provider at every patient encounter. This is especially true for patients whose encounter frequency is such that they would see the same provider multiple times in the same EHR reporting period. Measuring by every patient encounter places an undue burden on the EPs, eligible hospitals and CAHs and may have unintended consequences of affecting the provision of care to patients merely to comply with meaningful use. Given the emphasis placed on the reporting burden by commenters as described in the beginning of this section, we believe that our concerns about the burden of measurement were well founded. We also continue to believe that the use of patient encounters could have unintended consequences on the provision of care by providers.

Comment: Some commenters asked whether the CPOE objective and associated measure require transmission of the order. Most of these commenters were opposed to such transmission in Stage 1 for various reasons such as the cost of developing interfaces between EHRs and laboratory and radiology service providers, the volume of transmissions would outpace the capacity to connect, HIE infrastructure is not yet mature enough and the lack of the requirement for non-eligible entities to participate (for example, laboratory vendors, pharmacies). Some commenters supported the inclusion of the transmission of the order as they believed this would provide better outcomes than if the transmission was not required.

Response: In the proposed rule, we stated, "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." While a few commenters recommended that this objective be changed to require transmission, given the large opposition to the objective and measure as proposed and the reasons commenters presented against transmission, it would not be responsive to the vast majority of commenters to expand this objective beyond our proposal. We agree with the commenters that said the HIE infrastructure is still being developed in most parts of the country. Furthermore, we note that in the hospital setting, most medication orders would not require transmission outside of the certified EHR technology of the hospital. For EPs, we already address transmission of the medication order in a separate objective for e-prescribing. Therefore, we finalize the proposal that the transmission of the order is not included in the objective or the associated measure for Stage 1.

After consideration of the public comments received, we are modifying the meaningful use measure for EPs at 495.6(d)(1)(ii) of our regulations and for eligible hospitals, and CAHs at § 495.6(f)(1)(ii) of our regulations to "More than 30 percent of all unique patients with at least one medication in their medication list seen by the EP or admitted to the eligible hospital's or CAH's inpatient or emergency department (POS 21 or 23) during the EHR reporting period have at least medication one order entered using CPOE".

We further specify that in order to meet this objective and measure, an EP, eligible hospital, or CAH must use the capabilities Certified EHR Technology includes as specified and standards at 45 CFR 170.304(a) for EPs and 45 CFR 170.306(a) for eligible hospitals and CAHs. The ability to calculate the measure is included in certified EHR technology. Thus, for example, an EP, eligible hospital or CAH must use a certified functionality in entering the medication order, and could not use a functionality that has been added by the EHR vendor, but that is outside the scope of the certification. We believe this rule is necessary to ensure that the EP, eligible hospital, or CAH is actually making meaningful use of "certified" EHR technology, and is not using non-certified technology. In addition, requiring providers to use functionalities that are certified will ensure the interoperability of information maintained in the EHR as providers will be able to operate according to consistent standards. We believe this standardization and consistency is key to realizing the goal of using EHR technology to improve health care.

As noted previously in this section under our discussion of the burden created by the measures associated with the Stage 1 meaningful use objectives, the only patients that are included in the denominator are those patients whose records are maintained using certified EHR technology.

To calculate the percentage, CMS and ONC have worked together to define the following for this objective:

- *Denominator:* Number of unique patients with at least one medication in their medication list seen by the EP or admitted to an eligible hospital's or CAH's inpatient or emergency department (POS 21 or 23) during the EHR reporting period
- *Numerator:* The number of patients in the denominator that have at least one medication order entered using CPOE.
- *Threshold:* The resulting percentage must be more than 30 percent in order for an EP, eligible hospital or CAH to meet this measure.

Exclusion: If an EP's writes fewer than one hundred prescriptions during the EHR reporting period they would be excluded from this requirement as described previously in this section in our discussion whether certain EP, eligible hospital or CAH can meet all Stage 1 meaningful use objectives given established scopes of practices. We do not believe that any eligible hospital or CAH would have less than one hundred prescriptions written for patients admitted to their inpatient and emergency departments during the EHR reporting period.

NPRM EP/Eligible Hospital Objective: Implement drug-drug, drug-allergy, drug-formulary checks

In the proposed rule, we did not elaborate on this objective.

Comment: Many commenters requested clarification as to what formulary the checks would be conducted against.

Response: Ideally, this check would be performed against any formulary that may affect the patient's welfare, inform the provider as to the best drug to prescribe or provide the patient and provider information on the drug's cost to both the patient and any third party payer. We recognize, however, that not every available third party payer, pharmacy benefit management, preferred drug list is standardized and made available for query through certified EHR technology. As we cannot through this regulation impose such a requirement on every developer of a formulary, we do not require that an EP/eligible hospital/CAH would have to accommodate every formulary in their implementation. However, at a minimum an EP/eligible hospital/CAH must have at least one formulary that can be queried. This may be an internally developed formulary or an external formulary. The formularies should be relevant for patient care during the prescribing process. To further address this, we expect that this measure will be expanded to be counted on a transactional basis for future stages.

Comment: Commenters suggested separating the objective into one objective for the clinical checks (drug-drug and drug-allergy) and a second objective for the administrative check

(drug-formulary). The rationale stated for the division was that clinical measures are focused on preventing medication errors versus encouraging consideration of cost when prescribing medications. In addition, the two types involve connections to different kinds of resources (drug safety information versus formulary information).

Response: We agree that these should be separate objectives for the reasons stated by the commenters and split them accordingly.

Comment: We received comments that these functions were really part of CPOE and electronic prescribing. Commenters most commonly noted that the drug formulary is part of electronic prescribing, as is currently the case under the Medicare e-Prescribing program.

Response: While we agree that the drug-drug, drug-allergy, drug-formulary checks, CPOE, e-prescribing meaningful use objectives all serve the same broader goal of ensuring accurate ordering and prescribing that takes into account all available information about the patient the functions and their readiness for Stage 1 of meaningful use are distinct. In terms of functions, CPOE and e-prescribing could be performed without the drug to drug, drug-allergy or drug-formulary checks. Similarly, it is not necessary for CPOE or e-Prescribing to take place in order for a drug to drug allergy check to occur. In terms of readiness and ability to measure progress for Stage 1 of meaningful use, CPOE and e-prescribing both are percentage based measures of a distinct activity that creates a record even in today's EHR's and paper patient records. The viewing and consideration of information presented to the provider on possible drug interactions is not a similarly distinct activity and does not currently create a record. So while the goal of these functionalities is similar, we believe drug-drug, drug-allergy, drug-formulary checks create unique concerns for implementation and demonstration of meaningful use, and therefore we maintain them as separate objectives.

Comments: Several commenters expressed concern of "alert fatigue" occurring with drug-drug interaction checks. Alert fatigue or otherwise known as "pop-up" fatigue is a commonly perceived occurrence with electronic medical records and clinical decision support tools in which alerts are presented to the user when a potential safety issue is identified by the system (for example, drug to drug interaction). The alerts, while beneficial in some cases, can result in a type of "fatigue" whereby the provider, after receiving too many alerts, begins to ignore and/or override the alerts. Receiving too many alerts can result in slowing the provider down rendering the alert useless. Commenters recommended some changes to the objective and associated measure to mitigate the risk of "alert fatigue" such as limiting the checks for interactions to only the most critical medications or allowing for adjustment of risk levels rather than an on/off functionality.

Response: We recognize "alert fatigue" is a potential occurrence with drug-drug and drug-allergy checks. However, meaningful use seeks to utilize the capabilities of certified EHR technology and any means to address alert fatigue requires a critical evaluation of each alert. We believe this is beyond the scope of the definition of meaningful use. We believe these checks are valuable and improve patient care and therefore do not remove them to address alert fatigue.

Comment: Commenters recommended food allergies be included in the drug-allergy check as some drugs contain ingredients that are contraindicated in individuals with certain allergies.

Response: We certainly agree that some allergies other than drug can interact with drugs; however, as we stated under our discussion of the objective "Medication Allergy List", the ability to identify other types of allergies in a useful way are not yet available to the extent necessary to require them in Stage 1 of meaningful use. This certainly does not preclude any EP, eligible hospital, or CAH from working with the designers of their certified EHR technology to include this functionality.

Comment: A commenter requested clarification as to whether the drug-drug, drug-allergy and drug-formulary checks are required for contrast media and imaging agents used by radiologists.

Response: We do not link the checks to specific drugs or agents. However, we note that is common practice in radiology to identify a patient's past drug and food allergies and take appropriate interventions if necessary. Therefore, the drug-drug, drug-allergy and drug-formulary checks would be appropriate prior to administration of contrast media and imaging agents to patients.

After consideration of the public comments received, we are finalizing the meaningful use objective for EPs at § 495.6(d)(2)(i) and for eligible hospitals and CAHs at § 495.6(f)(2)(i) as "Implement drug-drug and drug-allergy checks." We include this objective in the core set as it is integral to the initial or on-going management of a patient's current or future healthcare and would give providers the necessary information to make informed clinical decisions for improved delivery of patient care.

In addition, we are finalizing the meaningful use objective at for EPs at § 495.6(e)(1)(i) and for eligible hospitals and CAHs at § 495.6(g)(1)(i) of our regulations as "Implement drug-formulary checks."

NPRM EP/Eligible Hospital Measure: The EP/eligible hospital/CAH has enabled the drug-drug, drug-allergy, and drug-formulary check functionality

In the proposed rule we discussed that the capability of conducting automated drug-drug, drug-allergy, and drug-formulary checks is included in the certification criteria for certified EHR technology. This automated check provides information to advise the EP, eligible hospital, or CAH's decisions in prescribing drugs to a patient. The only action taken by the EP, eligible hospital, or CAH 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, eligible hospital, or CAH would be required to enable this functionality and ensure they have access to at least one drug formulary. While this does not ensure that an EP, eligible hospital or CAH is considering the information provided by the check, it does ensure that the information is available.

After consideration of the public comments received on the objective, we believe the measure as proposed requires more clarity on the length of time for which the functionality must be enabled, which we clarify to be the entire EHR reporting period. Therefore, we are modifying the meaningful use measure for "Implement drug-drug and drug-allergy checks for the entire EHR reporting period" for EPs at § 495.6(d)(2)(ii) and for eligible hospitals and CAHs at § 495.6(f)(2)(ii) of our regulations to "The EP/eligible hospital/CAH has enabled this functionality for the entire EHR reporting period."

We further specify that in order to meet this objective and measure, an EP, eligible hospital, or CAH must use the capabilities Certified EHR Technology includes as specified and standards at 45 CFR 170.302(a). The ability to calculate the measure is included in certified EHR technology.

As this objective only requires that functionalities of certified EHR technology be enabled, we do not believe that any EP, eligible hospital or

CAH would need an exclusion for this objective and its associated measure.

After consideration of the public comments received on the objective, we are modifying the meaningful use measure for "Implement drug-formulary checks" for EPs at § 495.6(e)(1)(ii) and for eligible hospitals and CAHs at § 495.6(g)(1)(ii) of our regulations to "The EP/eligible hospital/CAH has enabled this functionality and has access to at least one internal or external formulary for the entire EHR reporting period."

We further specify that in order to meet this objective and measure, an EP, eligible hospital, or CAH must use the capabilities Certified EHR Technology includes as specified and standards at 45 CFR 170.302(b). The ability to calculate the measure is included in certified EHR technology.

The consideration of whether a drug is in a formulary or not only applies when considering what drug to prescribe. Therefore, we believe that any EP who writes fewer than one hundred prescriptions during the EHR reporting period should be excluded from this objective and associated measure as described previously in our discussion of whether certain EP, eligible hospital or CAH can meet all Stage 1 meaningful use objectives given established scopes of practices.

NPRM EP/Eligible Hospital Objective: Maintain an up-to-date problem list of current and active diagnoses based on ICD–9–CM–CM or SNOMED CT®

In the proposed rule, we described the term "problem list" as a list of current and active diagnoses as well as past diagnoses relevant to the current care of the patient.

Comment: Several commenters noted that the coding of problem lists at the point of care is outside the normal workflow process and would be disruptive.

Response: We did not and do not intend that coding of the diagnosis be done at the point of care. This coding could be done later and by individuals other than the diagnosing provider.

Comment: Commenters suggested including ICD–10–CM, the Diagnostic and Statistical Manual of Mental Disorders and explicitly allowing subsets of SNOMED CT®.

Response: We have removed the references to specific standards, as we believe specifying the relevant standards falls within the purview of ONC. For ONC's discussion of this functionality and the relevant standards including response to the above comment, we refer readers to ONC's final rule.

After consideration of the public comments received, we are modifying the meaningful use objective for EPs at § 495.6(d)(3)(i) and for eligible hospitals at § 495.6(f)(3)(i) of our regulations to "Maintain an up-to-date problem list of current and active diagnoses".

We include this objective in the core set as it is integral to the initial or on-going management of a patient's current or future healthcare and would give providers the necessary information to make informed clinical decisions for improved delivery of patient care.

NPRM EP/Eligible Hospital 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 recorded as structured data.

In the proposed rule, we introduced the concept of "unique patients" in the discussion of this objective. We received many comments requesting clarification of this term and address those in the comment and response section under our discussion of the CPOE measure.

Comment: A few commenters stated that "None" is not a clinically relevant term and should be replaced with no known problem or no problem.

Response: Our intent is not to dictate the exact wording of the specific value. Rather we are focused on the overall goal of making a distinction between a blank list because a patient does not have known problems and a blank list because either no inquiry of the patient has been made, or problems have been recorded through other means. As long as the indication accomplishes this goal and is structured data, we do not believe it is necessary to prescribe the exact terminology, thus leaving that level of detail to the designers and users of certified EHR technology.

Comment: Commenters requested clarification of the term "up-to-date".

Response: The term "up-to-date" means the list is populated with the most recent diagnosis known by the EP, eligible hospital, or CAH. This knowledge could be ascertained from previous records, transfer of information from other providers, or querying the patient. However, not every EP has direct contact with the patient and therefore has the opportunity to update the list. Nor do we believe that an EP, eligible hospital, or CAH should be required through meaningful use to update the list at every contact with the patient. There is also the consideration of the burden that reporting places on the EP, eligible hospital, or CAH. The measure, as finalized, ensures the EP, eligible hospital, or CAH has a problem list for patients seen during the EHR reporting period, and that at least one piece of information is presented to the EP, eligible hospital, or CAH. The EP, eligible hospital, or CAH can then use their judgment in deciding what further probing or updating may be required given the clinical circumstances.

Comment: Commenters stated that this measure should be replaced with either a simple attestation of yes, the problem list exists or the percentage of the measure should be replaced with a count. Alternatively, that the percentage should be maintained, but that the threshold should be lowered. Commenters generally supported this lowering of the threshold for one or all of the following reasons: It may require a change in traditional workflow; implementation and rollout of certified EHR technology creates unforeseeable system downtimes, complications, and the required clinical classification systems are not geared toward clinical information.

Response: For reasons discussed earlier in this section under our discussion of the burden created by the measures associated with the Stage 1 meaningful use objectives, we believe a percentage is a more appropriate measure than those suggested by comments. 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 is appropriate to set a high percentage threshold. In the proposed rule, we 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. We proposed 80 percent for every measure with a percentage that met the criteria of relying solely on a capability included as part of certified EHR technology and are not, for purposes of Stage 1 meaningful use criteria, reliant on the electronic exchange of information. Commenters generally agreed with this alignment; however, they disagreed that 80 percent sufficiently allows for "technical hindrances and other barriers". Commenters have highlighted numerous barriers towards successfully meeting an 80 percent threshold including technical barriers, barriers to implementation, applicability to all patients and all provider types eligible for the EHR incentives, patient requested exclusions and others. We address some of these with specific exclusions from the measure as

discussed previously in this section under our discussion of whether certain EP, eligible hospital or CAH can meet all Stage 1 meaningful use objectives given established scopes of practices. Although some technical issues exist, recording an up-to-date problem list remains largely within the individual provider's control and does not rely to a large degree on some external sender or receiver of structured electronic health data. In addition, there is a standard of practice for collecting the elements required for an up-to-date problem list. Although the commenters may be right that some clinical workflow needs to change, that is an integral part of meaningful use of EHRs. Although we do not expect all clinical workflow to adapt in Stage 1, there is an expectation that the clinical workflow necessary to support the Stage 1 priority of data capture and sharing will be in place in order to effectively advance meaningful use of EHRs. In addition, given the wide range of activities that must occur for meaningful use, we believe that most EPs, eligible hospitals and CAHs will have fully rolled out the capabilities required by this objective and the others with an 80 percent threshold prior to the start of the EHR reporting period thereby reducing the likelihood of unexpected system downtime and other implementation complications.

For situations in which there is an existing standard of practice and complying is fundamentally within the provider's control and where the 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, for the final rule, we adopt, the reasonably high threshold of 80 percent. We believe existing infrastructure and expectations support this relatively high target. This foundational step of structured data capture is a prerequisite for many of the more advanced functionalities (for example, clinical decision support, clinical quality measurement, etc.) for which a solid evidence base exists for improved quality, safety and efficiency of care. Without having most of a provider's up-to-date problem lists in structured, electronic data, that provider will have major challenges in building more advanced clinical processes going forward.

For other situations, where the objective may not be fundamentally within the provider's control and is not an existing standard of practice, but where objective continues to rely solely on a capability that is included as part of certified EHR technology and is not reliant on electronic exchange of information, we are setting the percentage at 50 percent. This was the most commonly recommended percentage for these objectives that rely solely on a capability included as part of certified EHR technology and do not rely on the electronic exchange of information.

After consideration of the public comments received, we are modifying the meaningful use measure for EPs at § 495.6(d)(3)(i) and for eligible hospitals at § 495.6(f)(3)(i) of our regulations to "More than 80 percent of all unique patients seen by the EP or admitted to the eligible hospital's or CAH's inpatient or emergency departments (POS 21 or 23) have at least one entry or an indication that no problems are known for the patient recorded as structured data".

We further specify that in order to meet this objective and measure, an EP, eligible hospital, or CAH must use the capabilities Certified EHR Technology includes as specified and standards at 45 CFR 170.302(c). The ability to calculate the measure is included in certified EHR technology.

To calculate the percentage, CMS and ONC have worked together to define the following for this objective:

- *Denominator:* Number of unique patients seen by the EP or admitted to an eligible hospital's or CAH's inpatient or emergency department (POS 21 or 23) during the EHR reporting period.
- *Numerator:* The number of patients in the denominator who have at least one entry or an indication that no problems are known for the patient recorded as structured data in their problem list.
- *Threshold:* The resulting percentage must be more than 80 percent in order for an EP, eligible hospital, or CAH to meet this measure.

We do not believe that any EP, eligible hospital, or CAH would be in a situation where they would not need to know at least one active diagnosis for a patient they are seeing or admitting to their hospital. Therefore, there are no exclusions for this objective and its associated measure.

NPRM EP Objective: Generate and transmit permissible prescriptions electronically (eRx).

Comment: Some commenters requested clarification of the term "permissible prescription."

Response: As discussed in the proposed rule, the concept of only permissible prescriptions refers to the current restrictions established by the Department of Justice on electronic prescribing for controlled substances in Schedule II. (The substances in Schedule II can be found at *http://www.deadiversion.usdoj.gov/schedules/orangebook/e_cs_sched.pdf*). Any prescription not subject to these restrictions would be permissible. We note that the Department of Justice recently released a notice of proposed rulemaking that would allow the electronic prescribing of these substances; however, given the already tight timeframe for Stage 1 of meaningful use we are unable to incorporate any final changes that may result from that proposed rule. Therefore, the determination of whether a prescription is a "permissible prescription" for purposes of the eRx meaningful use objective should be made based on the guidelines for prescribing Schedule II controlled substances in effect when the notice of proposed rulemaking was published on January 13, 2010. We define a prescription as the authorization by an EP to a pharmacist to dispense a drug that the pharmacist would not dispense to the patient without such authorization. We do not include authorizations for items such as durable medical equipment or other items and services that may require EP authorization before the patient could receive them. These are excluded from the numerator and the denominator of the measure.

Comment: Some commenters recommended combining this objective and measure with other meaningful use objectives such as CPOE or the drug-drug, drug-allergy, drug-formulary checks

Response: We addressed these comments under our discussion of the CPOE objective.

After consideration of the public comments received, we are finalizing the meaningful use objective at 495.6(d)(4)(i) as proposed.

We have also included this objective in the core set. Section 1848(o)(2)(A)(i) of the Act specifically includes electronic prescribing in meaningful use for eligible professionals. This function is the most widely adopted form of electronic exchange occurring and has been proven to reduce medication errors. We included this objective in the core set based on the combination of the maturity of this objective, the proven benefits and its specific mention as the only example provided in the HITECH Act for what is meaningfully using certified EHR technology.

NPRM EP Measure: At least 75 percent of all permissible prescriptions written by the EP are transmitted electronically using certified EHR technology.

In the proposed rule, we said that while this measure does rely on the electronic exchange of information based on the public input previously discussed and our own experiences with e-prescribing programs, we believe this is the most robust electronic exchange currently occurring and proposed 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.

Comment: A majority of commenters commenting on this measure believe the 75 percent threshold is too high. Several issues were raised to explain why the commenters believe the threshold is too high. The first is that barriers to e-prescribing exist at the pharmacies and they must be brought into the process to ensure compliance on the receiving end. The second represents the most common barrier cited by commenters and that is patient preference for a paper prescription over e-prescribing. A patient could have this preference for any number of reasons cited by commenters such as the desire to shop for the best price (especially for patients in the Part D "donut hole"), the ability to obtain medications through the VA, lack of finances, indecision to have the prescription filled locally or by mail order and desire to use a manufacturer coupon to obtain a discount. Other barriers mentioned by individual commenters were the limited functionality of current e-prescribing systems such as the inability to distinguish refills from new orders. Suggestions for addressing these difficulties were either to lower the threshold (alternatives recommended ranged from ten to fifty percent) or replacing the percentage with a numerical count of 25 to align with the 2010 Medicare e-Prescribing program. Of the comments received that requested a specific lower threshold, about half of them suggested a 50 percent threshold, and about half suggested a threshold of 25 percent to 30 percent.

Response: We are finalizing the use of a percentage threshold for the reasons discussed previously in this section under our discussion of the burden created by the measures associated with the Stage 1 meaningful use objectives. In the proposed rule, we pointed out that we "believe this is the most robust electronic exchange currently occurring" to justify a high threshold of 75 percent given that this objective relies on electronic exchange. While we continue to believe this is the case, two particular issues raised by commenters caused us to reconsider our threshold. The first is the argument to include pharmacies in the Medicare and Medicaid EHR incentive programs to ensure compliance on the receiving end. Non-participation by pharmacies was presented by commenters as a major barrier to e-Prescribing. The second is patient preference for a paper prescription. In regards to the first argument, we do not have the ability to impose requirements on pharmacies through the HITECH legislation. However, prescriptions transmitted electronically have been growing at an exponential rate. The number of prescriptions sent electronically increased by 181 percent from 2007 to 2008 according to comments received. The number of pharmacies is also increasing rapidly. Yet this growth is uneven across the country and we wish to accommodate all EPs and do lower the threshold based on this argument. In regards to the second argument, we also have neither the ability nor the desire to limit patient preference. We considered allowing an EP to exclude from the denominator those instances where a patient requested a paper prescription. However, the burden of tracking when this occurs, the disincentive it would create for EPs to work with patients on establishing a relationship with a pharmacy and the hindrance to moving forward with e-prescribing lead us to address this through further reduction of the threshold as opposed to an exclusion. To address these concerns we are lowering the threshold for the e-prescribing measure to 40 percent. As pointed out by commenters, e-prescribing it is not yet standard of practice and there may be important external barriers beyond the provider's control. In particular, for e-prescribing, providers are dependent upon an external receiver of electronic health data, and there are significant variations depending on where the provider practices.

After consideration of the public comments received, we are modifying the meaningful use measure at § 495.6(d)(4)(ii) of our regulations to "More than 40 percent of all permissible prescriptions written by the EP are transmitted electronically using certified EHR technology".

We further specify that in order to meet this objective and measure, an EP, eligible hospital, or CAH must use the capabilities Certified EHR Technology includes as specified and standards at 45 CFR 170.304(b). The ability to calculate the measure is included in certified EHR technology.

As noted previously in this section under our discussion of the burden created by the measures associated with the Stage 1 meaningful use objectives, the prescriptions in the denominator are only those for patients whose records are maintained using certified EHR technology.

To calculate the percentage, CMS and ONC have worked together to define the following for this objective:

- *Denominator:* Number of prescriptions written for drugs requiring a prescription in order to be dispensed other than controlled substances during the EHR reporting period.
- *Numerator:* The number of prescriptions in the denominator generated and transmitted electronically.
- *Threshold:* The resulting percentage must be more than 40 percent in order for an EP, eligible hospital, or CAH to meet this measure.

As addressed in other objectives and in comment response, this objective and associated measure do not apply to any EP who writes fewer than one hundred prescriptions during the EHR reporting period, as described previously in this section under our discussion of whether certain EP, eligible hospital or CAH can meet all Stage 1 meaningful use objectives given established scopes of practices.

NPRM EP/Eligible Hospital Objective: Maintain active medication list.

Comment: Commenters requested clarification of the term "active medication list."

Response: We define an active medication list as a list of medications that a given patient is currently taking.

After consideration of the public comments received, we are finalizing this objective for EPs at § 495.6(d)(5)(i) and for eligible hospitals and CAHs at § 495.6(f)(4)(i) of our regulations as proposed.

We include this objective in the core set as it is integral to the initial or on-going management of a patient's current or future healthcare and would give providers the necessary information to make informed clinical decisions for improved delivery of patient care.

NPRM 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.

As with the objective of maintaining a problem list, we clarify that the indication of "none" should distinguish between a blank list that is blank

because a patient is not on any known medications and a blank list because no inquiry of the patient has been made. As long as the indication accomplishes this goal and is structured data, we do not believe it is necessary to prescribe the exact terminology, preferring to leave that level of detail to the designers and users of certified EHR technology.

Comment: Commenters stated that the measure should be replaced with a numerical count or attestation and that the threshold was too high for reasons including the lack of current electronic exchange of information, difficulty capturing information as structured data and lack of readiness of HIE infrastructure.

Response: We are finalizing the use of a percentage for the reasons discussed previously in this section under our discussion of the burden created by the measures associated with the Stage 1 meaningful use objectives. For the same reasons we explained under the discussion of up-to-date problem list, medication list is a functionality for which there is an existing standard of practice, it is foundational data capture function to make more advanced clinical processes possible, and complying is fundamentally within the provider's control. Therefore, we maintain the reasonably high threshold of 80 percent because the existing infrastructure and expectations support this target.

Comment: Commenters requested clarification as to whether the measure is limited to patients seen during the EHR reporting period.

Response: Yes, the measure applies to all unique patients seen by the EP or admitted to the eligible hospital's or CAH's inpatient or emergency departments (POS 21 or 23) during the EHR reporting period.

Comment: A few commenters expressed concern regarding the requirement that the entry must be recorded as "structured data." The commenters state that there may not be a code for over the counter, homeopathic or herbal products and that would penalize the provider even though the data is collected and recorded.

Response: The distinction between structured data and unstructured data applies to all types of information. Structured data is not fully dependent on an established standard. Established standards facilitate the exchange of the information across providers by ensuring data is structured in the same way. However, structured data within certified EHR technology merely requires the system to be able to identify the data as providing specific information. This is commonly accomplished by creating fixed fields within a record or file, but not solely accomplished in this manner. For example, in this case for it to be structured, if the patient is on aspirin, then that information should be in the system so that it can be automatically identified as a medication and not as an order, note, or anything else. An example of unstructured data would be the word aspirin, but no ability of the system to identify it as a medication.

Comment: A few commenters pointed out their current health information system vendor does not utilize RxNorm as its standard.

Response: This is a certification issue best addressed in the ONC final rule. We therefore have referred these comments to ONC for their consideration.

Comment: We received comments suggesting that this requirement could create additional privacy/security concerns for patients who do not want all physicians and their clinical staff to have access to their entire medication history. Examples provided included antidepressant, antipsychotic or erectile dysfunction medications.

Response: We are only concerned with medications that are known to the provider through querying the patient, their own records and the transfer of records from other providers. Meaningful use cannot address situations where the information is withheld from the EP, eligible hospital, or CAH by the patient or by other providers. We understand that some patients would prefer not to have their entire medical history available to all physicians and clinical staff. We also understand that laws in some states restrict the use and disclosure of information (including that related to medication) that may reveal that a patient has a specific health condition (for example, HIV). Recording data in a structured manner will facilitate the implementation of these preferences and policies in an electronic environment. It is easier to identify and potentially withhold specific data elements that have been recorded in a structured format than information recorded as free text.

After consideration of the public comments received, we are modifying the meaningful use measure for EPs at § 495.6(d)(5)(ii) and for eligible hospitals at § 495.6(f)(4)(ii) of our regulations to "More than 80 percent of all unique patients seen by the EP or admitted to the eligible hospital's or CAH's inpatient or emergency departments (POS 21 or 23) have at least one entry (or an indication that the patient is not currently prescribed any medication) recorded as structured data".

We further specify that in order to meet this objective and measure, an EP, eligible hospital, or CAH must use the capabilities Certified EHR Technology includes as specified and standards at 45 CFR 170.302(d). The ability to calculate the measure is included in certified EHR technology.

To calculate the percentage, CMS and ONC have worked together to define the following for this objective:

- *Denominator:* Number of unique patients seen by the EP or admitted to an eligible hospital's or CAH's inpatient or emergency departments (POS 21 or 23) during the EHR reporting period. A definition of unique patient is discussed under the objective of CPOE.
- *Numerator:* The number of patients in the denominator who have a medication (or an indication that the patient is not currently prescribed any medication) recorded as structured data.
- *Threshold:* The resulting percentage must be more than 80 percent in order for an EP, eligible hospital, or CAH to meet this measure. Detailed discussion of the more than 80 percent threshold can be found under the objective of maintaining an up-to-date problem list. We do not believe that any EP, eligible hospital or CAH would be in a situation where they would not need to know whether their patients are taking any medications. Therefore, there are no exclusions for this objective and its associated measure.

NPRM EP/Eligible Hospital Objective: Maintain active medication allergy list.

Comment: We received comments that limiting this list to medication allergies instead of all allergies was not consistent with efficient workflow and that all allergies should be housed in the same location within the EHR. Commenters also highlighted that lack of knowledge of other allergies such as latex and food allergies could lead to significant harm to the patient.

Response: We agree that information on all allergies, including non-medication allergies, provide relevant clinical quality data. However, while we agree that collecting all allergies would be an improvement, current medication allergy standards exists in a structured data format that may be implemented in Stage 1. We hope to expand this measurement to include all allergies as the standards evolve and expand to include non-medication allergies. We believe EP/eligible hospitals/CAHs should continue to document all allergies, regardless of origin, consistent with standard of care practice for that EP/eligible hospital/CAH. We encourage

them to work with the designers of their certified EHR technology to make this documentation as efficient and structured as possible.

Comment: A commenter inquired why the Substance Registration System Unique Ingredient Identifier (UNII) was not indicated for use until 2013 yet the measure requires the information to be recorded as structured data.

Response: Any standards for the structured vocabulary for medication allergies or other aspects of meaningful use are included in ONC final rule. Structured data does not require an established standard as discussed under the objective of maintaining a medication list.

Comment: We received a few comments requesting a definition of "allergy."

Response: We adopt the commonly held definition of an allergy as an exaggerated immune response or reaction to substances that are generally not harmful. The definition is derived from Medline Plus, a service of the U.S. National Library of Medicine and the National Institutes of Health.

After consideration of the public comments received, we are finalizing the meaningful use objective for EPs at 495.6(d)(6)(i) and for eligible hospitals and CAHs at 495.6(f)(5)(i) as proposed.

We include this objective in the core set as it is integral to the initial or on-going management of a patient's current or future healthcare and would give providers the necessary information to make informed clinical decisions for improved delivery of patient care.

NPRM 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.

Comment: Multiple commenters noted that "none" is not a typical value to describe the absence of allergies in medical documentation and should be replaced with "no known allergies (NKA)," "no known drug allergies (NKDA)" or "no known medication allergies (NKMA)."

Response: Our intent is not to dictate the exact wording of the specific value. Rather we are focused on the overall goal of making a distinction between a blank list that is blank because a patient does not have known allergies and a blank list because no inquiry of the patient has been made or no information is available from other sources. As long as the indication accomplishes this goal and is structured data, we do not believe it is necessary to prescribe the exact terminology, preferring to leave that level of detail to the designers and users of certified EHR technology.

Comment: Given that the measure is only a one time check for a single entry, one commenter questioned whether this measure truly constitutes maintenance of an "active" list.

Response: We agree that this measure does not ensure that every patient under the care of every EP, eligible hospital, or CAH has an active or up-to-date medication list. However, not every EP comes in contact with the patient, and therefore has the opportunity to update the list. Nor do we believe that an EP, eligible hospital, or CAH should be required through meaningful use to update the list at every contact with the patient. There is also the consideration of the burden that reporting places on the EP, eligible hospital, or CAH. The measure as finalized ensures that the EP, eligible hospital, or CAH has not ignored having a medication allergy list for patients seen during the EHR reporting period and that at least one piece of information on medication allergies is presented to the EP, eligible hospital, or CAH. The EP, eligible hospital, or CAH can then use their judgment in deciding what further probing or updating may be required given the clinical circumstances at hand. Therefore, we are maintaining the measure of a one-time check for a single entry.

Comment: Several commenters recommended eliminating the percentage measurement and allowing the provider to attest that active medication lists are maintained in the certified EHR technology.

Response: We are retaining a percentage for the reasons discussed previously in this section under our discussion of the burden created by the measures associated with the Stage 1 meaningful use objectives. For the same reasons we explained under the discussion of up-to-date problem list, medication-allergy list is a functionality for which there is an existing standard of practice, it is foundational data capture function to make more advanced clinical processes possible, and complying is fundamentally within the provider's control. Therefore, we maintain the reasonably high threshold of 80 percent because the existing infrastructure and expectations support this target.

After consideration of the public comments received, we are modifying the meaningful use measure for EPs at § 495.6(d)(6)(ii) and for eligible hospitals at § 495.6(f)(5)(ii) of our regulations to "More than 80 percent of all unique patients seen by the EP or admitted to the eligible hospital's or CAH's inpatient or emergency departments (POS 21 or 23) have at least one entry (or an indication that the patient has no known medication allergies) recorded as structured data".

We further specify that in order to meet this objective and measure, an EP, eligible hospital, or CAH must use the capabilities Certified EHR Technology includes as specified and standards at 45 CFR 170.302(e). The ability to calculate the measure is included in certified EHR technology.

To calculate the percentage, CMS and ONC have worked together to define the following for this objective:

- *Denominator:* Number of unique patients seen by the EP or admitted to an eligible hospital's or CAH's inpatient or emergency departments (POS 21 or 23) during the EHR reporting period. The definition of "a unique patient" is provided under the objective of CPOE.
- *Numerator:* The number of unique patients in the denominator who have at least one entry (or an indication that the patient has no known medication allergies) recorded as structured data in their medication allergy list.
- *Threshold:* The percentage must be more than 80 percent in order for an EP, eligible hospital, or CAH to meet this measure. Detailed discussion of the rationale more than 80 percent threshold can be found at under the objective of maintain an up-to-date problem list.

We do not believe that any EP, eligible hospital or CAH would be in a situation where they would not need to know whether their patients have medication allergies and therefore do not establish an exclusion for this measure.

NPRM EP Objective: Record the following demographics: Preferred language, insurance type, gender, race and ethnicity, and date of birth.

NPRM Eligible Hospital Objective: 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.

In the proposed rule, we noted 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 maintain that proposal for the final rule.

Comment: Some commenters requested clarification of whether all of the demographics are required and under what circumstances no indication might be acceptable. Examples of acceptable circumstances from commenters include patient unwillingness to report, language

barriers, and requirement to report ethnicity and/or race contrary to some state laws.

Response: In general, we do require that all demographic elements that are listed in the objective be included in a patient's record in certified EHR technology. However, we do not desire, nor could we require, that a patient provide this information if they are otherwise unwilling to do so. Similarly, we do not seek to preempt any state laws prohibiting EPs, eligible hospitals, or CAHs from collecting information on a patient's ethnicity and race. Therefore if a patient declines to provide the information or if capturing a patient's ethnicity or race is prohibited by state law, such a notation entered as structured data would count as an entry for purposes of meeting the measure.

Comment: Several commenters asked for clarity on the definition of preferred language. Commenters also indicated that standards are in development (ISO 639 and ANSIX12N Claim/Reporting Transaction). Some commenters also requested that we include the requirement that the EP, eligible hospital or CAH also communicate with the patient in their preferred language.

Response: Preferred language is the language by which the patient prefers to communicate. This is just a record of the preference. We do not have the authority under the HITECH Act to require providers to actually communicate with the patient in his or her preferred language, and thus do not require EPs, eligible hospitals, and CAHs to do so in order to qualify as a meaningful EHR user as suggested by some commenters. In regards to standards, those would be adopted under the ONC final rule.

Comment: Some commenters also requested clarity on the definition of race and ethnicity. Some commenters noted an Institute of Medicine report entitled "Race, Ethnicity and Language Data: Standardization for Health Care Quality Improvement", which makes recommendations for how to ask questions to collect information and builds on the OMB Standards for language, race and ethnicity. Some commenters were also concerned about situations where the available choices were not granular enough, did not properly account for mixed race and ethnicity, and when the patient did not know their ethnicity.

Response: In the proposed rule, we said that EPs, eligible hospitals and CAHs, should use the race and ethnicity codes that follow current federal standards published by the Office of Management and Budget (*http://www.whitehouse.gov/omb/inforeg_statpolicy/#dr*). We continue to believe that these standards should be applied for purposes of implementing the Stage 1 meaningful use objectives, but will consider whether alternative standards or additional clarification would be appropriate for future stages of meaningful use criteria. We believe it is beyond the scope of the definition of meaningful use to provide additional definitions for race and ethnicity beyond what is established by OMB. In regards to patients who do not know their ethnicity, EPs, eligible hospitals, and CAHs should treat these patients the same way as patients who decline to provide the race or ethnicity, that is, they should identify in the patient record that the patient declined to provide this information.

Comment: Some commenters requested additional clarity on insurance type and others recommended the elimination of insurance type due to the complexity of insurance coverage, the function of the EHR as a medical tool and not a financial one, the volatility of this information due to patients frequently changing plans and concerns that information on a patient's insurance status will have a possible behavioral influence on the providers if this information were presented.

Response: Classifying insurance involves two distinctions—the source of coverage and insurance design. Source of coverage refers to the type of funding, such as public, private or self-pay. The design of the insurance program, such as health maintenance program (HMO), preferred provider organization (PPO), high-deductible consumer directed plan, fee-for-service, etc. Although not specified in the proposed rule, by insurance type we were referring to the first distinction—the source of funding for the insurance. We found two initiatives that could provide clarity on type. The first is the "Source of Payment Typology" developed by the Public Health Data Standards Consortium (*http://www.phdsc.org/standards/payer-typology.asp*). The consortium is currently in the process of working with States to implement this typology. The other initiative is established in the Uniform Data Set (UDS) collected by HRSA (*http://www.hrsa.gov/data-statistics/health-center-data/index.html*). The information in the UDS contains several caveats, however, that make it difficult to be used by all EPs, eligible hospitals and CAHs, and it does not accommodate patients with multiple types of insurance such as those dually eligible for Medicare and Medicaid or for those with both Medicare and MediGap coverage. Many EHRs that currently report on HRSA UDS Insurance Type standards account for multiple types of insurance by maintaining separate Reporting Insurance Groups and deriving the Insurance Type data from the primary insurance company on the encounter and mappings to that Insurance Type Reporting Group. This information is documented at the patient demographic level or the patient encounter/progress note. Given the complexity of defining insurance type and attributing it to patients in an agreed upon way, we are eliminating "insurance type" from this meaningful use objective.

Comment: A minority of commenters commenting on this objective recommended that CMS remove cause of death from the objective for eligible hospitals. The most common rationale is that the coroner or medical examiner officially determines cause of death when the case is referred to them. By law, the hospital cannot declare a cause of death in these cases.

Response: When a patient expires, in the routine hospital workflow, a clinician evaluates the patient to pronounce the patient's death. The clinician typically documents in the patient's chart, the sequence of events leading to the patient's death, conducts the physical exam and makes a preliminary assessment of the cause of death. We are requiring that eligible hospitals record in the patient's EHR the clinical impression and preliminary assessment of the cause of death, and not the cause of death as stated in any death certificate issued by the Department of Health or the coroner's office.

Comment: A few commenters requested inclusion of Advanced Directives under this objective as recommended by the HIT Policy Committee.

Response: We discuss advance directives separately in this final rule under its own objective.

Comment: Several commenters recommended requiring the submission of the demographic data to CMS.

Response: Stage 1 of meaningful use seeks to ensure certified EHR technology has the capability to record demographic information and that those capabilities are utilized. We believe the information recorded for this measure is for provider use in the treatment and care of their patients and therefore should not be submitted to CMS at this time.

Comment: Commenters suggested requiring the use of the demographic data from this measure to stratify clinical quality measure reporting and

the generation of reports for patient outreach and quality initiatives.

Response: While we encourage all providers and EHR developers to work together to develop reporting from the EHR system for use in the improvement of population and public health, for purposes of becoming a meaningful EHR user in Stage 1, we only require the recording of the specified demographics.

After consideration of the public comments received, we are modifying meaningful use objective at § 495.6(d)(7)(i) of our regulations for EPs to "Record the following demographics: Preferred language, gender, race and ethnicity, and date of birth".

After consideration of the public comments received, we are modifying meaningful use objective at § 495.6(f)(6)(i) of our regulations for eligible hospitals and CAHs to "Record the following demographics: Preferred language, gender, race and ethnicity, date of birth, and date and preliminary cause of death in the event of mortality in the eligible hospital or CAH".

We include this objective in the core set as it is integral to the initial or on-going management of a patient's current or future healthcare, recommended by the HIT Policy Committee and would give providers the necessary information to make informed clinical decisions for improved delivery of patient care.

NPRM 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.

Comment: Commenters said that this should be replaced with a count or attestation or alternatively that the threshold was too high.

Response: We are maintaining a percentage for the reasons discussed previously in this section under our discussion of the burden created by the measures associated with the Stage 1 meaningful use objectives. However, we do reduce the threshold to over 50 percent as this objective meets the criteria of relying 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. In contrast to our discussion of maintaining an up-to-date problem list/medication list/medication allergy list, we believe that some demographic elements (especially race, ethnicity and language) are not as straightforward to collect as objective data elements and therefore the standard of practice for demographic data is still evolving. As we believe this measure may not be within current standard of practice, we are adopting the lower threshold of 50 percent (rather than 80 percent).

After consideration of the public comments received, we are modifying the meaningful use measure for EPs at § 495.6(d)(7)(ii) and for eligible hospitals at § 495.6(f)(6)(ii) of our regulations to "More than 50 percent of all unique patients seen by the EP or admitted to the eligible hospital's or CAH's inpatient or emergency department (POS 21 or 23) have demographics recorded as structured data".

We further specify that in order to meet this objective and measure, an EP, eligible hospital, or CAH must use the capabilities Certified EHR Technology includes as specified and standards at 45 CFR 170.304(c) for EPs and 45 CFR 170.304(b) for eligible hospitals and CAHs. The ability to calculate the measure is included in certified EHR technology.

To calculate the percentage, CMS and ONC have worked together to define the following for this objective:

- *Denominator:* Number of unique patients seen by the EP or admitted to an eligible hospital's or CAH's inpatient or emergency departments (POS 21 or 23) during the EHR reporting period. A unique patient is discussed under the objective of CPOE.
- *Numerator:* The number of patients in the denominator who have all the elements of demographics (or a specific exclusion if the patient declined to provide one or more elements or if recording an element is contrary to state law) recorded as structured data.
- *Threshold:* The resulting percentage must be more than 50 percent in order for an EP, eligible hospital or CAH to meet this measure. Most EPs and all eligible hospitals and CAHs would have access to this information through direct patient access. Some EPs without direct patient access would have this information communicated as part of the referral from the EP who identified the service as needed by the patient. Therefore, we did not include an exclusion for this objective and associated measure.

NPRM EP/Eligible Hospital Objective: 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.

In the proposed rule, we described why we included growth charts in this objective. The reason given was that BMI was not a sufficient marker for younger children.

Comment: Over two thirds of the commenters commenting on this objective expressed concern about the applicability of the listed vital signs to all provider types and care settings.

Response: While this objective could be met by receiving this information from other providers or non-provider data sources, we recognize that the only guaranteed way for a provider to obtain this information is through direct patient interaction and that this information is not always routinely provided from the EP ordering a service because of a direct patient interaction. EPs who do not see patients 2 years or older would be excluded from this requirement as described previously in this section under our discussion of whether certain EP, eligible hospital or CAH can meet all Stage 1 meaningful use objectives given established scopes of practices. We would also allow an EP who believes that measuring and recording height, weight and blood pressure of their patients has no relevance to their scope of practice to so attest and be excluded.

Comment: Several commenters stated this objective should be removed in favor of clinical quality measures addressing BMI and blood pressure as these measures serve the same purpose and to require both is to require duplicative reporting.

Response: We disagree that these two measures serve the same purpose and therefore that the measure should be eliminated in favor of clinical quality measures addressing BMI and blood pressure. The objective included here seeks to ensure that information on height, weight and blood pressure and the extractions based on them are included in the patient's record. Furthermore, the objective seeks to ensure that the data is stored in a structured format so that it can be automatically identified by certified EHR technology for possible reporting or exchanging. We also note that the clinical quality measure focuses on a smaller subset of the patient population.

After consideration of the public comments received, we are finalizing the objective for EPs at 495.6(d)(8)(i) and for eligible hospitals and CAHs at 495.6(f)(7)(i) as proposed.

We include this objective in the core set as it is integral to the initial or on-going management of a patient's current or future healthcare and would give providers the necessary information to make informed clinical decisions for improved delivery of patient care.

NPRM 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.

Comment: Commenters suggested replacement of the percentage measurement with a count or attestation or alternatively that that the threshold was too high.

Response: We are retaining a percentage for the reasons discussed previously in this section under our discussion of the burden created by the measures associated with the Stage 1 meaningful use objectives. However, we did reduce the threshold from 80 percent to greater than 50 percent as this objective meets the criteria of relying 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. In addition, in contrast to the measures associated with maintaining an up-to-date problem list, an active medication list, and an active medication-allergy list, we believe that for many specialties, the current practice on vital signs may not be as well-established. We believe there may not be the same level of consensus regarding the relevance to patient care of vital signs for many specialties and the frequency with which such vital signs should be collected. Thus, for this measure, we adopt a percentage of 50 percent, rather than 80 percent.

Comment: Commenters requested clarification of the frequency and methods of recording the vital signs included in the measure.

Response: As discussed in the objective, the EP/eligible hospital/CAH is responsible for height, weight and blood pressure so we will focus our discussion on those items. First, we do not believe that all three must be updated by a provider at every patient encounter nor even once per patient seen during the EHR reporting period. For this objective we are primarily concerned that some information is available to the EP/eligible hospital/CAH, who can then make the determination based on the patient's individual circumstances as to whether height, weight and blood pressure needs to be updated. The information can get into the patient's medical record as structured data in a number of ways. Some examples include entry by the EP/eligible hospital/CAH, entry by someone on the EP/eligible hospital/CAH's staff, transfer of the information electronically or otherwise from another provider or entered directly by the patient through a portal or other means. The measure hinges on access of the information. Therefore, any EP/eligible hospital/CAH that sees/admits the patient and has access to height, weight and blood pressure information on the patient can put that patient in the numerator.

Comment: Some commenters requested clarification regarding the role of both the EP/eligible hospital/CAH and the certified EHR technology for the calculation of BMI and the plotting and displaying of growth charts. Other commenters recommended the exclusion of growth charts for certain patients and care settings. Another commenter also expressed the desire for the exclusion of growth charts for patients over the age of 18, inpatient care settings and more specifically, non-pediatric inpatient care settings.

Response: We believe a clarification is in order about which of the listed vital signs are data inputs to be collected by the EP/eligible hospital/CAH and which are calculations made by the certified EHR technology. The only information required to be inputted by the provider is the height, weight and blood pressure of the patient. The certified EHR technology will calculate BMI and the growth chart if applicable to patient based on age. As this requirement imposes no duty or action on the provider, we see no reason to limit its availability to any EP, eligible hospital, or CAH based on setting or other consideration. Concerns on presentation and interface are best left to designers of certified EHR technology and users. Finally, as certified EHR technology is able to automatically generate BMI and the growth chart if height and weight are entered as structured data we see no reason to include BMI and growth chart in the measure. We therefore will limit the final measure to data requiring provider data entry points.

Comment: A few commenters suggested that "reported height" by the patient should be acceptable when measurement is not appropriate such as in the case of severe illness.

Response: We agree and would allow height self-reported by the patient to be used.

After consideration of the public comments received, we are modifying the meaningful use measure for EPs at 495.6(d)(8)(ii) and for eligible hospitals § 495.6(f)(7)(ii) of our regulations to "For more than 50 percent of all unique patients age 2 and over seen by the EP or admitted to eligible hospital's or CAH's inpatient or emergency department (POS 21 or 23), height, weight and blood pressure are recorded as structured data".

We further specify that in order to meet this objective and measure, an EP, eligible hospital, or CAH must use the capabilities Certified EHR Technology includes as specified and standards at 45 CFR 170.302(f). The ability to calculate the measure is included in certified EHR technology.

As noted previously in this section under our discussion of the burden created by the measures associated with the Stage 1 meaningful use objectives, the percentage is based on patient records that are maintained using certified EHR technology. To calculate the percentage, CMS and ONC have worked together to define the following for this objective:

- *Denominator:* Number of unique patients age 2 or over seen by the EP or admitted to an eligible hospital's or CAH's inpatient or emergency department (POS 21 or 23) during the EHR reporting period. A unique patient is discussed under the objective of CPOE.
- *Numerator:* The number of patients in the denominator who have at least one entry of their height, weight and blood pressure are recorded as structure data.
- *Threshold:* The resulting percentage must be more than 50 percent in order for an EP, eligible hospital, or CAH to meet this measure. As addressed in other objectives and in comment response, an EP who sees no patients 2 years old or younger would be excluded from this requirement as described previously in this section under our discussion of whether certain EP, eligible hospital or CAH can meet all Stage 1 meaningful use objectives given established scopes of practices. We would also allow an EP who believes that all three vital signs of height, weight and blood pressure have no relevance to their scope of practice to so attest and be excluded. However, we believe this attestation and exclusion from recording height, weight, and blood pressure does not hold for other patient specific information collection objectives, like maintaining an active medication allergy list. We do not believe that any EP would encounter a situation where the patient's active medication and allergy list is not pertinent to care and therefore would be outside of the scope of work for an EP. We believe the exclusion based on EP determination of their scope of practice for the record vital signs objective, as written in Stage 1, should be studied for relevance in further stages. We do not believe eligible hospitals or CAHs would ever only have a patient population for patients 2 years old or younger or that these vital signs would have no relevance to their scope of practice. Therefore, we do not include an exclusion for eligible hospitals or CAHs.

NPRM EP/Eligible Hospital Objective: Record smoking status for patients 13 years old or older

In the proposed rule, we explained that we believe it is necessary to add an age restriction to this objective as we do not believe this objective is applicable to patients of all ages and there is no consensus in the health care community as to what the appropriate cut off age may be. We encouraged comments on whether this age limit should be lowered or raised. We received many comments on the age limit and address them below.

Comment: Several commenters requested a different age limitation. Commenters suggested ages anywhere between 5 years old up to 18 years old.

Response: For the purposes of this objective and for meaningful use, our interest is focused on when a record of smoking status should be in every patient's medical record. Recording smoking status for younger patients is certainly not precluded. We do believe there would be situations where an EP/eligible hospital/CAH's knowledge about other risk factors would indicate that they should inquire about smoking status if it is unknown for patients under 13 years old. However, in order to accurately measure and thereby assure meaningful use, for this objective we believe that the age limit needs to be high enough so that the inquiry is appropriate for all patients. Therefore, we are maintaining the age limitation at 13 years old or older.

Comment: Some commenters suggested expanding smoking status to any type of tobacco use.

Response: While we agree that an extended list covering other types of tobacco use may provide valuable insight for clinical care for certified EHR technology ONC has adopted the CDC's NHIS standard recodes for smoking status. This will provide a standard set of questions across providers and standardize the data. The extended list does not make the collection of multiple survey questions clear. For example, a patient may be a current tobacco user as well as a smoker. For these reason in Stage 1 we will use the standards adopted by ONC for certified EHR technology at 45 CFR 170.302(g). For future stages, we will review this measure for possible inclusion of other questions. This is a minimum set. We do not intend to limit developers of EHR technology from creating more specific fields or to limit EPs/eligible hospitals/CAHs from recording more specific information.

Comment: We also received comments requesting that second-hand smoking be included in the objective for children and adolescents.

Response: Including second-hand smoking introduces much more variability into the objective as to what constitutes a level of exposure and difficulty in measuring it successfully with different age limits to different aspects. For instance, how much exposure is acceptable for a given age and how is such exposure determined? How would these differing requirements be accounted for by certified EHR technology? As with the change from smoking status to tobacco use, we believe this introduces an unacceptable level of complexity for Stage 1 of meaningful use. For Stage 1 of meaningful use we are not adding second hand smoke exposure to this objective. However, we remind EPs, eligible hospitals and CAHs that nothing about the criteria for meaningful use prevents them from working with their EHR developer to ensure that their EHR system meets their needs and the needs of their patient population. We encourage all EPs, eligible hospitals and CAHs to critically review their implementation in light of their current and future needs both to maximize their own value and to prepare for future stages of meaningful use.

Comment: We received comments asking at what frequency the information must be recorded and whether the information can be collected by support staff.

Response: We clarify that this is a check of the medical record for patients 13 years old or older. If this information is already in the medical record available through certified EHR technology, we do not intend that an inquiry be made every time a provider sees a patient 13 years old or older. The frequency of updating this information is left to the provider and guidance is provided already from several sources in the medical community. The information could be collected by any member of the medical staff.

Comment: We received a number of comments recommending either removing this objective to record smoking status from the HIT functionality objectives or removing the smoking measure from the core clinical quality measures as these measures serve the same purpose and to require both is to require duplicative reporting.

Response: We disagree that these two measures serve the same purpose and therefore only one should be included. The objective included here seeks to ensure that information on smoking status is included in the patient's record. Furthermore, that the information is stored in a structured format so that it can automatically be identified by certified EHR technology as smoking status for possible reporting or exchanging. We also note that the clinical quality measure only focuses on patients 18 years or older, while the objective focuses on patients 13 years or older. In addition, many quality measures related to smoking are coupled with follow-up actions by the provider such as counseling. We consider those follow-up actions to be beyond the scope of what we hope to achieve for this objective for Stage 1 of meaningful use.

After consideration of the public comments received, we are finalizing the meaningful use objective for EPs at § 495.6(d)(9)(i) and for eligible hospitals at § 495.6(f)(8)(i) of our regulations as proposed.

We include this objective in the core set as it is integral to the initial or on-going management of a patient's current or future healthcare and would give providers the necessary information to make informed clinical decisions for improved delivery of patient care.

NPRM 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.

In the proposed rule, discussion of this measure referenced other sections exclusively.

Comment: We received comments recommending alternative thresholds for this measure. Commenters provided thresholds ranging from anything greater than zero to 60 percent in stage 1.

Response: In the proposed rule, we established a consistent threshold for measures not requiring the exchange of information. For the final rule, (other than up-to-date problem list, active medication list and active medication-allergy list), we have lowered the threshold associated with these measures to 50 percent. In our discussion of the objective, we noted many concerns by commenters over the appropriate age at which to inquire about smoking status. There were also considerable differences among commenters as to what the appropriate inquiry is and what it should include. Due to these concerns, we do not believe this objective and measure fit into the threshold category described under up-to-date problem lists and therefore we adopt a 50 percent (rather than an 80 percent) threshold for this measure. After consideration of the public comments received, we are modifying the meaningful use measure for EPs at § 495.6(d)(9)(ii) and for eligible hospitals at § 495.6(f)(8)(ii) of

our regulations to "More than 50 percent of all unique patients 13 years old or older seen by the EP or admitted to the eligible hospital's or CAH's inpatient or emergency departments (POS 21 or 23) have smoking status recorded as structured data".

We further specify that in order to meet this objective and measure, an EP, eligible hospital, or CAH must use the capabilities Certified EHR Technology includes as specified and standards at 45 CFR 170.302(g). The ability to calculate the measure is included in certified EHR technology.

As noted previously in this section under our discussion of the burden created by the measures associated with the Stage 1 meaningful use objectives, the percentage is based on patient records that are maintained using certified EHR technology.

To calculate the percentage, CMS and ONC have worked together to define the following for this objective:

• *Denominator:* Number of unique patients age 13 or older seen by the EP or admitted to an eligible hospital's or CAH's inpatient or emergency departments (POS 21 or 23) during the EHR reporting period. A unique patient is discussed under the objective of maintaining an up-to-date problem list.

• *Numerator:* The number of patients in the denominator with smoking status recorded as structured data.

• *Threshold:* The resulting percentage must be more than 50 percent in order for an EP, eligible hospital, or CAH to meet this measure. As addressed in other objectives, EPs, eligible hospitals or CAHs who see no patients 13 years or older would be excluded from this requirement as described previously in this section under our discussion of whether certain EP, eligible hospital or CAH can meet all Stage 1 meaningful use objectives given established scopes of practices. Most EPs and all eligible hospitals and CAHs would have access to this information through direct patient access. Some EPs without direct patient access would have this information communicated as part of the referral from the EP who identified the service as needed by the patient. Therefore, we did not include an exclusion based on applicability to scope of practice or access to the information for this objective and associated measure.

NPRM EP/Eligible Hospital Objective: Record advance directives.

In the proposed rule, we discussed this objective, but did not propose it as a requirement for demonstrating meaningful use, for a number of reasons, including: (1) It was unclear whether the objective would be met by indicating that an advance directive exists or by including the contents of the advance directive; (2) the objective seems relevant only to a limited and undefined patient population when compared to the patient populations to which other objectives of Stage 1 of meaningful use apply; and (3) we believe that 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 require information about a patient's advance directive only in rare circumstances.

Comment: We received several comments including a comment from the HIT Policy Committee that we should include advance directives in the final rule. The HIT Policy Committee clarified that this would be an indication of whether a patient has an advanced directive. Furthermore, they recommend limiting this measure to patients 65 and older. We received other comments that said this should be a requirement for eligible hospitals. Other commenters reported that having this information available for the patient would allow eligible hospitals to make decisions that were better aligned with the patient's expressed wishes.

Response: In the proposed rule, we said that confusion as to whether this objective would require an indication of the existence of an advanced directive or the contents of the advance directive itself would be included in certified EHR technology was one of the reasons for not including the objective in Stage 1 of meaningful use. We expressed concerns that the latter would not be permissible in some states under existing state law. As commenters have clarified that advance directives should be just an indication of existence of an advance directive and recommended a population to apply the measure to, we reinstate this objective for eligible hospitals and CAHs. We believe that the concern over potential conflicts with state law are alleviated by limiting this to just an indication. We also believe that a restriction to a more at risk population is appropriate for this measure. By restricting the population to those 65 years old and older, we believe we focus this objective appropriately on a population likely to most benefit from compliance with this objective and its measure. This objective is in the menu set so if an eligible hospital or CAH finds they are unable to meet it then can defer it. However, we believe 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 require information about a patient's advance directive in rare circumstances. For other meaningful use objectives, we have focused our exclusions on rare situations, which would not be the case for this objective. Therefore, we do not include this objective for EPs.

After consideration of the public comments received, we are including this meaningful use objective for eligible hospitals and CAHs at § 495.6(g)(2)(i) of our regulations as "Record whether a patient 65 years old or older has an advanced directive as structured data ".

NPRM EP/Eligible Hospital Measure: N/A.

While we did not receive specific percentage recommendations from commenters, this objective is the recording of a specific data element as structured data in the patient record. This is identical to other objectives with established measures such as, recording vital signs, recording demographics and recording smoking status. Therefore, we adopt the measure format and the lower threshold (50 percent) from those objectives. We also believe that this information is a level of detail that is not practical to collect on every patient admitted to the eligible hospital's or CAH's emergency department, and therefore, have limited this measure only to the inpatient department of the hospital.

In the final rule, this meaningful use measure for eligible hospitals at § 495.6(g)(2)(ii) of our regulations: "More than 50 percent of all unique patients 65 years old or older admitted to the eligible hospital's or CAH's inpatient department (POS 21) have an indication of an advance directive status recorded as structured data".

We further specify that in order to meet this objective and measure, an EP, eligible hospital, or CAH must use the capabilities Certified EHR Technology includes as specified and standards at 45 CFR 170.306(h). The ability to calculate the measure is included in certified EHR technology.

As noted previously in this section under our discussion of the burden created by the measures associated with the Stage 1 meaningful use objectives, the percentage is based on patient records that are maintained using certified EHR technology.

To calculate the percentage, CMS and ONC have worked together to define the following for this objective:

• *Denominator:* Number of unique patients age 65 or older admitted to an eligible hospital's or CAH's inpatient department (POS 21) during the EHR

reporting period. A unique patient is discussed under the objective of CPOE.

- *Numerator:* The number of patients in the denominator with an indication of an advanced directive entered using structured data.
- *Threshold:* The resulting percentage must be more than 50 percent in order for eligible hospital or CAH to meet this measure. An exclusion, as described previously in this section under our discussion of whether certain EP, eligible hospital or CAH can meet all Stage 1 meaningful use objectives given established scopes of practices, would apply to an eligible hospital or CAH who admits no patients 65 years old or older during the EHR reporting period.

NPRM EP/Eligible Hospital Objective: Incorporate clinical lab-test results into EHR as structured data.

In the proposed rule, we defined structured data as data that has a specified data type and response categories within an electronic record or file. We have revised that definition for the final rule as discussed below.

Comment: Some commenters requested clarification on what constitutes structured data.

Response: The distinction between structured data and unstructured data applies to all types of information. Structured data is not fully dependent on an established standard. Established standards facilitate the exchange of the information across providers by ensuring data is structured in the same way. However, structured data within certified EHR technology merely requires the system to be able to identify the data as providing specific information. This is commonly accomplished by creating fixed fields within a record or file, but not solely accomplished in this manner.

After consideration of the public comments received, we finalize the meaningful use objective or EPs at § 495.6(e)(2)(i) and eligible hospitals and CAHs at § 495.6(g)(3)(i) as proposed.

NPRM 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 either in a positive/negative or numerical format are incorporated in certified EHR technology as structured data.

In the proposed rule, we identified this objective and associated measure as dependent on electronic exchange and therefore requiring special consideration in establishing the threshold. We said that we are cognizant that in most areas of the country, the infrastructure necessary to support such exchange is still being developed. Therefore, we stated our belief that 80 percent is too high a threshold for the Stage 1 criteria of meaningful use. As an alternative, we proposed 50 percent as the threshold based on our discussions with EHR vendors, current EHR users, and laboratories. We then invited comment on whether 50 percent is feasible for the Stage 1 criteria of meaningful use. Finally, we indicated that we anticipate raising the threshold in future stages of meaningful use as the capabilities of HIT infrastructure increase. We received several comments on the appropriateness of this 50 percent threshold and discuss them in the comment and response section below.

Comment: Commenters requested clarification as to whether the measure includes only electronic exchange of information with a laboratory or if it also includes manual entry.

Response: We encourage every EP, eligible hospital and CAH to utilize electronic exchange of the results with the laboratory based on the certification and standards criteria in the 45 CFR 170.302(h). If results are not received in this manner, then they are presumably received in another form such as fax, telephone call, mail, etc. These results then must be incorporated into the patient's medical record in some way. We encourage that this way use structured data; however, that raises the concerns about the possibility of recording the data twice; for example scanning the results and then entering the results as structured data. Telephoned results could be entered directly. We also recognize the risk of entry error, which is why we highly encourage the electronic exchange of the results with the laboratory, instead of manual entry through typing, option selecting, scanning or other means. Reducing the risk of entry error is one of the primary reasons we lowered the measure threshold for Stage 1 during which providers are changing their workflow processes to accurately incorporate information into EHRs through either electronic exchange or manual entry. However, for this measure, we do not limit the EP, eligible hospital or CAH to only counting structured data received via electronic exchange, but count in the numerator all structured data. By entering these results into the patient's medical record as structured data, the EP, eligible hospital or CAH is accomplishing a task that must be performed regardless of whether the provider is attempting to demonstrate meaningful use or not. We believe that entering the data as structured data encourages future exchange of information.

Comment: A majority of commenters commenting on this measure believe the proposed 50 percent threshold is too high. Suggestions for alternative thresholds ranged from more than zero to eighty percent. Some commenters suggested that the percentage calculation be replaced with a numeric count.

Response: We are finalizing a percentage calculation for the reasons discussed previously in this section under our discussion of the burden created by the measures associated with the Stage 1 meaningful use objectives. We based the 50 percent threshold in the proposed rule on our discussions with EHR vendors, current EHR users, and laboratories and specifically requested comment on whether the 50 percent threshold was feasible. While only a small number of commenters commented on this objective, those that did were overwhelming in favor of either a count or a lower threshold. EPs especially were concerned with our inability to impose any requirements on laboratory vendors. Based on the comments received, we have modified our assessment of the current environment for incorporating lab results into certified EHR technology, and believe that a threshold lower than fifty percent is warranted. We want to create a threshold that encourages, but does not require, the electronic exchange of this information and commenters indicated that 50 percent was too high given the current state of electronic exchange of lab results. Therefore, we lower the threshold to 40 percent.

Comment: Commenters requested clarification on what types of laboratories could generate the lab results.

Response: The focus of this objective is to get as many lab results as possible into a patient's electronic health record as structured data. Limiting the objective to a specific type of laboratory would not further this objective so therefore we leave it open to all lab tests and laboratories.

Comment: Several commenters expressed concern regarding the financial burden of establishing lab interfaces, especially for smaller hospitals and practices.

Response: The ability to exchange information is a critical capability of certified EHR technology. Exchange between lab and provider and provider to provider of laboratory results reduces errors in recording results and prevents the duplication of testing. Therefore, we continue to include this objective within Stage 1 of meaningful use although as noted above the measure

does not rely on the electronic exchange of information between the lab and the provider.

Comment: We received comments requesting a listing of laboratory tests with results that are in a numerical or positive/negative format.

Response: We consider it impractical to develop an exhaustive list of such tests. Moreover, we believe further description of these tests is unnecessary. It should be self-evident to providers when a test returns a positive or negative result or a result expressed in numeric characters. In these case, the results should be incorporated into a patient's EHR as structured data.

Comment: Several commenters pointed out that many current EHR vendors do not support the use of LOINC® codes and there is no federal regulatory requirement for labs to transmit using this code set or for that matter, any structured code set.

Response: Standards such as LOINC® codes are included in the ONC final rule. However, this measure requires incorporation of lab test results as structured data, but does not include a requirement for transmission or electronic receipt of the results using certified EHR technology.

After consideration of the public comments received, we are modifying the meaningful use measure for EPs at § 495.6(e)(2)(ii) and eligible hospitals at § 495.6(g)(3)(ii) of our regulations to "More than 40 percent of all clinical lab tests results ordered by the EP or by an authorized provider of the eligible hospital or CAH for patients admitted to its inpatient or emergency department (POS 21 or 23) during the EHR reporting period whose results are in either in a positive/negative or numerical format are incorporated in certified EHR technology as structured data".

We further specify that in order to meet this objective and measure, an EP, eligible hospital, or CAH must use the capabilities Certified EHR Technology includes as specified and standards at 45 CFR 170.302(h). The ability to calculate the measure is included in certified EHR technology.

As noted previously in this section under our discussion of whether certain EP, eligible hospital or CAH can meet all Stage 1 meaningful use objectives given established scopes of practices, the percentage is based on labs ordered for patients whose records are maintained using certified EHR technology.

To calculate the percentage, CMS and ONC have worked together to define the following for this objective:

- *Denominator:* Number of lab tests ordered during the EHR reporting period by the EP or authorized providers of the eligible hospital or CAH for patients admitted to an eligible hospital's or CAH's inpatient or emergency department (POS 21 & 23) whose results are expressed in a positive or negative affirmation or as a number.
- *Numerator:* The number of lab test results whose results are expressed in a positive or negative affirmation or as a number which are incorporated as structured data.
- *Threshold:* The resulting percentage must be more than 40 percent in order for an EP, eligible hospital, or CAH to meet this measure.

If an EP orders no lab tests whose results are either in a positive/negative or numeric format during the EHR reporting period they would be excluded from this requirement as described previously in this section under our discussion of whether certain EP, eligible hospital or CAH can meet all Stage 1 meaningful use objectives given established scopes of practices. We do not believe any eligible hospital or CAH would order no lab tests whose results are either in a positive/negative or numeric format during the EHR reporting period.

NPRM EP/Eligible Hospital Objective: Generate lists of patients by specific conditions to use for quality improvement, reduction of disparities, research, and outreach.

Comment: A few commenters recommended eliminating this requirement because they believe it is redundant of clinical quality reporting.

Response: We disagree that this is redundant of clinical quality reporting. Clinical quality reporting does not guarantee usability for all the purposes in the objective. One example of such a use is a provider could not only generate list of patients with specific conditions, but could stratify the output using other data elements in the certified EHR technology that are entered as structured data. The lists could also be utilized at an aggregate level for purposes of research into disparities, which could result in targeted outreach efforts.

Comment: Some commenters requested that if we finalize our proposal to only require one report that we change the "and" in the objective to "or".

Response: We are finalizing our measurement of only requiring one report for Stage 1 of meaningful use and will change "and" to "or". However, we note that all measures will be reconsidered in later stages of meaningful use and multiple reports could be required in those stages.

Comment: We received a few comments requesting the removal of the terms "reduction of disparities" and "outreach" as there are no actionable items or measures associated with the term. We also received comments that the measurement should include the requirement that the lists be stratified by race, ethnicity, preferred language, and gender for initiatives targeted at reducing disparities.

Response: We disagree that actions to reduce disparities or conduct outreach could not be guided by this report, especially if stratified and aggregated reports of many providers are combined within large organizations or among organizations. While we do not require such stratification or aggregation or specify specific uses, that does not preclude them.

Comment: Some commenters requested clarification of the term specific condition.

Response: Specific conditions are those conditions listed in the active patient problem list.

After consideration of the public comments received, we are modifying the meaningful use objective for EPs at § 495.6(e)(3)(i) and for eligible hospitals at § 495.6(g)(4)(i) of our regulations to "Generate lists of patients by specific conditions to use for quality improvement, reduction of disparities, research, or outreach".

NPRM EP/Eligible Hospital Measure: Generate at least one report listing patients of the EP or eligible hospital with a specific condition.

In the proposed rule, we said that 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. However, in order to ensure the capability can be utilized we proposed to require EPs and hospitals to attest to the ability of the EP or eligible hospital to create a report listing patients by specific condition and to attest that they have actually done so at least once. We received comments on this and address them and any revisions to the proposed rule in the comment and response section below.

Comment: Commenters requested clarification that only one report per EHR reporting period is required to meet the measure.

Response: Yes, only one report in required for any given EHR reporting period. The report could cover every patient whose records are maintained using certified EHR technology or a subset of those patients at the discretion of the EP, eligible hospital or CAH.

Comment: A few commenters suggested the measure should be

expanded to require submission of the report to CMS or the States or to the local health department.

Response: Submission raises many questions about what types of information can be sent to different entities, how the information is used, patient consent for sending the information, and many of the issues, which add considerable complexity to this meaningful use objective. Therefore, we are not requiring submission of the report to CMS, the States or local health departments for Stage 1 of meaningful use. We do note that this is one of the objectives for which a State can submit modifications to CMS for approval.

Comment: Several commenters requested a list of condition categories, a model report or the core data elements required to satisfy the measure.

Response: As stated in the rule, we believe an EP, eligible hospital, or CAH is best positioned to determine which reports are most useful to their care efforts. Therefore, we do not propose to direct certain reports be created.

Comment: For eligible hospitals, commenters stated that the analysis of patient data is derived from post-discharge coding of diagnosis and procedures and not problem lists.

Response: We do not specify that the list is limited to being generated from the data problem list; rather, for the definition of conditions we refer providers to those conditions contained in the problem list.

Comment: One commenter stated that for privacy and confidentiality reasons, patients should be allowed to opt out of any provider outreach initiatives.

Response: Stage 1 of meaningful use does not require the submission of these reports to other entities; rather, we require that the provider generate these reports for their own use. We therefore do not believe the generation of such reports raises privacy and confidentiality concerns. We understand, however, that some patients may have concerns about such lists being exchanged with others and will consider such concerns should future meaningful use requirements focus on exchange of these reports.

After consideration of the public comments received, we are finalizing the meaningful use measure for EPs at § 495.6(e)(3)(ii) and for eligible hospitals and CAHs at § 495.6(g)(4)(ii) of our regulations as proposed.

We further specify that in order to meet this objective and measure, an EP, eligible hospital, or CAH must use the capabilities Certified EHR Technology includes as specified and standards at 45 CFR 170.302(i). The ability to calculate the measure is included in certified EHR technology.

As this measure relies on data contained in certified EHR technology the list would only be required to include patients whose records are maintained using certified EHR technology as discussed previously in this section under our discussion of the burden created by the measures associated with the Stage 1 meaningful use objectives.

We do not believe anything included in this objective or measure limit any EP, eligible hospital or CAH from completing the measure associated with this objective, therefore, we do not include an exclusion.

NPRM EP Objective: Report ambulatory quality measures to CMS (or, for EPs seeking the Medicaid incentive payment, the States).

Specific comments on the quality measures are discussed in section II.A.3 of this final rule.

We are finalizing this meaningful use objective at § 495.6(d)(10)(i) of our regulations "Report ambulatory clinical quality measures to CMS (or, for EPs seeking the Medicaid incentive payment, the States)" to better align with the descriptions in section II.A.3.

In response to our revised requirements for meeting meaningful use, we are including this objective in the core set. Section 1848 (o)(2)(A)(iii) of the Act specifically includes submitting clinical quality measures in meaningful use for EPs. Section 1903(t)(6)(D) of the Act also anticipates that the demonstration of meaningful use may include quality reporting to the States for the Medicaid program.

NPRM Eligible Hospital Objective: Report ambulatory quality measures to CMS (or, for eligible hospitals seeking the Medicaid incentive payment, the States).

We make a technical correction to this objective from the proposed rule to ensure that it is clear to the public that we were referring to hospital quality measures.

Specific comments on the quality measures are discussed in section II.A.3 of this final rule.

After consideration of the public comments received, we are finalizing this meaningful use objective at § 495.6(d)(9)(i) to account for our technical correction and to better align with the descriptions in section II.A.3 as "Report hospital clinical quality measures to CMS (or, for eligible hospitals seeking the Medicaid incentive payment, the States)".

In response to our revised requirements for meeting meaningful use, we are including this objective in the core set. Section 1886 (n)(3)(A)(iii) of the Act specifically includes submitting clinical quality measures in meaningful use for eligible hospitals and CAHs. Section 1903(t)(6)(D) of the Act also anticipates that the demonstration of meaningful use may include quality reporting to the States for the Medicaid program.

NPRM EP Measure: For 2011, an EP would provide the aggregate level data for the numerator, denominator, and exclusions through attestation as discussed in section II.A.3 of this final rule. For 2012, an EP would electronically submit the measures that are discussed in section II.A.3. of this final rule.

Specific comments on the quality measures themselves are discussed in section II.A.3 of this final rule.

After consideration of the public comments received, we are finalizing this meaningful use objective at § 495.6(d)(10)(ii) as proposed.

NPRM Eligible Hospital Measure: For 2011, an eligible hospital or CAH would provide the aggregate level data for the numerator, denominator, and exclusions through attestation as discussed in section II.A.3 of this final rule. For 2012, an eligible hospital or CAH would electronically submit the measures as discussed in section II.A.3. of this final rule. Specific comments on the quality measures are discussed in section II.A.3 of this final rule. After consideration of the public comments received, we are finalizing this meaningful use objective at 495.6(f)(9)(ii) as proposed.

NPRM EP Objective: Send reminders to patients per patient preference for preventive/follow-up care.

In the proposed rule, we described patient preference as the patient's choice between internet based delivery or delivery not requiring internet access. We are revising that description based on comments as discussed below.

Comment: Commenters have pointed out that requirements to accommodate reasonable requests by individuals to receive communications by means other than the means preferred by the provider already exist under HIPAA at 45 CFR 164.522(b).

Response: As we stated in the proposed rule, patient preference refers to the patient's preferred means of transmission of the reminder from the provider to the patient, and not inquiries by the provider as to whether the patient would like to receive reminders. In the proposed rule, we had proposed that patient preference be limited to the choice between internet based or non-internet based. In order to avoid unnecessary confusion and duplication of requirements, EPs meet

the aspect of "per patient preference" of this objective if they are accommodating reasonable requests as outlined in 45 CFR 164.522(b), which are the guidance established under HIPAA for accommodating patient requests.

After consideration of the public comments received, we are finalizing the meaningful use objective at § 495.6(e)(4)(i) of our regulations as proposed.

NPRM 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.

For the final rule, we are changing the measure to recognize that this is an EP only objective. Therefore, we make the technical correction of striking "or admitted to the eligible hospital".

Comment: Commenters indicated that "practice management systems" or "patient management systems" are commonly used for this function and that integrating them into certified EHR technology would be expensive and time consuming for little value in return.

Response: While we disagree with commenters who suggest there is little to no value in having information about reminders sent to patients available across all the systems used by the provider, we do not assert that such integration of systems must be in place to meet this measure. ONC provides for a modular approach that would allow these systems to be certified as part of certified EHR technology.

Comment: Some commenters pointed out that many patients seen during an EHR reporting period will not be sent a reminder during that same period. Commenters said this is especially true for the 90-day EHR reporting period, but for some services could be true of the full year EHR reporting period as well. Other commenters also pointed out that reminders are not limited to the older population and that children especially may require many reminders on immunizations.

Response: We agree with commenters that many patients not seen during the EHR reporting period would benefit from reminders. As the action in this objective is the sending of reminders, we base the revised measure on that action. This focus is supported by numerous public comments, including those by the HIT Policy Committee. Therefore, we are changing the requirement to account for all patients whose records are maintained using certified EHR technology regardless of whether they were seen by the EP during the EHR reporting period. This greatly expanded denominator caused us to reconsider both our threshold and the age limit. In order to increase the probability that a patient whose records are maintained in certified EHR technology will be eligible for a reminder we change the age limit of the population to 65 years old or older or 5 years old or under. We believe that older patient populations are more likely to have health statuses that will indicate the need for reminders to be sent and this segment of the population is have higher rates of chronic diseases which will require coordination in preventive care such as vaccine reminders. Likewise, the 5 years old and under population will require a multitude of childhood vaccinations such as influenza and will benefit from reminders. However, we do not believe that changing the age limit of the affected population will result in 50 percent of every patient whose records maintained in certified EHR technology requiring a reminder during the EHR reporting period. This is especially true for the first payment year when the EHR reporting period is only 90 days. We are also concerned about the variability among specialists' scopes of practice that may affect the number of patients in the denominator for which a reminder is appropriate. Therefore, we lower the threshold to 20 percent. The EP has the discretion to determine the frequency, means of transmission and form of the reminder limited only by the requirements of 45 CFR 164.522(b) and any other applicable federal, state or local regulations that apply to them. After consideration of the public comments received, we are modifying the meaningful use measure at § 495.6(e)(4)(ii) to "More than 20 percent of all patients 65 years or older or 5 years old or younger were sent an appropriate reminder during the EHR reporting period".

We further specify that in order to meet this objective and measure, an EP must use the capabilities Certified EHR Technology includes as specified and standards at 45 CFR 170.304(d). The ability to calculate the measure is included in certified EHR technology.

As noted previously in this section under our discussion of the burden created by the measures associated with the Stage 1 meaningful use objectives, the denominator is based on patients whose records are maintained using certified EHR technology.

To calculate the percentage, CMS and ONC have worked together to define the following for this objective:

- *Denominator:* Number of unique patients 65 years old or older or 5 years older or younger.
- *Numerator:* The number of patients in the denominator who were sent the appropriate reminder.
- *Threshold:* The resulting percentage must be more than 20 percent in order for an EP to meet this measure.

As addressed in other objectives and in comment responses, if an EP has no patients 65 years old or older or 5 years old or younger with records maintained using certified EHR technology that EP is excluded from this requirement as described previously in this section under our discussion of whether certain EP, eligible hospital or CAH can meet all Stage 1 meaningful use objectives given established scopes of practices.

NPRM EP/Eligible Hospital Objective: Document a progress note for each encounter. In the proposed rule, we discussed this objective, but did not propose it for Stage 1 of meaningful use. We noted our belief that 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.

Comment: We received a limited number of comments regarding our decision not to include documentation of progress notes as an objective. The commenters generally fell into three categories: Those who supported inclusion of this objective in the final rule, those who supported its inclusion only if certain caveats are met and those who supported our proposal not to include it as an objective for Stage 1 of meaningful use. Concerns raised by those supporting the inclusion of this objective included the possibility that an EP may keep paper progress notes in conjunction with use of certified EHR technology as prescribed by Stage 1 of meaningful use and that such a choice by EPs would create the possibility of handwriting illegibility, loss of information and reduced access to health information by both patients and other providers. Another concern raised is that if the objective is not included in the criteria for the definition of meaningful use designers of EHR technology will not include the function in their products. The advocates in the second category agree with the above, but only support inclusion with certain caveats. Some of these caveats include preserving the option of transcription, voice recognition software, and direct entry by an EP or any combination of these. Another caveat is that progress notes not be required to be entered as structured data. The third category supports exclusion of progress notes as an objective for two fundamentally different reasons. Some commenters

supported exclusion because they believe that the volume of objectives was already too high for Stage 1 of meaningful use and therefore opposed anything that would increase the volume.

Other commenters agree with our proposal that progress notes is already a fundamental part of current EHR products and did not represent a move that advances the use of EHRs.

Response: We predicated our discussion in the proposed rule on the assumption that progress notes are a component of basic EHR functionality. We still believe this is the case and have not received evidence to the contrary. However, we failed to clearly articulate the ramifications of our belief. Our view continues to be that an EP who incorporates the use of EHRs into a practice and complies with meaningful use criteria is unlikely to maintain separate paper progress notes outside of the EHR system. We believe that the potential disruption in workflow of the efforts to merge paper progress notes with the other records in certified EHR technology in order to have a complete medical record far outweighs the burden of electronically capturing progress notes. Moreover, we continue to believe this is a highly unlikely scenario. As with any meaningful use objective, it is important to have clear, definitive definitions. However, our observations of discussions held in public forums by the medical community and review of literature have led us to conclude that it not possible to provide a clear, definitive definition of a progress note at this time. We note that commenters recommending the documentation of a progress note be included as an objective did not attempt to define the term. Nor did commenters suggest an associated measure. We continue to believe that there is insufficient need and upon review believe there is insufficient consensus regarding the term progress note to include this objective for Stage 1 of meaningful use.

After consideration of the public comments received, we do not include this meaningful use objective in the final rule.

NPRM EP/Eligible Hospital Measure: N/A.

NPRM EP 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.

NPRM Eligible Hospital Objective: 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.

First, we make a technical correction. On page 1856 of the proposed rule, we described this objective for eligible hospitals as "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." The underlined language was inappropriately carried over from the EP objective in this instance and in the regulation text. The table contained our intended language of "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." Many commenters pointed this discrepancy out to us and we appreciate their diligence.

Comment: Nearly half of the commenters mentioning clinical decision support suggested that the term needed additional clarification. Some commenters said that the term was too vague and open to interpretation while others said it was too specific. Other commenters provided recommendations on what a clinical decision support rule should mean or which elements it should include. These were evidence-based medicine templates, decision trees, reminders, linked online resources, scientific evidence, and consensus.

Response: In the proposed rule, we described clinical decision support as HIT 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 purposefully used a description that would allow a provider significant leeway in determining the clinical decision support rules that are more relevant to their scope of practice and benefit their patients in the greatest way. In the proposed rule, we asked providers to relate the rules they select to clinical priorities and diagnostic test ordering. We do not believe that adding a more limiting description to the term clinical decision support would increase the value of this objective. We believe that this determination is best left to the provider taking into account their workflow and patient population.

Comment: Several commenters objected to the requirement of five clinical decision support rules when the HIT Policy Committee only recommended one. Others disagreed with our proposed assertion that most EPs would report on at least five clinical quality measures from section II.A.3 of the proposed rule and eligible hospitals will all report on at least five.

Response: We accept the argument that there is value in focusing initial CDS efforts on a single CDS rule in order to get it right the first time and lay the foundation for future, broader CDS implementation. This will help to prevent the unintended negative consequences associated with poorly implemented CDS systems when providers have attempted to do too much too soon.

We agree that the appropriate balance is to require some degree of meaningful use of CDS in Stage 1 without overburdening providers with too many areas to focus on at once. Since CDS is one area of health IT in which significant evidence exists that it can have a substantial positive impact on the quality, safety and efficiency of care delivery, it is important that it be included as a core objective with this more limited expectation. That requirement will assure that all meaningful users have taken the first steps in CDS implementation but allow them to focus as necessary on a single high-priority area at the outset in order to ensure that they can devote the appropriate level of attention to their first CDS priority. We anticipate that this will set the foundation for much more expansive CDS support in the near future.

Comment: A commenter inquired if modification of the clinical decision support tool negates the EHR's certification status.

Response: We believe this is a question on certification status and is outside of the scope of this rule. ONC discusses what would affect Certified EHR Technology's certified status in their final rule (75 FR 36157) entitled "Establishment of the Temporary Certification Program for Health Information Technology".

After consideration of the public comments received, we are modifying the meaningful use objective for EPs at 495.6(d)(11)(i) to "Implement one clinical decision support rule relevant to specialty or high clinical priority along with the ability to track compliance with that rule."

After consideration of public comments received, we are modifying the meaningful use objective for eligible hospitals and CAHs at § 495.6(f)(10)(i) of our regulations as "Implement one clinical decision support rule related to a high priority hospital condition along with the ability to track compliance with that rule."

We believe that clinical decision support is one of the most common tools that uses the information collected as structured data included in the core set and therefore also include clinical decision support in the core as the information needed to support it are already included in the core set.

NPRM 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. of this final rule.

In the proposed rule, we said that 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.

Comment: Commenters, both in the requests for clarification of the term clinical decision support and explicitly in response to this measure, expressed concern about the linkage to a particular quality measure.

Response: We agree that such linkage puts constraints on the provider and eliminates many types of clinical decision support rules that may be beneficial. Therefore, we revise this measure to require that at least one of the five rules be related to a clinical quality measure, assuming the EP, eligible hospital or CAH has at least one clinical quality measure relevant to their scope of practice. However, we strongly encourage EPs, eligible hospitals and CAHs to consider the clinical quality measures as described in section II.A.3 when deciding which additional rules to implement for this measure.

Comment: Several commenters, including the HIT Policy Committee, recommended that we focus at least one clinical decision support rule on efficiency of care.

Response: In light of decision to limit the objective to one clinical decision support rule, we do not believe that it is appropriate to further to link that rule to specific requirements and therefore give the EP, eligible hospital or CAH discretion on what to focus the clinical decision support rule used to satisfy this measure.

Comment: A few commenters asked for clarification of how the "* * * with the ability to track compliance with those rules" language of the proposed objective for clinical decision support rules relates to the associated measures.

Response: While an integral part of the objective and certified EHR technology, we did not include this aspect of the objective in the measure for Stage 1 of meaningful use. An EP, eligible hospital, or CAH is not required to demonstrate to CMS or the States its compliance efforts with the CDS recommendations or results for Stage 1 either at initial attestation or during an subsequent review of that attestation.

After consideration of the public comments received, we are modifying the meaningful use measure for EPs at § 495.6(e)(11)(ii) and for eligible hospitals and CAHs at § 495.6(g)(10)(ii) to "Implement one clinical decision support rule.

We further specify that in order to meet this objective and measure, an EP, eligible hospital, or CAH must use the capabilities Certified EHR Technology includes as specified and standards at 45 CFR 170.304(e) for EPs and 45 CFR 170.306(c). The ability to calculate the measure is included in certified EHR technology.

Given the added flexibility added to this measure in the final rule, we do not believe that any EP, eligible hospital, or CAH would be in a situation where they could not implement one clinical decision support rules as described in the measure. Therefore, there are no exclusions for this objective and its associated measure.

NPRM EP/Eligible Hospital Objective: Submit claims electronically to public and private payers.

Comment: Over three quarters of those commenting on this objective recommended that it be eliminated for various reasons. The majority of the other commenters requested a modification. Reasons given are:

—Electronic claims submission is already covered under HIPAA;
—Electronic claims submission is not part of traditional EHR technology;
—Billing systems would have to be certified adding to cost and burden of compliance with meaningful use even though when electronic claims submission for Medicare is already in place for all by the very smallest of providers;
—Electronic claims submission falls outside of the scope of the statutory mandate given by Congress to implement the HITECH legislation to improve care delivery through broad scale adoption and utilization of Electronic Health Record technologies. This function does not impact the quality of care delivered and relies on product components that are traditionally part of practice management systems;
—Private payers may customize the HIPAA-recognized standard transactions, which limits the ability of practices to obtain accurate information prior to receiving an Explanation of Benefits based on the actual services provided and negates many of the benefits of having standardized transactions;
—Workers' compensation and auto insurers do not accept electronic claims; and
—Many providers use clearinghouses and they requested that the burden of electronic submission be shifted to the clearinghouse.

Response: In our proposed rule, we specifically cite that the existence of standard transactions available under HIPAA for submitting claims as a reason for including this objective as a meaningful use objective for Stage 1. We also disagree that this objective is outside the scope of meaningful use as defined by the HITECH legislation. The HITECH legislation states the Secretary shall seek to improve not only health care quality, but also the use of electronic health records. In addition, we note that sections 1848(o)(2)(A) and 1886(n)(3)(A) of the Act provide that to be considered a meaningful EHR user, an EP, eligible hospital, or CAH must demonstrate use of certified EHR technology in a meaningful manner as defined by the Secretary. In the Medicaid context, any demonstration of meaningful use must be "acceptable to the Secretary" under 1903(t)(6). We believe this language gives us broad discretion to require the use of certified EHR technology in a manner that not only improves health care quality, but results in gains in efficiency, patient engagement and enhances privacy and security. Under the broad definition of electronic health record established by ONC in their final rule, electronic exchange of eligibility information and claims submission could certainly improve the use of electronic health records.

We believe that inclusion of administrative simplification in meaningful use is an important long-term policy goal for several reasons. First, administrative simplification can improve the efficiency and reduce unnecessary costs in the health care system as a whole; the small percentage of paper claims submitted represent a disproportionate administrative cost for health plans; the reconciliation of billing charges for services not eligible for payment creates a significant burden for providers, health plans, and most

significantly, for patients. Second, the integration of administrative and clinical information systems is necessary to support effective management and coordinated care in physician practices. The ability to leverage clinical documentation in support of appropriate charge capture (for example, for preventive counseling, or immunizations provided), the ability to link lists of patients needing clinical reminders with patient contact information, the ability to stratify quality measures by patient demographic factors (for example, race/ethnicity) and insurer status (for example, Medicare beneficiaries), are examples.

In addition, there are important benefits to the inclusion of administrative transactions in criteria and standards for the certification of EHR technologies. The option of modular certification provides an opportunity for eligible professionals and hospitals to use practice management systems or clearinghouses that provide these functions as components of their certified EHR technologies. However, we recognize there is not current agreement as to which systems constitute an EHR and that many entities may view their billing system to be outside their EHR and that the vendors of some practice management systems that provide these functionalities in doctors' offices today may not be prepared to seek certification for these legacy products in 2010/2011. We also recognize that the introduction of the X12 5010 standards in January 2012 would further complicate the certification process for stage 1. We also acknowledge that we do not have the ability to impose additional requirements on third-party payers or clearinghouses to participate in this exchange beyond what is required by HIPAA. Based on these considerations, we are not including this objective in the final rule for Stage 1 of meaningful use.

However, the introduction of these new X12 5010 standards, and the coming introduction of ICD–10 in 2013 provides an opportunity for change in Stage 2 of meaningful use. In order to meet these and other administrative simplification provisions, most providers will have to upgrade their practice management systems or implement new ones. This provides an important opportunity to achieve alignment of capabilities and standards for administrative transactions in EHR technologies with the administrative simplification provisions that the Affordable Care Act provides for health plans and health plan clearinghouses. We therefore intend to include administrative transactions as a part of Stage 2 of meaningful use, and expect providers and vendors to take this into consideration in their decisions leading up to 2013.

Comment: Commenters focusing on how meaningful use would translate into the Medicare Advantage program said that the measure of checking eligibility electronically and submitting claims electronically for 80 percent of patients seen would not be possible. They explained that for most of their visits, there is no insurance company with which to check, and there is no insurance company to whom to submit claims. They described themselves as a capitated system and for most of the patient visits, the concept of checking eligibility and submitting claims in not relevant.

Response: This comment illustrates the difficulties in adopting FFS Medicare meaningful use measures for qualifying MA organizations, MA-affiliated hospitals and MA EPs. For purposes of determining meaningful use in a Medicare Advantage environment, we agree that submitting claims electronically is not a useful standard in a capitated environment where virtually all patients are members of the same insurance plan.

After consideration of the public comments received, we are not finalizing the objective "Submit claims electronically to public and private payers".

NPRM EP/Eligible Hospital Measure: At least 80 percent of all claims filed electronically by the EP or the eligible hospital.

We received many comments on the difficulty in calculating this measure. However, as all measures are tied to objectives and we do not finalize this objective we also do not finalize the measure.

NPRM EP/Eligible Hospital Objective: Check insurance eligibility electronically from public and private payers.

Comment: Over three quarters of those commenting on this objective recommended that it be eliminated for various reasons. Some of the most common reasons for elimination are:

—Electronic eligibility checks are already covered under HIPAA;
—Electronic eligibility checks are not part of traditional EHR technology;
—Billing and practice management systems that are used for electronic eligibility checks would have to be certified as certified EHR technology adding to cost and burden;
—Electronic eligibility checks is outside of the scope of the mandate given by Congress to implement the HITECH legislation in such a way as to improve care delivery through broad scale adoption and utilization of Electronic Health Record technologies. This function does not impact the quality of care delivered and relies on product components that are traditionally part of practice management systems;
—Information returned on typical electronic eligibility checks is of little use to providers—as responses are usually a yes/no answer on coverage, but not the specificity of coverage;
—The current poor adoption rate of the use of electronic eligibility verification is indicative of the deficiencies in current methods;
—Once eligibility checking becomes easy to use and reliable, no incentive will be required as providers will adopt the process readily;
—Payers do not guarantee their eligibility results;
—Many payers are still not in compliance with the HIPAA 270/271 electronic eligibility standard. Therefore the objective should only be required if compliance with the standard by health plans can be guaranteed; and
—Private payers may customize the HIPAA-recognized standard transactions, which limits the ability of practices to obtain accurate information prior to receiving an Explanation of Benefits based on the actual services provided and negates many of the benefits of having standardized transactions.

Response: In our proposed rule, we specifically cite the existence of the standard transaction for eligibility checks available under HIPAA as an enabling factor for the inclusion this objective. As with the electronic claims submission objective discussed above, we disagree that this objective is outside the scope of meaningful use as defined by the HITECH legislation. The HITECH legislation requires the Secretary to seek to improve not only health care quality, but also the use of electronic health records. Under the broad definition of electronic health record established by ONC in their final rule, electronic exchange of eligibility information could certainly improve the use of electronic health records. However, we recognize there is not current agreement as to which systems constitute an EHR and that many entities may view their practice management system to be outside their EHR. We also acknowledge that we do not have the ability to impose additional requirements on third-party payers to participate in this

exchange beyond what is required by HIPAA. Third-party payers can provide simple yes/no responses, modify the standard transactions and do not have to guarantee their results. We agree with commenters that this significantly devalues the results of this objective. However, we do believe that as electronic records and exchange based on this and considerations that commenters nearly universally considered this to not be a function of EHR, we are not including this objective in the final rule for Stage 1 of meaningful use. However, we do believe that inclusion of a robust system to check insurance eligibility electronically is an important long term policy goal for meaningful use of certified EHR technology and we intend to include this objective as well as electronic claims submission Stage 2.

After consideration of the public comments received, we are not finalizing the objective to "Check insurance eligibility electronically from public and private payers" or any modification thereof. Given that we are not finalizing the objective, we also are not finalizing the associated EP and eligible hospital/CAH measures.

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.

As explained in the proposed rule, we do not intend 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, we defer to existing Federal and State laws as to what is appropriate for disclosure to the patient or their 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.

Comment: Several commenters requested that all objectives under the health care policy priority be combined, as they are redundant.

Response: We disagree that they are redundant and believe each serves a unique purpose. We will more fully describe those purposes in the discussion of each objective.

NPRM EP Objective: Provide patients with an electronic copy of their health information (including diagnostics test results, problem list, medication lists, allergies) upon request.

NPRM Eligible Hospital Objective: Provide patients with an electronic copy of their health information (including diagnostic test results, problem list, medication lists, allergies, discharge summary, procedures), upon request

The purpose of this objective is to provide a patient's health information to them electronically and in a human readable format and in accordance with the standards specified in the ONC final rule subject to its availability to the provider electronically and any withholding under regulations related to the HIPAA Privacy Act at 45 CFR 164.524, Access of individuals to protected health information.

In the proposed rule, we indicated that electronic copies may be provided through a number of secure electronic methods (for example, personal health record (PHR), patient portal, CD, USB drive). We have changed this description in response to comments to that when responding to patient requests for information, the EP, eligible hospital, or CAH should accommodate patient requests in accordance with 45 CFR 164.524, Access of individuals to protected health information. The objective provides additional criteria for meeting meaningful use concerning the electronic copy or provision of information that the EP, eligible hospital or CAH maintains in or can access from the certified EHR technology and is maintained by or on behalf of the EP, eligible hospital or CAH.

Comment: We received requests for clarification that only information that the EP, eligible hospital, or CAH has available electronically must be provided to the patient.

Response: Yes, we limit the information that must be provided electronically to that information that exists electronically in or accessible from the certified EHR technology and is maintained by or on behalf of the EP, eligible hospital or CAH. We believe it is impractical to require information maintained on paper to be transmitted electronically. Furthermore, given the other criteria of Stage 1 of meaningful use, we believe sufficient information will be available through certified EHR technology, especially given the inclusion of many of the foundational objectives that were included in the core set.

Comment: Commenters pointed out that the HIPAA Privacy Rule permits licensed healthcare professionals to withhold certain information if its disclosure would cause substantial harm to the patient or another individual.

Response: As previously discussed for patient preference, we do not seek to conflict with or override HIPAA through meaningful use requirements. Therefore, an EP, eligible hospital, or CAH may withhold information from the electronic copy of a patient's health information in accordance with the regulations at 45 CFR 164.524, Access of individuals to protected health information.

Comment: Commenters requested clarification of the term "health information" or alternatively a list of elements required to satisfy the objective.

Response: Subject to the withholding described above, an EP, eligible hospital, or CAH should provide a patient with all of the health information they have available electronically. At a minimum, this would include the elements listed in the ONC final rule at 45 CFR 170.304(f) for EPs and 45 CFR 170.306(d) for eligible hospitals and CAHs as required for EHR technology to become certified.

Comment: Several commenters indicated that a provider should be allowed to charge a fee for providing an electronic copy of a patient's health information.

Response: We do not have the authority under the HITECH Act to regulate fees in this manner. Rather, the charging of fees for this information is governed by the HIPAA Privacy Rule at 45 CFR 164.524(c)(4) (which only permits HIPAA covered entities to charge an individual a reasonable, cost-based fee for a copy of the individual's health information). We would expect these costs to be very minimal considering that the ability to generate the copy is included in certified EHR technology. Additional clarification on the fee that a HIPAA covered entity may impose on an individual for an electronic copy of the individual's health information will be addressed in upcoming rulemaking.

Comment: Commenters pointed out that the general term "allergies" is inconsistent with other objectives of Stage 1 and with the capabilities mandated by certification under the ONC IFR, which address only medication allergies.

Response: As we have stated on several other objectives, we encourage all EPs, eligible hospitals, and CAHs to work with their EHR technology designers to make capabilities most relevant to their individual practices of care. However, we have maintained that at a minimum the capabilities that are part of certification should be included

and those should be the basis for meaningful use so we do modify this objective to medication allergies to align it with other objectives and certification.

After consideration of the public comments received, we are modifying the meaningful use objective for EPs at § 495.6(d)(12)(i) of our regulations to "Provide patients with an electronic copy of their health information (including diagnostics test results, problem list, medication lists, medication allergies) upon request" and for eligible hospitals and CAHs at § 495.6(f)(11)(i) of our regulations to "Provide patients with an electronic copy of their health information (including diagnostic test results, problem list, medication lists, medication allergies, discharge summary, procedures), upon request".

We include this objective in the core set as it is integral to involving patients and their families in their provision of care and was recommended by the HIT Policy Committee for inclusion in the core set.

NPRM 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.

In the proposed rule, we pointed out that all patients have a right under ARRA to an electronic copy of their health information. We said that our purpose for including it in meaningful use was to ensure that this requirement in met in a timely fashion. We also said that 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 received requests for clarifications on what must be provided and in what timeframe. We address those requests in the comment and response section below. We note here that participation in the Medicare and Medicaid EHR incentive programs is voluntary. Nothing in the Stage 1 criteria of meaningful use supersedes or exempts an EP, eligible hospital or CAH from complying with otherwise applicable requirements to provide patients with their health information.

Comment: An overwhelming majority of commenters commenting on this objective indicated that the 48-hour time frame is too short and inconsistent with the HIPAA Privacy Rule.

Response: We discuss the reasoning for the time frame in the proposed rule. We state that this measure seeks to ensure that a patient's request 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. We also believe that certified EHR technology will provide EPs, eligible hospitals, and CAHs more efficient means of providing copies of health information to patients, which is why we proposed that a request for an electronic copy be provided to the patient within 48 hours.

In the final rule, we further point out that this objective is limited to health information maintained and provided electronically while HIPAA can require the retrieval, copying and mailing of paper documents. For this reason, we do not believe the timeframes under this meaningful use objective and the HIPAA Privacy Rule must be aligned. However, we appreciate that the 48-hour timeframe may be burdensome for some providers, particularly for those providers who do not operate 24/7. We therefore are lengthening the timeframe to three business days. Business days are defined as Monday through Friday excluding federal or state holidays on which the EP, eligible hospital, or CAH or their respective administrative staffs are unavailable. As an example if a patient made a request for an electronic copy of their health information on Monday then the EP, eligible hospital, or CAH would have until the same time on Thursday to provide the information assuming there were no intervening holidays. If provision of the copy involves the mailing of physical electronic media, then it would need to be mailed on the Thursday.

Comment: Some commenters believed the 80 percent threshold was too high or introduced examples of extraordinary circumstances such as natural disasters or system crashes that would indicate a lower threshold is needed to accommodate them.

Response: We reduce the threshold to over 50 percent as this objective meets the criteria of relying 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, as explained under our discussion of the objective of maintain an up-to-date problem list. As this is a relatively new capability that was not available to either providers or patients before the introduction of EHRs, we do not believe it meets the same standard of practice as maintaining an up-to-date problem list and therefore adopt a threshold of 50 percent (rather than 80 percent).

Comment: We received comments that were concerned about the reporting burden of this requirement.

Response: We believe that as long as the request by the patient is accurately recorded in the certified EHR technology then the certified EHR technology should be able to calculate the measure. Recording patient requests for certain actions should be part of the expectations of meaningful use of certified EHR technology. If the EP, eligible hospital, or CAH records the requests using certified EHR technology, certified EHR technology will be able to assist in calculating both the numerator and denominator. If the requests are recorded by another means at the choice of the provider, the provider would be responsible for determining the denominator.

Comment: Commenters inquired if third-party requests for information are included in the denominator.

Response: Only specific third party requests for information are included in the denominator. As we stated in the opening discussion for this health care priority, providing the copy to a family member or patient's authorized representative consistent with federal and state law may substitute for a disclosure of the information to the patient and count in the numerator. A request from the same would count in the denominator. All other third party requests are not included in the numerator or the denominator.

Comment: Commenters inquired if asking the patient to register for their own personal health record (PHR) satisfies the intent of the objective.

Response: EPs, eligible hospitals and CAHs are to provide the information pursuant to the reasonable accommodations for patient preference under 45 CFR164.522(b). To be included in this measure, the patient has already requested an electronic method. While having a third party PHR certainly would be one method, assuming the provider could populate the PHR with all the information required to meet this objective. The provider should provide the same level of assistance to the patient that would be provided as if they maintained their own patient portal.

Comments: Comments were received requesting the format and media for the provision of the health information.

Response: As this is for use by the patient, the form and format should be human readable and comply with the HIPAA Privacy Rule, as specified at 45 CFR 164.524(c). In addition, efforts should be made to make it easily understandable to the patient. The media could be any electronic form such as patient portal, PHR, CD, USB fob, etc. As stated in the previous response, EPs, eligible hospitals and CAHs are expected to make reasonable

accommodations for patient preference as outlined in 45 CFR 164.522(b).

After consideration of the public comments received, we are modifying the meaningful use measure for EPs at § 495.6(d)(12)(i) and for eligible hospitals at § 495.6(f)(11)(i) of our regulations to "More than 50 percent of all patients of the EP or the inpatient or emergency departments of the eligible hospital or CAH (POS 21 or 23) who request an electronic copy of their health information are provided it within 3 business days."

We further specify that in order to meet this objective and measure, an EP, eligible hospital, or CAH must use the capabilities Certified EHR Technology includes as specified and standards at 45 CFR 170.304(f) for EPs and 45 CFR 170.306(d) for eligible hospitals and CAHs. The ability to calculate the measure is included in certified EHR technology.

As the provision of the electronic copy is limited to the information contained within certified EHR technology, this measure is by definition limited to patients whose records are maintained using certified EHR technology as described previously in this section under our discussion of the burden created by the measures associated with the Stage 1 meaningful use objectives.

To calculate the percentage, CMS and ONC have worked together to define the following for this objective:

- *Denominator:* The number of patients of the EP or eligible hospital's or CAH's inpatient or emergency departments (POS 21 or 23) who request an electronic copy of their electronic health information four business days prior to the end of the EHR reporting period.
- *Numerator:* The number of patients in the denominator who receive an electronic copy of their electronic health information within three business days.
- *Threshold:* The resulting percentage must be more than 50 percent in order for an EP, eligible hospital, or CAH to meet this measure. As addressed in other objectives and in comment response, if the EP, eligible hospital, or CAH has no requests from patients or their agents for an electronic copy of patient health information during the EHR reporting period they would be excluded from this requirement as described previously in this section under our discussion of whether certain EP, eligible hospital or CAH can meet all Stage 1 meaningful use objectives given established scopes of practices.

NPRM Eligible Hospital Objective: Provide patients with an electronic copy of their discharge instructions and procedures at time of discharge, upon request.

The purpose of this objective is to provide the option to patients to receive their discharge instructions electronically. Discharge instructions would not necessarily be included in a copy of health information and it is unlikely that a patient would request a copy of their health information at every discharge. This objective is unique to eligible hospitals and CAHs.

Comment: We received several comments suggesting that we eliminate or clarify the term "procedures."

Response: As we believe the terms "instructions" and "procedures" are interchangeable as used in this objective, we are removing the term "procedures" from the objective. We left this term in the provision of electronic copy of health information as the term "instructions" is not in that objective. We clarify that the term "instructions" means any directions that the patient must follow after discharge to attend to any residual conditions that need to be addressed personally by the patient, home care attendants, and other clinicians on an outpatient basis.

Comment: Commenters pointed out that the HIPAA Privacy Rule permits licensed healthcare professionals to withhold certain information if its disclosure would cause substantial harm to the patient or another individual.

Response: We reiterate that it is not our intent for the meaningful use objectives to conflict or override the HIPAA Privacy Rule through meaningful use requirements. Therefore an EP, eligible hospital, or CAH may withhold information from the electronic copy to the extent they are permitted or required to do so in accordance with the regulations at 45 CFR 164.524.

Comment: Some commenters recommended that hospitals should be required to either provide every patient an electronic copy of their discharge instructions or at least inform them of the option to receive it electronically.

Response: We believe it would be too burdensome to provide every patient an electronic copy of his or her discharge instructions. Furthermore, we anticipate that many, if not most, patients will prefer a paper copy during the years of Stage 1. While we certainly encourage eligible hospitals to inform their patients of the option to receive their discharge instructions electronically, we do not see requiring this as within the scope of meaningful use of certified EHR technology for Stage 1.

Comment: Comments were received requesting a clarification of the data that should be included in the discharge instructions.

Response: This objective simply refers to the option of the electronic provision of instructions that would be provided to the patient. We believe eligible hospitals are the appropriate entity to determine the information that should be included in the discharge instructions.

Comment: Comments were received requesting the format and media for the discharge instructions.

Response: As this is for use by the patient, the form and format should be human readable and comply with the HIPAA Privacy Rule, as specified at 45 CFR 164.524(c). In addition, efforts should be made to make it easily understandable to the patient. The media could be any electronic form such as patient portal, PHR, CD, USB fob, etc. EPs, eligible hospitals and CAHs are expected to make reasonable accommodations for patient preference as outlined in 45 CFR 164.522(b).

After consideration of the public comments received, we are finalizing the objective at 495.6(f)(12)(i) of our regulations as proposed.

We include this objective in the core set as it is integral to involving patients and their families in their provision of care and was recommended by the HIT Policy Committee for inclusion in the core set.

NPRM 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.

Comment: Some commenters believed the 80 percent threshold was too high or introduced examples of extraordinary circumstances that would indicate that a lower threshold is needed to accommodate them.

Response: We reduce the threshold to over 50 percent as this objective meets the criteria of relying 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. However, as this is a relatively new capability that was not available to either providers or patients before the introduction of EHRs we do not believe it meets the same standard of practice as maintaining an up-to-date problem list and therefore adopt a threshold of 50 percent (rather than 80 percent).

Comment: Some commenters expressed concern about the reporting burden imposed by this requirement.

Response: We believe that as long as the request by the patient is accurately recorded in the certified EHR

technology then the certified EHR technology should be able to calculate the measure. We believe that recording patient requests for certain actions that involve the use of certified EHR technology should be part of EPs, eligible hospitals and CAHs standard practice. If the eligible hospital or CAH records the requests using certified EHR technology, certified EHR technology will be able to assist in calculating both the numerator and denominator. If the requests are recorded by another means at the choice of the provider, the provider would be responsible for determining the denominator.

Comment: Several of the comments requested clarification of the timeframe in which the discharge instructions should be provided to the patient.

Response: As discussed previously, this objective simply refers to the option of the electronic provision of instructions that would be provided to the patient at the time of discharge. Therefore, we believe for the information to be useful to the patient, the instructions themselves or instructions on how to access them electronically should be furnished at the time of discharge from the eligible hospital or CAH.

Comment: Some comments expressed concern that providing an electronic copy of discharge instructions to the patient at the time of discharge would disrupt workflows and lengthen the discharge process resulting in reduced bed turnover in emergency departments.

Response: As discussed previously, this objective simply refers to the option of the electronic provision of instructions that would be provided to the patient at the time of discharge. We do not believe the provision of an electronic copy of the discharge instructions, upon request, at the time of discharge alters current workflow or lengthens the discharge process. A patient could be provided instructions on how to access an Internet Web site where they can get the instructions or asked to provide an e-mail address or simply be handed electronic media instead of or in addition to a paper copy.

After consideration of the public comments received, we are modifying the meaningful use measure at § 495.6(f)(12)(ii) of our regulations to "More than 50 percent of all patients who are discharged [1] from an eligible hospital's or CAH's inpatient or emergency department (POS 21 or 23) and who request an electronic copy of their discharge instructions are provided it."

We further specify that in order to meet this objective and measure, an EP, eligible hospital, or CAH must use the capabilities Certified EHR Technology includes as specified and standards at 45 CFR 170.306(e). The ability to calculate the measure is included in certified EHR technology.

As with the previous objective, the provision of the electronic copy of the discharge summary is limited to the information contained within certified EHR technology; therefore this measure is by definition limited to patients whose records are maintained using certified EHR technology as described previously in this section under our discussion of the burden created by the measures associated with the Stage 1 meaningful use objectives.

To calculate the percentage, CMS and ONC have worked together to define the following for this objective:

- *Denominator:* Number of patients discharged from an eligible hospital's or CAH's inpatient or emergency department (POS 21 or 23) who request an electronic copy of their discharge instructions and procedures during the EHR reporting period.
- *Numerator:* The number of patients in the denominator who are provided an electronic copy of discharge instructions.
- *Threshold:* The resulting percentage must be more than 50 percent in order for an EP, eligible hospital, or CAH to meet this measure.

As addressed in other objectives and in comment response, if the eligible hospital or CAH has no requests from patients or their agents for an electronic copy during the EHR reporting period they would be excluded from this requirement as described previously in this section under our discussion of whether certain EP, eligible hospital or CAH can meet all Stage 1 meaningful use objectives given established scopes of practices.

NPRM EP Objective: Provide patients with timely electronic access to their health information (including lab results, problem list, medication lists, and allergies) within 96 hours of the information being available to the EP.

In the proposed rule, we described timely as within 96 hours of the information being available to the EP through either the receipt of final lab results or a patient interaction that updates the EP's knowledge of the patient's health. We said we judged 96 hours to be a reasonable amount of time to ensure that certified EHR technology is up to date and welcomed comment on if a shorter or longer time is advantageous. We did receive comments on the time frame and have revised it as discussed below in the comment and response section.

Comment: We received comments recommending that "access" be clarified to determine whether this is online access as indicated in the ONC certification criteria for certified EHR technology or just electronic access.

Response: We believe we inadvertently created confusion by listing the examples of electronic media (CD or USB drive) in which this access could be provided. As many commenters inferred, it was our intention that this be information that the patient could access on demand such as through a patient portal or PHR. We did not intend for this to be another objective for providing an electronic copy of health information upon request.

Comment: Several commenters requested that all objectives included in the health care policy priority "engage patients and their families" be combined, as they are redundant.

Response: We disagree that they are redundant and believe each serves a unique purpose. We regret any confusion created by the inclusion of CD or USB drive as examples of electronic media caused in the intent of this measure. The difference between electronic access and an electronic copy is that a patient with electronic access can access the information on demand at anytime while a patient must affirmatively request an electronic copy from the EP, eligible hospital or CAH at a specific time and the information in the copy is current only as of the time that the copy is transferred from the provider to the patient.

Comment: Some commenters asserted that some results and other sensitive information are best communicated at a face-to-face encounter.

Response: We agree that there may be situations where a provider may decide that electronic access of a portal or Personal Health Record is not the best forum to communicate results. Within the confines of laws governing patient access to their medical records, we would defer to EP's, eligible hospital or CAH's judgment as to whether to hold information back in anticipation of an actual encounter between the provider and the patient. Furthermore just as in the provision of electronic copy, an EP may withhold information from being

[1] Please note that although the final rule meaningful use measures refer to patients discharged from an emergency department, such emergency room releases are not eligible hospital discharges for purpose of determining hospital payment incentives under section 1886(n) of the Act. Section 1886(n) payments are only with respect to "inpatient" hospital services pursuant to section 1886(n)(1)(A) of the Act.

accessible electronically by the patient in accordance with regulations at 45 CFR 164.524. Any such withholding would not affect the EP's, eligible hospital's or CAH's ability to meet this objective as that information would not be included. We do not believe there would be a circumstance where all information about an encounter would be withheld from the patient and therefore no information would be eligible for uploading for electronic access. If nothing else, the information that the encounter occurred can be provided. Please note that providers must comply with all applicable requirements under the HIPAA Privacy Rule, including 45 CFR 164.524.

Comment: We received several comments stating that the time frame of 96 hours is too burdensome for EPs.

Response: While we believe that 96 hours is sufficient, most EPs do not operate 24/7. Therefore, we will limit the timeframe to business days, in effect changing the timeframe from 96 hours in the proposed rule to four business days. Business days are defined as Monday through Friday excluding federal or state holidays on which the EP, eligible hospital or CAH or their respective administrative staffs are unavailable.

Comment: Commenters pointed out that allergies is inconsistent with other objectives of Stage 1 and with the capabilities mandated by certification under the ONC final rule.

Response: As we have stated on several other objectives, we encourage all EPs, eligible hospitals, and CAHs to work with their EHR technology designers to make capabilities as relevant to their individual practices of care as possible. However, we maintain that at a minimum the capabilities that are part of certification should be included in certified EHR technology so we do modify this objective to medication allergies to align it with other objectives and certification.

After consideration of the public comments received, we are modifying the objective for EPs at § 495.6(d)(6)(i) of our regulations to "Provide patients with timely electronic access to their health information (including lab results, problem list, medication lists, medication allergies) within four business days of the information being available to the EP".

NPRM EP Measure: At least 10 percent of all unique patients seen by the EP are provided timely electronic access to their health information.

In the proposed rule, we said that 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. We received comments on this justification for the threshold and requests for clarification, which are addressed in the comment and response section below.

Comment: Some commenters expressed concern about the calculation of the percentage and expressed the preference to use an absolute count instead of a percentage.

Response: We acknowledge there are unique concerns about calculating this percentage as it involves determining the timeliness of the information. Certified EHR technology would be able to ascertain the time from when the information was entered into its system to when the information was available for electronic access. As certified EHR technology can provide the access, any perceivable delay or requirement for affirmative action would be built in by the user to allow for review of the information before posting. Certified EHR technology could not be distinguish the difference in time when the information was available to the provider and when it was entered into certified EHR technology. However, we see no reasonable way to track this time frame that does not impose a heavy burden on the EP. Therefore, for the measure, we define the four business days time frame as the time frame when the information is updated in the certified EHR technology to when it is available electronically to the patient, unless the provider indicates that the information should be withheld. It is acceptable for a provider to set an automated withhold on certain information at their discretion. As we have discussed previously in this section, we do not believe absolute counts are an adequate substitute for percentage calculations.

Comment: We received comments requesting clarification on what data must be made available.

Response: Certified EHR technology must be able to make certain data available according to the ONC final rule. At a minimum, the data specified in the ONC final rule at 45 CFR 170.304(g) must be available subject to the ability of the provider to withhold it discussed previously.

Comment: Commenters suggested that some EPs might not have 10 percent of their patient population who desire or could utilize such access.

Response: We agree that this is a possibility. We stated in the proposed rule that "we recognize that many patients may not have internet access, may not be able or interested in the use of 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. However, this 30 percent threshold may not be realistic for many practices in the short term and therefore serves justification for the 10 percent threshold. However, the objective and measure focus on the availability of the access and the timeliness of the data in it, not its utilization. Therefore, we focus on the fact that more than 10 percent of unique patients seen during the EHR reporting period could access it and that the information is timely. The EP is not responsible for ensuring that 10 percent request access or have the means to access. However, we encourage EPs to make the availability of electronic access known to their patients.

Comment: A commenter inquired about the provider's liability versus the EHR technology vendor for a security breach of the system.

Response: Depending on the facts surround the security breach, the provider may be liable for a violation under the HIPAA Privacy and Security Rules, as well as under any other applicable federal or state laws. Additionally, there may be circumstances where the EHR technology vendor acted as a business associate and may potentially have liability under the HIPAA Privacy and Security Rules. The issue of business associate liability under the HIPAA Privacy and Security Rules will be addressed in upcoming rulemaking.

After consideration of the public comments received, we are modifying the meaningful use measure for EPs at § 495.6(d)(6)(ii) of our regulations to "At least 10 percent of all unique patients seen by the EP are provided timely (available to the patient within four business days of being updated in the certified EHR technology) electronic access to their health information subject to the EP's discretion to withhold certain information".

We further specify that in order to meet this objective and measure, an EP, eligible hospital, or CAH must use the capabilities Certified EHR Technology includes as specified and standards at 45 CFR 170.304(g). The ability to calculate the measure is included in certified EHR technology.

To calculate the percentage, CMS and ONC have worked together to define the following for this objective:

- *Denominator:* Number of unique patients seen by the EP during the EHR

reporting period. A unique patient is discussed under the objective of CPOE.

- *Numerator:* The number of patients in the denominator who have timely (available to the patient within four business days of being updated in the certified EHR technology) electronic access to their health information online.
- *Threshold:* The resulting percentage must be at least 10 percent in order for an EP to meet this measure.

As addressed in other objectives and in comment response, if an EP neither orders nor creates any of the information listed in the ONC final rule 45 CFR 170.304(g) and therefore included in the minimum data for this objective during the EHR reporting period they would be excluded from this requirement as described previously in this section under our discussion of whether certain EP, eligible hospital or CAH can meet all Stage 1 meaningful use objectives given established scopes of practices.

NPRM EP Objective: Provide clinical summaries for patients for each office visit.

In the proposed rule, we discussed why we were basing the objective on office visits rather than encounters. We said that we did want encounter to be construed to mean every time a provider interacts with the patient. We received comments requesting that we further define office visit and address those in the comment and response section below. In discussing the measure in the proposed rule, we also said that the clinical summary can be provided through a PHR, patient portal on the web site, secure email, 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.

Comment: We received requests for clarification as to what constitutes an "office visit".

Response: An office visit is defined as any billable visit that includes: (1) Concurrent care or transfer of care visits, (2) Consultant visits and (3) Prolonged Physician Service without Direct (Face-To-Face) Patient Contact (tele-health). A consultant visit occurs when a provider is asked to render an expert opinion/service for a specific condition or problem by a referring provider.

Comment: Some commenters believed the requirement for the provision of a clinical summary at an office visit should be linked to the type or purpose of the office visit. Samples of the suggested visits are—

—Level 4 or level 5 evaluation and management services;
—Visits conducted at the conclusion of an episode of care;
—Visits conducted at each transition of care;
—Visits relevant to specific conditions such as asthma; and
—Provider to patient face-to-face visits.

Response: We believe that a clinical summary should be provided at all office visits included in the definition of office visit as defined in this final rule. We believe all of the office visits described in our definition result in the EP rendering a clinical judgment that should be communicated to the patient.

Comment: Commenters requested CMS define "clinical summary" and offered several specific data elements that should be included in the definition such as patient name, provider name, date of visit, location of visit, reason for visit, updated medication list, laboratory orders, diagnostic orders, patient instructions based on discussions with the provider and a nutrition care management plan.

Response: After reviewing the comments we define clinical summary as an after-visit summary that provides a patient with relevant and actionable information and instructions containing, but not limited to, the patient name, provider's office contact information, date and location of visit, an updated medication list and summary of current medications, updated vitals, reason(s) for visit, procedures and other instructions based on clinical discussions that took place during the office visit, any updates to a problem list, immunizations or medications administered during visit, summary of topics covered/considered during visit, time and location of next appointment/testing if scheduled, or a recommended appointment time if not scheduled, list of other appointments and testing patient needs to schedule with contact information, recommended patient decision aids, laboratory and other diagnostic test orders, test/laboratory results (if received before 24 hours after visit), and symptoms.

Comment: Commenters pointed out that the HIPAA Privacy Rule permits licensed healthcare professionals to withhold certain information if its disclosure would cause substantial harm to the patient or another individual.

Response: As the EP is proactively providing this information to the patient, 45 CFR 164.524 of the HIPAA Privacy rule does not apply to this situation. However, we still believe that an EP should be able to withhold information if its disclosure would cause substantial harm to the patient or another individual. Therefore, if in their judgment substantial harm may arise from the disclosure of particular information, an EP may choose to withhold that particular information from the clinical summary

Comment: Most commenters noted that other than "at the time of the visit", there was no specific time period given in which to comply with this objective. If CMS intended "at the time of the visit" to mean before the patient leaves the building or upon the patient's request, neither are possible due to workflow and review processes. Most commenters assumed we would associate the 48 hours related to the 'copy' requirement or the 96 hours related to the 'access' requirement to address this comment and stated that both were too short a period for a clinical visit summary. Others recommended the 30-day timeframe for the provision information set forth under the HIPAA Privacy Rule.

Response: We agree that our proposed objective lacked specificity about the time to comply. To provide such specificity, we adopt the timeframe of three business days from our objective of providing electronic health information to the patient. That is three business days following the day of the visit excluding holidays as described in the providing electronic health information to the patient objective.

Comment: Several commenters requested changes to the media through which this information could be provided. Differing commenters recommended eliminating the paper option, while others recommended only the paper option.

Response: We believe that more options give the EP needed flexibility. The EP could choose any of the listed means from the proposed rule of PHR, patient portal on a Web site, secure email, electronic media such as CD or USB fob, or printed copy. If the EP chooses an electronic media, they would be required to provide the patient a paper copy upon request. Both forms can be and should be produced by certified EHR technology.

Comment: Several commenters indicated that a provider should be allowed to charge a fee for providing the copy.

Response: As this is a proactive requirement on the part of the EP and not a response to a request from the patient, we do not believe it is appropriate to charge the patient a fee for this copy. We note that we give the EP considerable flexibility in the

manner in which the copy is provided including the provision of a paper copy. The only accommodation an EP is required to make is the provision of a paper copy that can be automatically generated certified EHR technology. We therefore believe that costs of this will be negligible.

Comment: A number of commenters expressed concern regarding whether the current available technology could produce a summary of the required information in a standardized format, the use of clinical nomenclature rather than lay terms and the fact that some providers use multiple modules to document the care of the patient.

Response: We believe it is appropriate to leave the design of EHR technology systems and their outputs to the system developers and the EHR technology users. However, we note that the capability to meet this objective is included in the ONC final rule at 45 CFR 170.304(h) as a criteria for certified EHR technology and we are confident that vendors will be able to produce certified EHR technologies.

After consideration of the public comments received, we are finalizing the objective for EPs at § 495.6(d)(13)(i) of our regulations as proposed.

We include this objective in the core set as it is integral to involving patients and their families in their provision of care and was recommended by the HIT Policy Committee for inclusion in the core set.

NPRM EP Measure: Clinical summaries provided to patients for at least 80 percent of all office visits.

Comment: Some commenters believed the threshold was too high or should be replaced with a numerical count or attestation.

Response: We reduce the threshold to over 50 percent as this objective meets the criteria of relying 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. Also, as this is a relatively new capability that was not available to either providers or patients before the introduction of EHRs, we do not believe it meets the same standard of practice as maintaining an up-to-date problem list and therefore adopt a threshold of 50 percent (rather than 80 percent).

After consideration of the public comments received, we are modifying the meaningful use measure for EPs at § 495.6(d)(13)(ii) of our regulation to "Clinical summaries provided to patients for more than 50 percent of all office visits within 3 business days".

We further specify that in order to meet this objective and measure, an EP, eligible hospital, or CAH must use the capabilities Certified EHR Technology includes as specified and standards at 45 CFR 170.304(h). The ability to calculate the measure is included in certified EHR technology.

As with the previous objective, the provision of the clinical summary is limited to the information contained within certified EHR technology; therefore this measure is by definition limited to patients whose records are maintained using certified EHR technology as described previously in this section under our discussion of the burden created by the measures associated with the Stage 1 meaningful use objectives.

To calculate the percentage, CMS and ONC have worked together to define the following for this objective:

- *Denominator:* Number of unique patients seen by the EP for an office during the EHR reporting period. A unique patient is discussed under the objective of using CPOE.
- *Numerator:* Number of patients in the denominator who are provided a clinical summary of their visit within three business days.
- *Threshold:* The resulting percentage must be more than 50 percent in order for an EP, eligible hospital, or CAH to meet this measure.

As addressed in other objectives, EPs who have no office visits during the EHR reporting period would be excluded from this requirement as described previously in this section under our discussion of whether certain EP, eligible hospital or CAH can meet all Stage 1 meaningful use objectives given established scopes of practices.

NPRM EP/Eligible Hospital Objective: "Provide access to patient-specific education resources upon request."

In the proposed rule, we discussed this objective, but did not propose it. We stated that there was a paucity of knowledge resources that are integrated with EHR, and that also are widely available. We also noted that the ability to provide education resources in multiple languages might be limited. We stated our intent to further explore the objective in subsequent stages of meaningful use.

Comment: We received many comments, including comments from both the HIT Policy Committee and MedPAC, to include this measure in the final rule. These commenters disagreed with our assertion in the proposed rule that "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." Specific examples of the availability of knowledge resources integrated with current EHRs were provided. The HIT Policy Committee amended their recommendation in their comments on the proposed rule to:

—EPs and hospitals should report on the percentage of patients for whom they use the EHR to suggest patient-specific education resources.

Other recommended language for the objective includes:

—Provide patients educational information that is specific to their health needs as identified by information contained in their EHR technology such as diagnoses and demographic data, and

—The original HIT Policy Committee objective of "Provide access to patient-specific education resources upon request."

Response: We are convinced by commenters that the availability of education resources linked to EHRs is more widely available than we had indicated in the proposed rule. Therefore, for the final rule we will include this objective for the Stage 1 of meaningful use. We note that the new recommendation of the HIT Policy Committee is a hybrid of a measure and an objective, whereas in developing the meaningful use criteria we consistently identify both an objective and associated measure. However, we agree with the HIT Policy Committee and others that the objective and associated measure should make clear that the EP, eligible hospital or CAH should utilize certified EHR technology in a manner where the technology suggests patient-specific educational resources based on the information stored in the certified EHR technology. Therefore, we are including a revised version of this objective in the final rule for Stage 1 of meaningful use.

We also believe it is necessary to state what level of EP, eligible hospital and CAH discretion is available when deciding whether to provide education resources identified by certified EHR technology to the patient. Therefore, we include the phrase "if appropriate", which allows the EP or the authorized provider in the eligible hospital or CAH final decision on whether the education resource is useful and relevant to a specific patient.

After consideration of the public comments received, we are including this meaningful use objective for EPs at § 495.6(e)(6)(i) and eligible hospitals and CAHs at § 495.6(g)(5)(i) of our regulations as "Use certified EHR technology to identify patient-specific education resources and provide those resources to the patient if appropriate".

NPRM EP/Eligible Hospital Measure: Not applicable.

Comment: CMS received a comment requesting an 80 percent threshold of appropriate patients and/or caregivers receiving patient-specific educational materials. In addition, the HIT Policy Committee's revised objective suggests a patient based percentage.

Response: As with the addition of the recording of advance directives, we are able to relate this measure to one that is based on patients and can be accomplished solely using certified EHR technology. As this objective requires more than just the recording of information in certified EHR technology, we adopt a lower threshold of 10 percent.

After consideration of the public comments received, we are including this meaningful use measure for EPs at § 495.6(e)(6)(ii) and eligible hospitals at § 495.6(g)(5)(ii) of our regulations as "More than 10 percent of all unique patients seen by the EP or admitted to the eligible hospital's or CAH's inpatient or emergency department (POS 21 or 23) are provided patient-specific education resources".

We further specify that in order to meet this objective and measure, an EP, eligible hospital, or CAH must use the capabilities Certified EHR Technology includes as specified and standards at 45 CFR 170.302(m). The ability to calculate the measure is included in certified EHR technology.

To calculate the percentage, CMS and ONC have worked together to define the following for this objective:

- *Denominator:* Number of unique patients seen by the EP or admitted to the eligible hospital's or CAH's inpatient or emergency department (POS 21 or 23) during the EHR reporting period. A unique patient is discussed under the CPOE objective.
- *Numerator:* Number of patients in the denominator who are provided patient education specific resources.
- *Threshold:* The resulting percentage must be more than 10 percent in order for an EP, eligible hospital, or CAH to meet this measure.

We do not believe that any EP, eligible hospital, or CAH will not have more than 10 percent of their patients eligible to receive patient specific education resources and therefore do not believe an exclusion is necessary for this objective.

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.

NPRM 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.

NPRM 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.

In the proposed rule, we defined the term "diagnostic test results " as 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. We maintain this description for the final rule. We said that when the information was available in a structured format we expected that it be transferred in a structured format. However, if it was unavailable in a structured format, that the transmission of unstructured data was permissible. We provide additional information on structured data in the comment and response section, but maintain for the final rule the concept that the exchange can be of structured or unstructured data.

Comment: Commenters requested clarification of the term "key clinical information."

Response: By "clinical information", 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. We leave it to the provider's clinical judgment as to identifying what clinical information is considered key clinical information for purposes of exchanging clinical information about a patient at a particular time with other providers of care. The examples we provided in the proposed rule and the final rule below are not intended to be exhaustive. ONC in their final rule provides a minimum set of information that certified EHR technology must be able to exchange in order to be certified. A provider's determination of key clinical information could include some or all of this information as well as information not included in the ONC final rule at 45 CFR 170.304(i) for EPs and 45 CFR 170.306(f) for eligible hospitals and CAHs.

Comment: Commenters requested clarification of the term "patient authorized entities."

Response: By "patient authorized entities", we mean 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, an entity facilitating health information exchange among providers or a personal health record vendor identified by the patient. A patient would have to affirmatively grant access to these entities.

Comment: Commenters requested clarification of the term "exchange."

Response: We expect that this information, when exchanged electronically, would be exchanged in structured electronic format when available (for example, drug and clinical lab data). 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. We believe that the electronic exchange of information is most efficient when it is exchanged from a provider's certified EHR technology to another certified EHR technology either directly or through an entity facilitating health information exchange using structured data that can be automatically identified by the receiving system and integrated into the receiver's records. However, we know that much information cannot currently be, and may never be, transmitted in the way we just described.

Comment: Commenters requested clarification of the term "structured data."

Response: This distinction between structured data and unstructured data applies to all types of information. We have previously defined structured data in this section. To ensure that certified EHR technology has a certain level of functionality, ONC at 45 CFR 170.304(i) for EPs and 45 CFR 170.306(f) for eligible hospitals and CAHs specified certain types of information that a certified EHR technology must be able to exchange to become certified. ONC also provided standards to support this exchange. These standards do not preclude a vendor of EHR technology from enabling its product to exchange additional types of information nor limit the provider's discretion (either in exchanging more or less) in deciding what information is key and should be exchanged about a given patient at a given time.

Comment: Commenters expressed concern that the exchange of key

clinical information via certified EHR systems requires a unique or national patient identifier to ensure accurate exchange.

Response: While such an identifier could facilitate an exchange, it need only be unique to the parties involved in the exchange and need not be national in scope, nor is a specific unique identifier necessary for successful exchanges. Many current health information exchanges have had success identifying patients by a combination of several elements of information without a separate independent identifier.

Comment: Commenters pointed out that the general term "allergies" is inconsistent with other objectives of Stage 1 and with the capabilities mandated by certification under the ONC final rule, which uses the term "medication allergies".

Response: As we have stated on several other objectives, we encourage all EPs, eligible hospitals, and CAHs to work with their certified EHR technology designers to make capabilities most relevant to their individual practices of care. However, we have maintained that at a minimum the capabilities that are part of certification should be included so we modify the example to change allergies to medication allergies to align it with other objectives and certification.

After consideration of the public comments received, we are modifying the meaningful use objective for EPs at § 495.6(d)(14)(i) of our regulations to "Capability to exchange key clinical information (for example, problem list, medication list, medication allergies, and diagnostic test results), among providers of care and patient authorized entities electronically" and for eligible hospitals and CAHs at § 495.6(f)(13)(i) to "Capability to exchange key clinical information (for example, discharge summary, procedures, problem list, medication list, medication allergies, diagnostic test results), among providers of care and patient authorized entities electronically".

In response to our revised requirements for meeting meaningful use, we included this objective in the core set. Section 1848 (o)(2)(A)(ii) of the Act specifically includes electronic exchange of health information in meaningful use for eligible professionals.

NPRM EP/Eligible Hospital Measure: Performed at least one test of certified EHR technology's capacity to electronically exchange key clinical information.

In the proposed rule, we identified this objective as reliant on the electronic exchange of information. We said that we are aware 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 proposed that EPs and eligible hospitals test their ability to send such information at least once prior to the end of the EHR reporting period. We proposed that the testing could occur prior to the beginning of the EHR reporting period. We also said that 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. Finally, we attempted to define an "exchange" as the clinical information must be sent between different clinical entities with distinct certified EHR technology and not between organizations that share a certified EHR. We received many comments requesting further clarification on these concepts and we attempt to provide additional information in the comment and response section below.

Comment: Commenters expressed concern that the receiving entities are not required to have the same capabilities as meaningful users of certified EHR technology.

Response: The HITECH Act does not provide us the authority to require any entity (medical provider or otherwise) to conform to certain standards and criteria unless they seek to become a meaningful EHR user. The Act also limits the entities that are eligible to become meaningful EHR users. In developing the associated measure for this objective, we have ensured that eligible providers will be able to meet this objective as long as there is one other entity with which they can test their capability. As electronic exchange is not constrained by distance, we are confident that every provider seeking to test their system will be able to find another entity with which to conduct such test.

Comment: Commenters asked whether the test needs to be "live" or if it could be a "simulation."

Response: As specified in the proposed rule, this test must involve the actual submission of information to another provider of care with distinct certified EHR technology or other system capable of receiving the information.

Comment: Commenters asked whether the use of "test" or "dummy" data is permissible.

Response: While the use of test patient information may increase the risk that the system will not be testing to its full capability, given the privacy and security concerns surrounding the transmission of actual patient information we do not require it for the purposes of a test. Therefore, the use of test information about a fictional patient that would be identical in form to what would be sent about an actual patient would satisfy this objective.

Comment: Commenters suggested deferring the measure to a later stage due to the lack of a mature HIE infrastructure and/or to emulate the Health Information and Management System Society (HIMSS) EMR Adoption Model.

Response: We agree that many areas of the country currently lack the infrastructure to support the electronic exchange of information. As the goal of this meaningful use objective is to ensure that certified EHR technology has the capability to electronically exchange key clinical information, we only require a single test.

After consideration of the public comments received, we are finalizing the meaningful use measure at § 495.6(d)(14)(ii) and § 495.6(f)(13)(ii) of our regulations as proposed.

We further specify that in order to meet this objective and measure, an EP, eligible hospital, or CAH must use the capabilities Certified EHR Technology includes as specified and standards at 45 CFR 170.304(i) for EPs and 45 CFR 170.306(f) for eligible hospitals and CAHs. The ability to calculate the measure is included in certified EHR technology. EPs, eligible hospitals, and CAHs should attempt to identify one other entity with whom to conduct a test of the submission of electronic data. This test must include the transfer of either actual or "dummy" data to the chosen other entity. The testing could occur prior to the beginning of the EHR reporting period, but must occur prior to the end of the EHR reporting period and every payment year would require its own, unique test as infrastructure for health information exchange is expected to mature over time. Therefore, if an eligible hospital or CAH were to become a meaningful EHR user in 2011 for their first payment year, they would have to conduct another, unique test to become a meaningful EHR user in 2012 for their second payment year. 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" for this objective and measure the clinical information must be sent between different legal entities with distinct certified EHR technology or other system that can accept the information and not between organizations that share certified EHR technology. CMS will accept a yes/no attestation to verify all of the above for EPs, eligible hospitals, and CAHs.

As the measure already accounts for the possibility of a failed test and we are confident that everyone will be identify an entity with which to conduct a test, we do not believe an exception is required for EPs, eligible hospitals or CAHs.

NPRM EP/Eligible Hospital Objective: Perform medication reconciliation at relevant encounters and each transition of care.

In the proposed rule, we described "medication reconciliation" as the process of identifying the most accurate list of all medications that the patient is taking, including name, dosage, frequency and route, by comparing the medical record to an external list of medications obtained from a patient, hospital or other provider. We maintain this description for the final rule. We also described "relevant encounter" and "transition of care"; however, as we received comments requested additional clarification of these terms we address them in the comment and response section below.

Comment: Several commenters requested that this objective be deferred until it can be conducted using the exchange of electronic information between certified EHR technology. Other commenters believed that the process is not one for avoiding medication errors, but a human workflow process supported by the EHR, and not an automated EHR process.

Response: We certainly look forward to a time when most medication reconciliation occurs as an automated process within the EHR reconciling information that has been exchanged. However, it is unlikely that an automated process within the EHR will fully supplant the medication reconciliation conducted between the provider and the patient. In order for this automated reconciliation process to occur and be useful, the relevant structured data exchanged needs to be as accurate as possible. Requiring medication reconciliation as part of meaningful use in Stage 1 lays the groundwork for future reliable electronic exchange. We therefore do not believe this objective should be deferred to a later stage.

Comment: Commenters requested additional clarity of the term "relevant encounter." Only a few suggestions on such clarity were provided by commenters. Two examples of commenters' recommendations are "when a prescription is generated" and "a significant change in the patient's condition that resulted in change in medication regimen which could include significant change in dosing of more than 1 medication, identification of a new medical condition, decline in functional status or change in advanced directive."

Response: We finalize our proposal by defining "relevant encounter" as an encounter during which the EP, eligible hospital or CAH performs a medication reconciliation due to new medication or long gaps in time between patient encounters or for other reasons determined appropriate by the EP, eligible hospital or CAH. Essentially an encounter is relevant if the EP, eligible hospital, or CAH judges it to be so. This flexibility has implications for the measure that were not fully considered in the proposed rule. We will discuss those below in connection with our discussion of the associated measure.

Comment: Commenters requested additional clarity of the term "transition of care." A few suggestions were provided by commenters including expanding the description to include all transfers to different settings within a hospital or revising the definition to "the movement of a patient from one setting of care (hospital, ambulatory primary care practice, ambulatory specialty care practice, long-term care, home health, rehabilitation facility) to another".

Response: In the proposed rule we clarified "transition of care" as the 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, eligible hospital, or CAH (as defined by CCN) to another. We believe that different settings within one hospital using certified EHR technology would have access to the same information so reconciliation would not be necessary. We modify our clarification to account for some of the revisions provided. We clarify "transition of care" as the movement of a patient from one setting of care (hospital, ambulatory primary care practice, ambulatory specialty care practice, long-term care, home health, rehabilitation facility) to another. We also clarify that the receiving eligible hospital or EP would conduct the medication reconciliation.

Comment: Some commenters requested clarification on which EP, eligible hospital or CAH would conduct the medication reconciliation. The one to whom the patient is transferred or the one who transfers the patient.

Response: When conducting medication reconciliation during a transfer of care, we believe that it is the EP, eligible hospital or CAH that receives the patient into their care that should conduct the medication reconciliation. It is for this provider that the information is most crucial, as they will be making the future clinical judgments regarding the patient. Therefore, we revise this objective and its associated measure to reflect this clarification.

Comment: Commenters requested a standard list be defined for the process including prescription and non prescription medications, herbal products, dietary supplements, prescriber, drug name, regimen and allergies.

Response: We believe the information included in the process of medication reconciliation is appropriately determined by the provider and patient.

After consideration of the public comments received, we are modifying the meaningful use objective for EPs at § 495.6(e)(7)(i) and for eligible hospitals and CAHs at § 495.6(g)(6)(i) of our regulations to "The EP, eligible hospital or CAH who receives a patient from another setting of care or provider of care or believes an encounter is relevant should perform medication reconciliation".

NPRM EP/Eligible Hospital Measure: Perform medication reconciliation for at least 80 percent of relevant encounters and transitions of care.

Comment: Commenters believed it was an unjustifiable burden to record which encounters were relevant and which were not given our flexible definition of "relevant encounter".

Response: We agree that the inclusion of relevant encounters creates a burden that one commenter described as "non-value-added work". We also believe that when the EP, eligible hospital, or CAH identifies the encounter as relevant, it is unlikely that the EP, eligible hospital, or CAH would then not carry out the medication reconciliation. For these reasons, we are removing relevant encounters from the measure for this objective.

Comment: Commenters said the percent measurements should be replaced with a numerical count or an attestation the objective has been met or the demonstration of the capability by performing one test of certified EHR technology's capacity to present

providers with patient medication information that supports the reconciliation of medications at time of admission and discharge. Other commenters stated the proposed 80 percent threshold was too high.

Response: We are maintaining a percentage for the reasons discussed previously in this section. However, we do reduce the threshold to over 50 percent as this objective meets the criteria of relying solely on a capability included as part of certified EHR technology and while not absolutely reliant on electronic exchange of information, it does involve the exchange of information between providers and therefore we adopt a threshold of 50 percent (rather than 8 percent).

Comment: Commenters requested we align this objective with The Joint Commission National Patient Safety Goal on medication reconciliation (Goal 8) in order to decrease confusion, prevent the slowing of adoption of best practices and match current hospital reconciliation processes.

Response: CMS understands the commenters' concerns regarding possible confusion if the meaningful use medication reconciliation requirement differs from The Joint Commission's requirement for those facilities accredited by that organization. However, currently there is no finalized Joint Commission standard as the Commission is currently in the process of re-evaluating their National Patient Safety Goal 8 (Accurately and completely reconcile medications across the continuum of care) given the difficulties that many organizations are having in meeting the complex requirements. In the absence of a definitive Joint Commission standard to take into consideration, this is not possible.

Comment: Some commenters expressed the desire to expand the scope of the measure to include the clinical decision making and patient counseling and education by a pharmacist.

Response: We believe that is both beyond the scope of meaningful use as pharmacists are not eligible professionals for the EHR incentive programs and that the provision of patient counseling is more aligned with the objectives of clinical quality measures. Information from the medication reconciliation could be used for the basis of clinical decision support rules, but is not in and of itself a clinical decision.

After consideration of the public comments received, we are modifying the meaningful use measure for EPs at § 495.6(e)(7)(ii) and for eligible hospitals and CAHs at § 495.6(g)(6)(ii) of our regulations to "The EP, eligible hospital or CAH performs medication reconciliation for more than 50 percent of transitions of care in which the patient is transitioned into the care of the EP or admitted to the eligible hospital's or CAH's inpatient or emergency department (POS 21 or 23)".

We further specify that in order to meet this objective and measure, an EP, eligible hospital, or CAH must use the capabilities Certified EHR Technology includes as specified and standards at 45 CFR 170.302(j). The ability to calculate the measure is included in certified EHR technology.

As discussed previously in this section under our discussion of the burden created by the measures associated with the Stage 1 meaningful use objectives, we only include in the denominator transitions of care related to patients whose records are maintained using certified EHR technology. To calculate the percentage, CMS and ONC have worked together to define the following for this objective:

- *Denominator:* Number of transitions of care during the EHR reporting period for which the EP or eligible hospital's or CAH's inpatient or emergency department (POS 21 to 23) was the receiving party of the transition.
- *Numerator:* The number of transitions of care in the denominator where medication reconciliation was performed.
- *Threshold:* The resulting percentage must be more than 50 percent in order for an EP, eligible hospital, or CAH to meet this measure. If an EP was not on the receiving end of any transition of care during the EHR reporting period they would be excluded as previously discussed in this section under our discussion of whether certain EP, eligible hospital or CAH can meet all Stage 1 meaningful use objectives given established scopes of practices. We do not believe that any eligible hospital or CAH would be in a situation where they would not need to know the precise medications their patients are taking.

NPRM EP/Eligible Hospital Objective: Provide summary care record for each transition of care or referral.

In the proposed rule, we pointed out that this objective was not explicitly included in the HIT Policy Committee's recommended objectives, but that they did include a measure for the "percent of transitions in care for which summary care record is shared." We said that 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 proposed 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. We received support for this inclusion from commenters and include this objective in the final rule for the reasons outlined in the proposed rule. We did receive comments requesting clarifications around this objective and address them in the comment and response section below.

Comment: We received several comments that requested clarification as to the purpose of this objective.

Response: The purpose of this objective is to ensure a summary of care record is provided to the receiving provider when a patient is transitioning to a new provider or has been referred to another provider while still remaining under the care of the referring provider. If the provider to whom the referral is made or to whom the patient is transitioned to has access to the medical record maintained by the referring provider then the summary of care record would not need to be provided. The most common example cited by commenters was a referral during which patient remains an inpatient of the hospital. Finally, unlike with medication reconciliation, where the receiving party of the transfer conducts the action, the transferring party would provide the summary care record to the receiving party.

Comment: Commenters requested additional clarity of the term "transition of care". A few suggestions were provided by the commenters including expanding the description to include all transfers to different settings within a hospital or revising the definition to "the movement of a patient from one setting of care (hospital, ambulatory primary care practice, ambulatory, specialty care practice, long-term care, home health, rehabilitation facility) to another".

Response: In the proposed rule we clarified that the term transition of care means a 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, eligible hospital, or CAH (as defined by CMS Certification Number (CCN) to another. We believe that different settings within a hospital using certified EHR technology would have access to the same information so

providing a clinical care summary would not be necessary. We further clarify transition of care as the movement of a patient from one setting of care (hospital, ambulatory primary care practice, ambulatory, specialty care practice, long-term care, home health, rehabilitation facility) to another.

Comment: Some commenters requested clarification on which EP, eligible hospital or CAH should provide the summary of care document; the one to whom the patient is transferred or referred or the one who transfers or refers the patient.

Response: We believe that it is the EP, eligible hospital or CAH that transfers or refers the patient to another setting of care or provider that should provide the summary of care document. It is for this provider that has the most recent information on the patient that may be crucial to the provider to whom the patient is transferred or referred. Therefore, we revise this objective and its associated measure to reflect this clarification.

Comment: Commenters asked for clarification on how the summary of care record should be transferred.

Response: The goal is to get the summary care record into the next provider's possession. While we highly encourage all EPs, eligible hospitals, and CAHs to explore ways to accomplish the transfer using electronic exchange, we realize that this capability is still in the development stages. Therefore, an EP, eligible hospital, or CAH could send an electronic or paper copy of the summary care record directly to the next provider or could provide it to the patient to deliver to the next provider, if the patient can reasonably expected to do so. Certified EHR technology would be used to generate the summary of care record and to document that it was provided to the patient or receiving provider.

After consideration of the public comments received, we are modifying the meaningful use objective for EPs at § 495.6(e)(8)(i) and for eligible hospitals and CAHs at § 495.6(g)(7)(i) of our regulations to "The EP, eligible hospital or CAH who transitions their patient to another setting of care or provider of care or refers their patient to another provider of care should provide summary care record for each transition of care or referral".

NPRM EP/Eligible Hospital Measure: Provide summary of care record for at least 80 percent of transitions of care and referrals.

Comment: Commenters said that this should be replaced with a count and that the threshold was too high.

Response: We are maintaining a percentage for the reasons discussed previously in this section. However, we do reduce the threshold to over 50 percent as this objective meets the criteria of relying solely on a capability included as part of certified EHR technology and while not absolutely reliant on electronic exchange of information, it does involve the exchange of information between providers and therefore we adopt a threshold of 50 percent (rather than 80 percent).

Comment: There were concerns about the ability of certified EHR technology to calculate this measure. As long as an EP, eligible hospital, or CAH records the order for a referral or transfer as structured data and a record is made that the summary care record was provided then certified EHR technology will be able to calculate this measure.

After consideration of the public comments received, we are modifying the meaningful use measure for EPs at § 495.6(e)(8)(ii) and for eligible hospitals and CAHs at § 495.6(g)(7)(ii) of our regulations to "The EP, eligible hospital or CAH who transitions or refers their patient to another setting of care or provider of care provides a summary of care record for more than 50 percent of transitions of care and referrals".

We further specify that in order to meet this objective and measure, an EP, eligible hospital, or CAH must use the capabilities Certified EHR Technology included as specified and standards at 45 CFR 170.304(i) for EPs and 45 CFR 170.306(f) for eligible hospitals and CAHs. The ability to calculate the measure is included in certified EHR technology.

As discussed previously in this section under our discussion of the burden created by the measures associated with the Stage 1 meaningful use objectives, we only include in the denominator transitions of care and referrals related to patients whose records that are maintained using certified EHR technology. To calculate the percentage, CMS and ONC have worked together to define the following for this objective:

- Denominator: Number of transitions of care and referrals during the EHR reporting period for which the EP or eligible hospital's or CAH's inpatient or emergency department (POS 21 to 23) was the transferring or referring provider.
- Numerator: The number of transitions of care and referrals in the denominator where a summary of care record was provided.
- Threshold: The percentage must be more than 50 percent in order for an EP, eligible hospital, or CAH to meet this measure.

As addressed in other objectives and in comment response, if an EP does not transfer a patient to another setting or refer a patient to another provider during the EHR reporting period then they would have a situation of a null denominator as described would be excluded from this requirement as described previously in this section under our discussion of whether certain EP, eligible hospital or CAH can meet all Stage 1 meaningful use objectives given established scopes of practices. We do not believe that any eligible hospital or CAH would be in a situation where they would never transfer a patient to another care setting or make a referral to another provider.

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." In the proposed rule, we explained that 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 the individuals who would communicate with public health agencies.

NPRM EP/Eligible Hospital Objective: Capability to submit electronic data to immunization registries and actual submission where required and accepted.

In the proposed rule, we did not elaborate on this objective.

Comment: Some commenters suggested out that not every EP, eligible hospital, or CAH administers immunization. Therefore, as proposed, this objective and its associated measure would require an EP, eligible hospital, or CAH to implement and test a capability that they would not use.

Response: We acknowledge that this objective is not relevant to all EPs, eligible hospitals or CAHs. Therefore, in this final rule, we clarify that this objective and its associated measure apply only to EPs, eligible hospitals or CAHs that administer one or more immunizations during the EHR reporting period.

Comment: Some commenters recommended revising the language of the immunization objective to be consistent with the language of the syndromic surveillance objective by

replacing "where required and accepted" with "according to applicable law and practice."

Response: First, we make a technical correction. The objective listed for EPs on page 1858 of the proposed rule listed this objective as "Capability to submit electronic data to immunization registries and actual submission where possible and accepted." The objective was intended to be "Capability to submit electronic data to immunization registries and actual submission where required and accepted" for EPs, eligible hospitals, and CAHs. It is written as such in every other instance in the proposed rule including the regulation text. Second, in response to the comment that "where required and accepted" be replaced with "according to applicable law and practice", we see little distinction between the two in terms of requirement as applicable law and practice would be the things imposing a requirement. Therefore, we adopt the proposed language, but modify the language slightly to "in accordance with applicable law and practice". We do note however, that applicable law and practice do not guarantee every receiving entity will be able to accept it electronically. Our measure for meeting this objective is one test of electronic data submission and if the test is successful follow up submission to that one entity. We do not seek to enforce through meaningful use every law and practice that may require submission of immunization data. We also make another consistency change to the objectives under the health care policy goal of improving population and public health. In this objective, we describe the capability as submitting electronic data. In the other objectives under this goal we describe the capability as providing electronic data. We believe that functionally these terms are interchangeable, but to avoid any confusion we adopt the same term of "submit" electronic data across all three objectives.

Comment: Some commenters suggested that the term "Immunization Information Systems (IIS)" has replaced the term "registry" and is referred to as such by the Centers for Disease Control (CDC).

Response: We modified the objective to account for both terms. After consideration of the public comments received, we are modifying the meaningful use objective for EPs at § 495.6(e)(9)(i) and for eligible hospitals and CAHs at § 495.6(g)(8)(i) of our regulations to Capability to submit electronic data to immunization registries or Immunization Information Systems and actual submission in accordance with to applicable law and practice.

NPRM EP/Eligible Hospital Measure: Performed at least one test of certified EHR technology's capacity to submit electronic data to immunization registries (unless none of the immunization registries to which the EP, eligible hospital, or CAH submits such information have the capacity to receive the information electronically).

In the proposed rule, we identified this as an objective where 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. This ability for the States is also included in our final rule.

Comment: As with the objective of exchanging key clinical information, some commenters asked whether the test needs to be "live" or if it could be a "simulation". Some commenters suggested that a simulation where the ability was tested without being transmitted to another party should be sufficient. Others suggested that the test needs to include transmission or difficulties in actual sending information might not be uncovered.

Response: As specified in the proposed rule, this test must involve the actual submission of information to a registry or immunization information system, if one exists that will accept the information.

Comment: Commenters asked whether the use of "test" or "dummy" data is permissible.

Response: While the use of test patient information may increase the risk that the system will not be testing to its full capability, given the privacy and security concerns surrounding the transmission of actual patient information we do not require it for the purposes of a test. Therefore, the use of test information about a fictional patient that would be identical in form to what would be sent about an actual patient would satisfy this objective. However, we note that this is one of the objectives that a State may modify in accordance with the discussion in II.A.2.c. of the proposed rule. Therefore, more stringent requirements may be established for EPs and eligible hospitals under the Medicaid program in states where this capability exists.

Comment: Commenters expressed concern about the burden of multiple requirements for submission from Federal, State, and local government agencies or non-governmental registries. They also raised the issue of lack of standardization of means and form of submission.

Response: Standards for content exchange and vocabulary are established in the ONC final rule at 45 CFR 170.302(k). As meaningful use seeks to utilize certified EHR technology for purposes of the test and subsequent submission (if test was successful) these are the standards that should be utilized. While we encourage all providers and registries to work together to develop efficient, electronic submission of immunization information to all registries where it can be used to improve population and public health, for purposes of becoming a meaningful EHR user, we only require a single test and follow up submission if that test is successful.

Comment: Commenters suggested deferring the measure to a later stage due to the lack of a mature HIE infrastructure.

Response: We agree that many areas of the country currently lack the infrastructure to support the electronic exchange of information. As meaningful use seeks to ensure certified EHR technology has the capability to submit electronic data to registries, we only require a single test if a receiving entity is available and follow up submission only if that test is successful. If none of the immunization registries to which the EP, eligible hospital or CAH submits information has the capacity to receive the information electronically, then this objective would not apply.

Comment: Commenters requested clarification whether on a failed attempted test satisfies the criteria of this measure and whether EPs in a group setting using identical certified EHR technology would only need to conduct a single test, not one test per EP.

Response: A failed attempt would meet the measure. We highly encourage EPs, eligible hospitals, and CAHs to work with their vendor and the receiving entity with whom they tested to identify the source of the failure and develop remedies, but for Stage 1 of meaningful use a failed attempt would meet the requirements. We had indicated in the proposed rule that only one test is required for EPs practicing in a group setting that shares the same certified EHR technology. We maintain that proposal for the final rule.

Comment: Commenters recommended the inclusion of electronically reporting to other types of registries in addition to immunization registries such as disease-specific registries such as the Cystic Fibrosis Registry.

Response: While we encourage all providers and registries to work together

to develop efficient, electronic submission of information to all registries where it can be used to improve population and public health, for purposes of becoming a meaningful EHR user, we only require a single test utilizing immunization data and follow up submission if that test is successful.

After consideration of the public comments received, we are modifying the meaningful use measure for EPs at § 495.6(e)(9)(ii) and for eligible hospitals and CAHs at § 495.6(g)(8)(ii) of our regulations to "Performed at least one test of certified EHR technology's capacity to submit electronic data to immunization registries and follow up submission if the test is successful (unless none of the immunization registries to which the EP, eligible hospital, or CAH submits such information have the capacity to receive the information electronically)".

We further specify that in order to meet this objective and measure, an EP, eligible hospital, or CAH must use the capabilities Certified EHR Technology includes as specified and standards at 45 CFR 170.302(k). The ability to calculate the measure is included in certified EHR technology. We require that an EP, eligible hospital, or CAH determine if they have given any immunizations during the EHR reporting period. Those that have not given any immunizations during the EHR reporting period are excluded from this measure according to the discussion of whether certain EP, eligible hospital or CAH can meet all Stage 1 meaningful use objectives given established scopes of practices. If they have given immunizations during the reporting period, they should then attempt to locate a registry or IIS with whom to conduct a test of the submission of electronic data. This test must include the transfer of either actual or "dummy" data to the chosen registry or IIS. The testing could occur prior to the beginning of the EHR reporting period, but must occur prior to the end 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. If the test is successful, then the EP, eligible hospital, or CAH should institute regular reporting to that entity in accordance with applicable law and practice. CMS will accept a yes/no attestation to verify all of the above for EPs, eligible hospitals or CAHs that have administered immunizations during the EHR reporting period.

NPRM Eligible Hospital Objective: 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.

In the proposed rule, we did not elaborate on this objective.

Comment: A few commenters requested this objective be applied to EPs as long as the EHR Certification requirements are met. A commenter remarked that electronic submission of reportable lab results should not put an additional burden on the providers as the EHR would be able to automate this process.

Response: We based the limitation on the recommendation of the HIT Policy Committee who in turn went through a considerable public development process. We do not believe that burden of reporting was the only limiting factor in keeping this objective from being applied to EPs; therefore, we maintain our proposal to limit this objective to eligible hospitals and CAHs. EPs usually send out lab test to other organizations on which reporting burdens may fall.

Comment: Commenters requested that the actual transmission of the information be required.

Response: In the discussion of the reporting immunization data objective, we discussed at length the need to align the language for the three objectives included under the health care policy priority of improve population and public health, which is one of the five priorities of the Stage 1 definition of meaningful use. Our interpretation is that the three phrases result in the same outcome, but introduce confusion due to the varied wordings. As commenters strongly preferred the phrase "according to applicable law and practice", we will so modify this objective. We do note however that applicable law and practice does not guarantee every receiving entity will be able to accept it electronically. Our measure for meeting this objective is one test of electronic data submission and if the test is successful, a follow up submission to that one entity. We do not seek to enforce through meaningful use every law and practice that may require submission of lab results.

After consideration of the public comments received, we are modifying the meaningful use objective for eligible hospitals and CAHs at § 495.6(g)(9)(i) of our regulations to "Capability to submit electronic data on reportable (as required by state or local law) lab results to public health agencies and actual submission in accordance with applicable law and practice".

NPRM 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).

In the proposed rule, we identified this as an objective where more stringent requirements may be established for eligible hospitals under the Medicaid program in states where this capability exists. This is just one example of a possible State proposed modification to

Comment: Commenters asked whether the test needs to be "live" or if it could be a "simulation".

Response: As specified in the proposed rule, this test must involve the actual submission of information to a public health agency, if one exists that will accept the information.

Comment: Commenters asked whether the use of "test" or "dummy" data is permissible.

Response: While the use of test patient information may increase the risk that the system will not be testing to its full capability, given the privacy and security concerns surrounding the transmission of actual patient information we do not require it for the purposes of a test. Therefore, the use of test information about a fictional patient that would be identical in form to what would be sent about an actual patient would satisfy this objective. However, we note that this is one of the objectives that a State may modify as discussed previously in this section. Therefore, more stringent requirements may be established for EPs and eligible hospitals under the Medicaid program in states where this capability exists.

Comment: Commenters requested that one national standard be established for reporting lab results to public health agencies.

Response: Standards for content exchange and vocabulary are established in the ONC final rule at 45 CFR 170.306(g). While we encourage all providers and public health agencies to work together to develop efficient, electronic submission of reportable lab results to all public health agencies, for purposes of becoming a meaningful EHR user, we only require a single test and follow up submission if that test is successful.

Comment: Commenters suggested deferring the measure to a later stage due to the lack of a mature HIE infrastructure and lack of a clear standard for exchanging bio-surveillance data.

Response: We agree that many areas of the country currently lack the infrastructure to support the electronic exchange of information. As meaningful use seeks to ensure certified EHR

technology has the capability to submit electronic data to public health agencies, we only require a single test if a receiving entity is available and follow up submission only if that test is successful.

After consideration of the public comments received, we are modifying the meaningful use measure for eligible hospitals and CAHs at § 495.6(g)(9)(ii) of our regulations to "Performed at least one test of certified EHR technology's capacity to provide electronic submission of reportable lab results to public health agencies and follow-up submission if the test is successful (unless none of the public health agencies to which eligible hospital or CAH submits such information have the capacity to receive the information electronically)".

We further specify that in order to meet this objective and measure, an EP, eligible hospital, or CAH must use the capabilities Certified EHR Technology includes as specified and standards at 45 CFR 170.306(g). The ability to calculate the measure is included in certified EHR technology. Eligible hospitals and CAHs should attempt to identify one public health agency with whom to conduct a test of the submission of electronic data. This test must include the transfer of either actual or "dummy" data to the chosen public health agency. The testing could occur prior to the beginning of the EHR reporting period, but must occur prior to the end of the EHR reporting period. If the test is successful, then the eligible hospital or CAH should institute regular reporting to that entity according to applicable law and practice. CMS will accept a yes/no attestation to verify all of the above for eligible hospitals and CAHs.

NPRM EP/Eligible Hospital Objective: Capability to provide electronic syndromic surveillance data to public health agencies and actual transmission according to applicable law and practice.

In the proposed rule, we did not elaborate on this objective.

Comment: Half of the commenters commenting on this objective recommended that the objective be deferred to Stage 2 or 3 as the objective is considered expensive, complex and imposes significant administrative burdens on EPs, eligible hospitals and CAHs unless the certified EHR technologies support the automate, electronic capture of the requisite data.

Response: The measure for this objective accounts for the possibility that such electronic exchange of syndromic data is not possible. Standards and certification for certified EHR technologies are covered under the ONC final rule and do support the automatic identification of the requisite data and its electronic capture. This greatly limits the cost, complexity and burden of this objective.

Comment: Commenters requested that an actual transmission be required.

Response: In discussing the reporting immunization data objective, we focused on the need to align the language for the three objectives contained in under the health care policy priority of improving population and public health. Our interpretation is that the three phrases result in the same outcome, but introduce confusion with the current language. We adopted the language from this objective for the others. We do note however that applicable law and practice does not guarantee every receiving entity will be able to accept it electronically. Our measure for meeting this objective is one test of electronic data submission and if the test is successful, then follow up submission to that one entity based on the reporting requirements of that entity. We do not seek to enforce through meaningful use every law and practice that may require submission of lab results.

Comment: Some commenters requested a clarification of the term "public health agencies."

Response: A public health agency is an entity under the jurisdiction of the U.S. Department of Health and Human Services, tribal organization, State level and/or city/county level administration that serves a public health function.

Comment: Some commenters recommended that providers be required to satisfy either electronic submission to immunization registries or electronic submission of syndromic surveillance data to a public health agency, but not both.

Response: We disagree. We believe these are fundamentally different types of information. Each may impose unique requirements in terms of ability to exchange information on both the EP, eligible hospital, or CAH and the receiving entity. Therefore, a test for one does not prove or disprove the ability to exchange information for the other.

After consideration of the public comments received, we are modifying the meaningful use objective for EPs at § 495.6(e)(10)(i) and eligible hospitals and CAHs at § 495.6(g)(10(i) of our regulations to "Capability to submit electronic syndromic surveillance data to public health agencies and actual submission in accordance with applicable law and practice."

NPRM 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, eligible hospital, or CAH submits such information have the capacity to receive the information electronically).

In the proposed rule, we identified this as an objective where 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.

First, a technical correction, in the proposed rule we incorrectly stated that the capability to send electronic data to immunization registries was included in the certification standards for certified EHR technology. We intended for this data to be sent to public health agencies and ONC in their final rule at 45 CFR 170.304(l) correctly stated this capability as such.

Comment: Commenters asked whether the test needs to be "live" or if it could be a "simulation".

Response: As specified in the proposed rule, this test must involve the actual submission of information to a public health agency, if one exists that will accept the information.

Comment: Commenters asked whether the use of "test" or "dummy" data is permissible.

Response: While the use of test patient information may increase the risk that the system will not be testing to its full capability, given the privacy and security concerns surrounding the transmission of actual patient information we do not require it for the purposes of a test. Therefore, the use of test information about a fictional patient that would be identical in form to what would be sent about an actual patient would satisfy this objective. However, we note that this is one of the objectives that a State may modify in accordance with the discussion in II.A.2.c. of the proposed rule. Therefore, more stringent requirements may be established for EPs and eligible hospitals under the Medicaid program in states where this capability exists.

Comment: A few commenters expressed confusion as to the required ferquency of the test.

Response: As stated in the proposed rule, the required frequency of a test in Stage 1 for EPs, eligible hospitals, and CAHs is at least once prior to the end of the EHR reporting period. We further clarify that each payment year would require it own unique test.

Comment: Commenters requested that one national standard be established for

reporting syndromic surveillance data to public health agencies.

Response: Standards for content exchange and vocabulary are established in the ONC final rule. While we encourage all providers and public health agencies to work together to develop efficient, electronic submission of syndromic surveillance data to all public health agencies, for purposes of becoming a meaningful EHR user, we only require a single test and follow up submission if that test is successful.

Comment: Commenters suggested deferring the measure to a later stage due to the lack of a mature HIE infrastructure.

Response: We agree that many areas of the country currently lack the infrastructure to support the electronic exchange of information. As meaningful use seeks to ensure certified EHR technology has the capability to submit electronic data to public entities, we only require a single test if a receiving entity is available and follow up submission only if that test is successful. We note that this measure only applies if there is a public health agency with the capacity to receive this information.

Comment: Commenters requested clarification on whether a failed attempted test satisfies the measure and whether EPs in a group setting using identical certified EHR technology would only need to conduct a single test, not one test per EP.

Response: A failed attempt would meet the measure. We highly encourage EPs, eligible hospitals, and CAHs to work with their vendor and the receiving entity with whom they tested to identify the source of the failure and develop remedies, but for Stage 1 of meaningful use a failed attempt would meet the requirements. We had indicated in the proposed rule that only on test is required for EPs practicing in a group setting that shares the same certified EHR technology. We maintain that proposal for the final rule.

After consideration of the public comments received, we are modifying the meaningful use measure for EPs at § 495.6(e)(10)(ii) and eligible hospitals and CAHs at § 495.6(g)(10)(ii) of our regulations to "Performed at least one test of certified EHR technology's capacity to provide electronic syndromic surveillance data to public health agencies and follow-up submission if the test is successful (unless none of the public health agencies to which an EP, eligible hospital, or CAH submits such information have the capacity to receive the information electronically.)"

We further specify that in order to meet this objective and measure, an EP, eligible hospital, or CAH must use the capabilities Certified EHR Technology includes as specified and standards at 45 CFR 170.302(l). The ability to calculate the measure is included in certified EHR technology. EPs, eligible hospitals, and CAHs should attempt to identify one public health agency with whom to conduct a test of the submission of electronic data. This test must include the transfer of either actual or "dummy" data to the chosen public health agency. The testing could occur prior to the beginning of the EHR reporting period, but must occur prior to the end of the EHR reporting period. If the test is successful, then the EP, eligible hospital, or CAH should institute regular reporting to that entity according to applicable law and practice. CMS will accept a yes/no attestation to verify all of the above for eligible hospitals and CAHs.

If an EP does not collect any reportable syndromic information on their patients during the EHR reporting period, then they are excluded from this measure according to the discussion of whether certain EP, eligible hospital or CAH can meet all Stage 1 meaningful use objectives given established scopes of practices.

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.

NPRM EP/Eligible Hospital Objective: Protect electronic health information created or maintained by the certified EHR technology through the implementation of appropriate technical capabilities.

In the proposed rule, we discussed how we were relating the objectives presented by the HIT Policy committee more tightly to the meaningful use of certified EHR technology as opposed to the broader success of the EP, eligible hospital or CAH in ensuring privacy and security. The primary reason we gave was that the proper vehicle for ensuring privacy and security is the HIPAA Privacy and Security Act and that we sought with this objective to ensure that certified EHR technology does not impede an EP's, eligible hospital's or CAH's ability to comply with HIPAA.

Comment: We received considerable support from many commenters who supported this objective and measure as proposed.

Response: We appreciate the support of these commenters for our proposed objective and measure.

Comment: Commenters requested clarification of appropriate technical capabilities.

Response: The ONC final rule specifies certain capabilities that must be in certified EHR technology. For the objective we simply mean that a technical capability would be appropriate if it protected the electronic health information created or maintained by the certified EHR technology. All of these capabilities could be part of the certified EHR technology or outside systems and programs that support the privacy and security of certified EHR technology. We could not develop an exhaustive list. Furthermore as we state in the proposed rule compliance with HIPAA privacy and security rules is required for all covered entities, regardless of whether or not they participate in the EHR incentive programs. Furthermore, compliance with the HIPAA Privacy and Security Rules constitutes a wide range of activities, procedures and infrastructure. We rephrased 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.

Comment: Several commenters urged CMS not to finalized requirements for the fair data sharing practices set forth in the Nationwide Privacy and Security Framework and to clarify the policies to which CMS is referring.

Response: While we stated in the proposed rule we rephrased the objective to ensure "compliance with fair sharing data practices outline in the Nationwide Privacy and Security Framework," we did not propose any practices or policies related to the Nationwide Privacy and Security Framework and do not finalize any in this final rule.

Comment: Several commenters requested the elimination of this objective as redundant to HIPAA.

Response: We do not see meaningful use as an appropriate regulatory tool to impose different, additional, and/or inconsistent privacy and security policy requirements from those policies already required by HIPAA. With that said, we do feel it is crucial that EPs, eligible hospitals, and CAHs evaluate the impact certified EHR technology has on their compliance with HIPAA and the protection of health information in general. Therefore, we retain this objective and measure for meaningful use in the final rule.

Comment: We received hundreds of comments that requested the cancelation of the EHR incentive payment program due to the privacy and security risks imposed by the implementation and use of certified EHR technology.

Response: We are required by the ARRA to implement the EHR incentive programs and cannot cancel them. We seek to mitigate the risks to the security and privacy of patient information by requiring EPs, eligible hospitals, and CAHs to 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.

After consideration of the public comments received, we are finalizing the meaningful use objective for EPs at § 495.6(d)(15)(i) and eligible hospitals and CAHs at § 495.6(f)(14)(i) of our regulations as proposed.

We include this objective in the core set. We believe maintaining privacy and security is crucial for every EP, eligible hospital or CAH that uses certified EHR technology and was recommended by the HIT Policy Committee for inclusion in the core set.

NPRM 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.

In the proposed rule, we discussed the role of certified EHR technology in privacy and security. We said that 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. We have maintained this discussion for the final rule, but modified the measure to account for requests discussed in the comment and response section below.

Comment: Some commenters requested clarification of the phrase "implement security updates as necessary".

Response: A security update would be required if any security deficiencies were identified during the risk analysis. A security update could be updated software for certified EHR technology to be implemented as soon as available, to changes in workflow processes, or storage methods or any other necessary corrective action that needs to take place in order to eliminate the security deficiency or deficiencies identified in the risk analysis. To provide better clarity on this requirement, we are modifying the measure.

After consideration of the public comments received, we are modifying the meaningful use measure for EPs at § 495.6(d)(15)(ii) and eligible hospitals and CAHs at § 495.6(f)(14)(ii) of our regulations "Conduct or review a security risk analysis per 45 CFR 164.308(a)(1) of the certified EHR technology, and implement security updates and correct identified security deficiencies as part of its risk management process."

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Table 2: Stage 1 Meaningful Use Objectives and Associated Measures Sorted by Core and Menu Set

CORE SET			
Health Outcomes Policy Priority	**Stage 1 Objectives**		**Stage 1 Measures**
	Eligible Professionals	**Eligible Hospitals and CAHs**	
Improving quality, safety, efficiency, and reducing health disparities	Use CPOE for medication orders directly entered by any licensed healthcare professional who can enter orders into the medical record per state, local and professional guidelines	Use CPOE for medication orders directly entered by any licensed healthcare professional who can enter orders into the medical record per state, local and professional guidelines	More than 30% of unique patients with at least one medication in their medication list seen by the EP or admitted to the eligible hospital's or CAH's inpatient or emergency department (POS 21 or 23) have at least one medication order entered using CPOE
	Implement drug-drug and drug-allergy interaction checks	Implement drug-drug and drug-allergy interaction checks	The EP/eligible hospital/CAH has enabled this functionality for the entire EHR reporting period
	Generate and transmit permissible prescriptions electronically (eRx)		More than 40% of all permissible prescriptions written by the EP are transmitted electronically using certified EHR technology
	Record demographics o preferred language o gender o race o ethnicity o date of birth	Record demographics o preferred language o gender o race o ethnicity o date of birth o date and preliminary cause of death in the event of mortality in the eligible hospital or CAH	More than 50% of all unique patients seen by the EP or admitted to the eligible hospital's or CAH's inpatient or emergency department (POS 21 or 23) have demographics recorded as structured data
	Maintain an up-to-date problem list of current and active diagnoses	Maintain an up-to-date problem list of current and active diagnoses	More than 80% of all unique patients seen by the EP or admitted to the eligible hospital's or CAH's inpatient or emergency department (POS 21 or 23) have at least one entry or an indication that no problems are known for the patient recorded as structured data

	Maintain active medication list	Maintain active medication list	More than 80% of all unique patients seen by the EP or admitted to the eligible hospital's or CAH's inpatient or emergency department (POS 21 or 23)have at least one entry (or an indication that the patient is not currently prescribed any medication) recorded as structured data
	Maintain active medication allergy list	Maintain active medication allergy list	More than 80% of all unique patients seen by the EP or admitted to the eligible hospital's or CAH's inpatient or emergency department (POS 21 or 23) have at least one entry (or an indication that the patient has no known medication allergies) recorded as structured data
	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 more than 50% of all unique patients age 2 and over seen by the EP or admitted to eligible hospital's or CAH's inpatient or emergency department (POS 21 or 23), height, weight and blood pressure are recorded as structured data
	Record smoking status for patients 13 years old or older	Record smoking status for patients 13 years old or older	More than 50% of all unique patients 13 years old or older seen by the EP or admitted to the eligible hospital's or CAH's inpatient or emergency department (POS 21 or 23) have smoking status recorded as structured data
	Implement one clinical decision support rule relevant to specialty or high clinical priority along with the ability to track compliance that rule	Implement one clinical decision support rule related to a high priority hospital condition along with the ability to track compliance with that rule	Implement one clinical decision support rule
	Report ambulatory clinical quality measures to CMS or the States	Report hospital clinical quality measures to CMS or the States	For 2011, provide aggregate numerator, denominator, and exclusions through attestation as discussed in section II(A)(3) of this

			final rule
			For 2012, electronically submit the clinical quality measures as discussed in section II(A)(3) of this final rule
Engage patients and families in their health care	Provide patients with an electronic copy of their health information (including diagnostic test results, problem list, medication lists, medication allergies), upon request	Provide patients with an electronic copy of their health information (including diagnostic test results, problem list, medication lists, medication allergies, discharge summary, procedures), upon request	More than 50% of all patients of the EP or the inpatient or emergency departments of the eligible hospital or CAH (POS 21 or 23) who request an electronic copy of their health information are provided it within 3 business days
		Provide patients with an electronic copy of their discharge instructions at time of discharge, upon request	More than 50% of all patients who are discharged from an eligible hospital or CAH's inpatient department or emergency department (POS 21 or 23) and who request an electronic copy of their discharge instructions are provided it
	Provide clinical summaries for patients for each office visit		Clinical summaries provided to patients for more than 50% of all office visits within 3 business days
Improve care coordination	Capability to exchange key clinical information (for example, problem list, medication list, medication 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, medication 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
Ensure adequate privacy and security protections for personal health information	Protect electronic health information created or maintained by the certified EHR technology through the implementation of appropriate technical capabilities	Protect electronic health information created or maintained by the certified EHR technology through the implementation of appropriate technical capabilities	Conduct or review a security risk analysis per 45 CFR 164.308 (a)(1) and implement security updates as necessary and correct identified security deficiencies as part of its risk management process

MENU SET		
Health Outcomes	Stage 1 Objectives	Stage 1 Measures

Policy Priority	Eligible Professionals	Eligible Hospitals and CAHs	
Improving quality, safety, efficiency, and reducing health disparities	Implement drug-formulary checks	Implement drug-formulary checks	The EP/eligible hospital/CAH has enabled this functionality and has access to at least one internal or external drug formulary for the entire EHR reporting period
		Record advance directives for patients 65 years old or older	More than 50% of all unique patients 65 years old or older admitted to the eligible hospital's or CAH's inpatient department (POS 21) have an indication of an advance directive status recorded
	Incorporate clinical lab-test results into certified EHR technology as structured data	Incorporate clinical lab-test results into certified EHR technology as structured data	More than 40% of all clinical lab tests results ordered by the EP or by an authorized provider of the eligible hospital or CAH for patients admitted to its inpatient or emergency department (POS 21 or 23) during the EHR reporting period whose results are either 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, research or outreach	Generate lists of patients by specific conditions to use for quality improvement, reduction of disparities, research or outreach	Generate at least one report listing patients of the EP, eligible hospital or CAH with a specific condition
	Send reminders to patients per patient preference for preventive/ follow up care		More than 20% of all unique patients 65 years or older or 5 years old or younger were sent an appropriate reminder during the EHR reporting period
Engage patients and families in their health care	Provide patients with timely electronic access to their health information (including lab results, problem list, medication lists, medication allergies) within four business days of the information being available to the		More than 10% of all unique patients seen by the EP are provided timely (available to the patient within four business days of being updated in the certified EHR technology) electronic access to their health information subject to the EP's discretion to withhold certain information

	EP		
	Use certified EHR technology to identify patient-specific education resources and provide those resources to the patient if appropriate	Use certified EHR technology to identify patient-specific education resources and provide those resources to the patient if appropriate	More than 10% of all unique patients seen by the EP or admitted to the eligible hospital's or CAH's inpatient or emergency department (POS 21 or 23) are provided patient-specific education resources
Improve care coordination	The EP, eligible hospital or CAH who receives a patient from another setting of care or provider of care or believes an encounter is relevant should perform medication reconciliation	The EP, eligible hospital or CAH who receives a patient from another setting of care or provider of care or believes an encounter is relevant should perform medication reconciliation	The EP, eligible hospital or CAH performs medication reconciliation for more than 50% of transitions of care in which the patient is transitioned into the care of the EP or admitted to the eligible hospital's or CAH's inpatient or emergency department (POS 21 or 23)
	The EP, eligible hospital or CAH who transitions their patient to another setting of care or provider of care or refers their patient to another provider of care should provide summary of care record for each transition of care or referral	The EP, eligible hospital or CAH who transitions their patient to another setting of care or provider of care or refers their patient to another provider of care should provide summary of care record for each transition of care or referral	The EP, eligible hospital or CAH who transitions or refers their patient to another setting of care or provider of care provides a summary of care record for more than 50% of transitions of care and referrals
Improve population and public health[2]	Capability to submit electronic data to immunization registries or Immunization Information Systems and actual submission in accordance with applicable law and practice	Capability to submit electronic data to immunization registries or Immunization Information Systems and actual submission in accordance with applicable law and practice	Performed at least one test of certified EHR technology's capacity to submit electronic data to immunization registries and follow up submission if the test is successful (unless none of the immunization registries to which the EP, eligible hospital or CAH submits such information have the capacity to receive the information electronically)

[2] Unless an EP, eligible hospital or CAH has an exception for all of these objectives and measures they must complete at least one as part of their demonstration of the menu set in order to be a meaningful EHR user.

		Capability to submit electronic data on reportable (as required by state or local law) lab results to public health agencies and actual submission in accordance with applicable law and practice	Performed at least one test of certified EHR technology's capacity to provide electronic submission of reportable lab results to public health agencies and follow-up submission if the test is successful (unless none of the public health agencies to which eligible hospital or CAH submits such information have the capacity to receive the information electronically)
	Capability to submit electronic syndromic surveillance data to public health agencies and actual submission in accordance with applicable law and practice	Capability to submit electronic syndromic surveillance data to public health agencies and actual submission in accordance with 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 and follow-up submission if the test is successful (unless none of the public health agencies to which an EP, eligible hospital or CAH submits such information have the capacity to receive the information electronically)

Table 3: Stage 1 Meaningful Use Objectives and Associated Measures Sorted by Method of Measure Calculation

Measures with a Denominator of Unique Patients Regardless of Whether the Patient's Records Are Maintained Using Certified EHR Technology		
Stage 1 Objectives		**Stage 1 Measures**
Eligible Professionals	**Eligible Hospitals and CAHs**	
Maintain an up-to-date problem list of current and active diagnoses	Maintain an up-to-date problem list of current and active diagnoses	More than 80% of all unique patients seen by the EP or admitted to the eligible hospital's or CAH's inpatient or emergency department (POS 21 or 23) have at least one entry or an indication that no problems are known for the patient recorded as structured data
Maintain active medication list	Maintain active medication list	More than 80% of all unique patients seen by the EP or admitted to the eligible hospital's or CAH's inpatient or emergency department (POS 21 or 23)have at least one entry (or an indication that the patient is not currently prescribed any medication) recorded as structured data
Maintain active medication allergy list	Maintain active medication allergy list	More than 80% of all unique patients seen by the EP or admitted to the eligible hospital's or CAH's inpatient or emergency department (POS 21 or 23) have at least one entry (or an indication that the patient has no known medication allergies) recorded as structured data
Record demographics o Preferred language o Gender o Race o Ethnicity o Date of Birth	Record demographics o Preferred language o Gender o Race o Ethnicity o Date of Birth o Date and preliminary cause of death in the event of mortality in the eligible hospital or CAH	More than 50% of all unique patients seen by the EP or admitted to the eligible hospital's or CAH's inpatient or emergency department (POS 21 or 23) have demographics recorded as structured data
Provide patients with timely electronic access to their health information (including lab results, problem list, medication lists, medication allergies) within four business days of the information being available to the EP		More than 10% of all unique patients seen by the EP are provided timely (available to the patient within four business days of being updated in the certified EHR technology) electronic access to their health information subject to the EP's discretion to withhold certain information

Use certified EHR technology to identify patient-specific education resources and provide those resources to the patient if appropriate	Use certified EHR technology to identify patient-specific education resources and provide those resources to the patient if appropriate	More than 10% of all unique patients seen by the EP or admitted to the eligible hospital's or CAH's inpatient or emergency department (POS 21 or 23) are provided patient-specific education resources
Measures with a Denominator of Based on Counting Actions for Patients whose Records are Maintained Using Certified EHR Technology		
Stage 1 Objectives		**Stage 1 Measures**
Eligible Professionals	**Eligible Hospitals and CAHs**	
Use CPOE for medication orders directly entered by any licensed healthcare professional who can enter orders into the medical record per state, local and professional guidelines	Use CPOE for medication orders directly entered by any licensed healthcare professional who can enter orders into the medical record per state, local and professional guidelines	More than 30% of unique patients with at least one medication in their medication list seen by the EP or admitted to the eligible hospital's or CAH's inpatient or emergency department (POS 21 or 23) have at least one medication order entered using CPOE
Generate and transmit permissible prescriptions electronically (eRx)		More than 40% of all permissible prescriptions written by the EP are transmitted electronically using certified EHR technology
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 more than 50% of all unique patients age 2 and over seen by the EP or admitted to eligible hospital's or CAH's inpatient or emergency department (POS 21 or 23), height, weight and blood pressure are recorded as structured data
Record smoking status for patients 13 years old or older	Record smoking status for patients 13 years old or older	More than 50% of all unique patients 13 years old or older seen by the EP or admitted to the eligible hospital's or CAH's inpatient or emergency department (POS 21 or 23) have smoking status recorded as structured data
	Record advance directives for patients 65 years old or older	More than 50% of all unique patients 65 years old or older admitted to the eligible hospital have an indication of an advance directive status recorded
Incorporate clinical lab-test results into certified EHR technology as structured data	Incorporate clinical lab-test results into certified EHR technology as structured data	More than 40% of all clinical lab tests results ordered by the EP or by an authorized provider of the eligible hospital or CAH for patients admitted to its inpatient or emergency department (POS 21 or 23) during the EHR reporting period whose results are either in a positive/negative or numerical format are incorporated in certified EHR technology as structured data

Provide patients with an electronic copy of their health information (including diagnostic test results, problem list, medication lists, medication allergies), upon request	Provide patients with an electronic copy of their health information (including diagnostic test results, problem list, medication lists, medication allergies, discharge summary, procedures), upon request	More than 50% of all patients of the EP or the inpatient or emergency departments of the eligible hospital or CAH (POS 21 or 23) who request an electronic copy of their health information are provided it within 3 business days
	Provide patients with an electronic copy of their discharge instructions at time of discharge, upon request	More than 50% of all patients who are discharged from an eligible hospital or CAH's inpatient department or emergency department (POS 21 or 23) and who request an electronic copy of their discharge instructions are provided it
Provide clinical summaries for patients for each office visit		Clinical summaries provided to patients for more than 50% of all office visits within 3 business days
Send reminders to patients per patient preference for preventive/ follow up care		More than 20% of all unique patients 65 years or older or 5 years old or younger were sent an appropriate reminder during the EHR reporting period
The EP, eligible hospital or CAH who receives a patient from another setting of care or provider of care or believes an encounter is relevant should perform medication reconciliation	The EP, eligible hospital or CAH who receives a patient from another setting of care or provider of care or believes an encounter is relevant should perform medication reconciliation	The EP, eligible hospital or CAH performs medication reconciliation for more than 50% of transitions of care in which the patient is transitioned into the care of the EP or admitted to the eligible hospital's or CAH's inpatient or emergency department (POS 21 or 23)
The EP, eligible hospital or CAH who transitions their patient to another setting of care or provider of care or refers their patient to another provider of care should provide summary of care record for each transition of care or referral	The EP, eligible hospital or CAH who transitions their patient to another setting of care or provider of care or refers their patient to another provider of care should provide summary of care record for each transition of care or referral	The EP, eligible hospital or CAH who transitions or refers their patient to another setting of care or provider of care provides a summary of care record for more than 50% of transitions of care and referrals
Measures Requiring Only a Yes/No Attestation		
Stage 1 Objectives		**Stage 1 Measures**
Eligible Professionals	**Hospitals**	
Implement drug-drug and drug-allergy interaction checks	Implement drug-drug and drug-allergy interaction checks	The EP/eligible hospital/CAH has enabled this functionality for the entire EHR reporting period

Implement drug-formulary checks	Implement drug-formulary checks	The EP/eligible hospital/CAH has enabled this functionality and has access to at least one internal or external drug formulary for the entire EHR reporting period
Generate lists of patients by specific conditions to use for quality improvement, reduction of disparities, research or outreach	Generate lists of patients by specific conditions to use for quality improvement, reduction of disparities, research or outreach	Generate at least one report listing patients of the EP, eligible hospital or CAH with a specific condition
Implement one clinical decision support rule relevant to specialty or high clinical priority along with the ability to track compliance that rule	Implement one clinical decision support rule related to a high priority hospital condition along with the ability to track compliance with that rule	Implement one clinical decision support rule
Capability to exchange key clinical information (for example, problem list, medication list, medication 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, medication 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
Capability to submit electronic data to immunization registries or Immunization Information Systems and actual submission in accordance with applicable law and practice	Capability to submit electronic data to immunization registries or Immunization Information Systems and actual submission in accordance with applicable law and practice	Performed at least one test of certified EHR technology's capacity to submit electronic data to immunization registries and follow up submission if the test is successful (unless none of the immunization registries to which the EP, eligible hospital or CAH submits such information have the capacity to receive the information electronically)
	Capability to submit electronic data on reportable (as required by state or local law) lab results to public health agencies and actual submission in accordance with applicable law and practice	Performed at least one test of certified EHR technology capacity's to provide electronic submission of reportable lab results to public health agencies and follow-up submission if the test is successful (unless none of the public health agencies to which eligible hospital or CAH submits such information have the capacity to receive the information electronically)
Capability to submit electronic syndromic surveillance data to public health agencies and actual submission in accordance with applicable law and practice	Capability to submit electronic syndromic surveillance data to public health agencies and actual submission in accordance with 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 and follow-up submission if the test is successful (unless none of the public health agencies to which an EP, eligible hospital or CAH submits such information have the capacity to receive the information electronically)

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 and correct identified security deficiencies as part of its risk management process

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3. Sections 4101(a) and 4102(a)(1) of the HITECH Act: Reporting on Clinical Quality Measures Using EHRs by EPs, Eligible Hospitals, and CAHs [3]

a. General

As discussed in the meaningful use background in section II.A.2.a. there are three elements of meaningful use. In this section, we discuss the third requirement: using certified EHR technology, the EP, eligible hospital, or CAH 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.c of this final rule. The two other elements of meaningful use are discussed in section II.A.2.d.1 of this final rule.

b. Requirements for the Submission of Clinical Quality Measures by EPs, Eligible Hospitals, and CAHs

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.

In the proposed rule, we stated that 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. We believe that 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 would depend 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 proposed that Medicare EPs, eligible hospitals, and CAHs use an attestation methodology to submit summary information to us on clinical quality measures as a condition of demonstrating meaningful use of certified EHR technology, rather than electronic submission.

We proposed that from the Medicaid perspective, delaying the onset of clinical quality measures electronic reporting until 2012 addresses concerns about States having the ready infrastructure to receive and store clinical quality measures data before then. More importantly, we recognized that since Medicaid providers are eligible to receive incentive payments for adopting, implementing, or upgrading certified EHR technology, Medicaid providers may not be focused on demonstrating meaningful use until 2012 or later.

We stated that 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 beginning in CY 2012 we proposed that an EP using a certified EHR technology or beginning in FY 2012 an eligible hospital or CAH using a certified EHR technology, as appropriate for clinical quality measures, must submit information on clinical quality measures electronically, in addition to submitting the other measures described in section II.2.d.2, in order for the EP, eligible hospital, or CAH 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. We stated in the proposed rule that should we not have the capacity to accept information on clinical quality measures electronically in 2012, we would 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.

We also are finalizing in this final rule that States must identify for us in their State Medicaid HIT Plans how they plan to accept data from Medicaid providers who seek to demonstrate meaningful use by reporting on clinical quality measures, either via attestation or via electronic reporting, subject to our prior approval. If they initiate their program by accepting attestations for clinical quality measures, they must also describe how they will inform providers of their timeframe to accept submission of clinical quality measures electronically. We expect that States will have the capacity to accept electronic reporting of clinical quality measures by their second year implementing their Medicaid EHR incentive program.

For purposes of the requirements under sections 1848(o)(2)(A)(iii) and 1886(n)(3)(iii) of the Act, we defined "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 noted 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

[3] For purposes of this final rule, the term "eligible hospital" for the Medicaid EHR incentive program is inclusive of Critical Access Hospitals (CAHs) as defined in this final rule.

section II.A.3.c.1 of this final rule. These limitations apply solely to the submission of clinical quality measures, and do not apply to other measures of meaningful EHR use. The clinical quality measures on which EPs, eligible hospitals, or CAHs will be required to submit information using certified EHR technology, the statutory requirements and other considerations that were used to select these measures, and the reporting requirements are described below.

With respect to Medicaid EPs and eligible hospitals, we noted 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. We proposed that in the interest of simplifying the program and guarding against duplication of meaningful use criteria, the clinical quality measures adopted for the Medicare EHR incentive program, would also apply to EPs and eligible hospitals in the Medicaid EHR incentive program.

Despite the statutory limitation prohibiting the Secretary from requiring the electronic submission of clinical quality measures in the Medicare EHR incentive program, 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, eligible hospitals, and CAHs. Although we proposed to require the electronic submission of information on clinical quality measures in 2012, we stated that we do not desire this to delay the use of certified EHR technology by EPs, eligible hospitals, and CAHs to measure and improve clinical quality. Specifically, we stated that using EHR functionalities that support measurement of clinical quality is critical to a central goal of the HITECH Act, improving health care quality. Measuring quality is a fundamental aspect of improving such quality, because it allows EPs, eligible hospitals, and CAHs to receive quantitative information upon which they can then act in order to improve quality.

Accordingly, although we did not propose under sections 1848(o)(2)(A)(iii) and 1886(n)(3)(A)(iii) of the Act to require that for 2011 EPs, eligible hospitals, and CAHs report clinical quality measures to us or States electronically, we proposed to require as an additional condition of demonstrating meaningful use of certified EHR technology under sections 1848(o)(2)(A)(i), 1886(n)(3)(A)(ii), and 1903(t)(6) of the Act that EPs and eligible hospitals use certified EHR technology to capture the data elements and calculate the results for certain clinical quality measures. Further, we proposed that EPs, eligible hospitals, and CAHs demonstrate that they have satisfied this requirement during the EHR reporting period for 2011 through attestation. We also proposed to require that Medicare EPs, eligible hospitals, and CAHs attest to the accuracy and completeness of the numerators and denominators for each of the applicable measures. 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, eligible hospitals, and CAHs demonstrate compliance with the meaningful use criteria, we proposed that EPs, eligible hospitals, and CAHs 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 us for all applicable patients. For the Medicaid incentive program, we proposed that States may accept provider attestations in the same manner to demonstrate meaningful use in 2011. However, we indicated that we expect that most 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 certified EHR technology in 2011, for their first payment year.

We stated that we recognize that considerable work needs to be done by measure owners and developers with respect to the clinical quality measures that we proposed. 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 recognized that some measures are further developed than others, as discussed in the measures section (see 75 FR 1871) of the proposed rule. Nevertheless we stated our belief that overall there is sufficient time to complete work on measures and measures specifications so as to allow vendors and EPs, eligible hospitals, and CAHs to implement such systems. We stated that it was our intention not to finalize those specific measures should the necessary work on measure specifications not be completed for particular measures according to the timetable we discuss below. As we discuss below, we finalize in this final rule only those clinical quality measures for which clearly defined electronic specifications have been finalized by the date of display of this final rule. Finalized clinical quality measures are listed in Table 6 for EPs and Table 7 for eligible hospitals and CAHs. We also clarify that while States may not have the capacity to accept electronic reporting of clinical quality measures in 2011 or their first year implementing their Medicaid EHR incentive program, we expect that they will have such capacity by their second implementation year. However, if they do not, as with the Federal government, the State would continue to rely on an attestation methodology for reporting clinical quality measures as a requirement for demonstrating meaningful use of certified EHR technology, subject to CMS prior approval via an updated State Medicaid HIT plan.

Comment: A few commenters requested that the definition of "clinical quality measures" be expanded to include "appropriate clinical prevention."

Response: We agree that appropriate clinical prevention is a pertinent topic for clinical quality measures, but we do not believe the definition of clinical quality measures needs to delineate every aspect of quality care included in the definition.

Comment: Several commenters said it will be difficult to develop the EHR capability to capture, integrate and train staff regarding measure specifications if the clinical quality measures are not posted with sufficient time to allow these activities. Other commenters said there is insufficient time allowed for vendors to retool their products and complete development of the reports and/or systems. Several commenters indicated that the clinical quality measures have not been tested, and reliability and validity testing should be performed. Other commenters indicated that standard, clearly defined electronic specifications do not exist and new specifications should be pilot tested and published for stakeholder/public comment. A commenter requested that CMS establish an explicit process for development and testing of evidence based electronically specified measures (eMeasure), and ensure adequate time for field testing.

Response: In general we agree with the desirability of having electronic specifications available, pilot tested, and published for stakeholder viewing sufficiently in advance so as to allow adequate time for modifications if necessary and vendors to incorporate them into certified EHR technology, and for EPs, eligible hospitals, and CAHs to

integrate the measures into their operations and train staff on the measures. In this case, however, there is a process for certification of certified EHR technology which includes testing of the capability of the certified EHR. The final rule issued by ONC (found elsewhere in this issue of the **Federal Register**) provides that certified EHR technology must have the ability to calculate clinical quality measures as specified by us. We interpret this requirement to mean that certified EHR technology must have the capability to calculate those clinical quality measures selected in this final rule based on the specifications we select and post on the CMS Web site. In order to provide sufficient time for vendors to retool their products and complete development of the necessary reports and/or systems for calculation of the results for the required clinical quality measures, and for certifying bodies to test and certify that EHR technologies adequately do so, we are adopting only those electronic specifications that are posted on the CMS Web site as of the date of display of this final rule. We believe testing that is part of the process for certification of EHR technology will substitute for testing that might otherwise occur. Additionally, some of the selected measures have undergone various amounts of testing already. For example, the Emergency Department Throughput, Stroke and Venous Thromboembolism (VTE) measures mentioned by the commenter were tested during the January 2010 Connectathon and demonstrated at the Health Information and Management Systems Society (HIMSS) 2010 Interoperability Showcase which demonstrated the use of the measures by participating vendors. However, we expect the EHR certification process to carry out the necessary testing to assure that applicable certified EHR technology can calculate sufficient number of EP, eligible hospital and CAH clinical quality measures required to qualify for the meaningful use incentive program. In order to permit greater participation by EHR vendors, including specialty EHRs, the certification program (*see* ONC final rule found elsewhere in this issue of the **Federal Register**) will permit EHRs to be certified if they are able to calculate at a minimum three clinical quality measures in addition to the six core and alternative core measures. In addition, the fact that EPs, eligible hospitals, and CAHs can adopt an EHR reporting period toward the end of FY/CY 2011, we believe, will provide additional time for providers to implement and train staff on the measures we adopt in this final rule.

c. Statutory Requirements and Other Considerations for the Selection of Clinical Quality Measures for Electronic Submission by EPs, Eligible Hospitals, and CAHs

(1) Statutory Requirements for the Selection of Clinical Quality Measures for Electronic Submission by EPs, Eligible Hospitals, and CAHs

Sections 1848(o)(2)(B)(i)(II) and 1886(n)(3)(B)(i) of the Act 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, eligible hospitals, and CAHs for 2011 and 2012 payment were listed in Tables 3 through 21 of the proposed rule (see 75 FR 1874 through 1900).

In the proposed rule, we noted that 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 section 1890(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 and CAHs, 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 section 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, we explained in the proposed rule that 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 will 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, we stated that when selecting the clinical quality measures eligible hospitals and CAHs 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 will 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 proposed measures for EPs, eligible hospitals, and CAHs that are not currently NQF endorsed in an effort to include a broader set of clinical quality measures. In the proposed rule, we noted that the HITECH Act does not require the use of NQF endorsed measures, nor limit the measures to those included in PQRI or RHQDAPU. We stated that 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 proposed certain clinical quality measures for EPs, eligible hospitals, and CAHs, and listed these measures in Tables 3 through 21 of the proposed rule (see 75 FR 1874–1900) for use in the 2011 and 2012 payment years. We stated that no changes (that is, additions of clinical quality measures) would be made after publication of the final rule, except through further rulemaking. However, we stated that 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. We stated that the 2011 specifications for user submission of clinical quality measures would be available on our Web site when they are sufficiently developed or finalized. Specifications for the EHR incentive programs must be obtained *only* from the specifications documents for the EHR incentive program clinical quality measures.

Comment: Numerous comments were received regarding the criteria for selection of clinical quality measures. Some commenters noted the importance of scientific and medical evidence supporting the measure, as well as

concerns regarding how the clinical quality measures are maintained. Many other commenters indicated that all clinical quality measures should be evidence-based and up-to-date with current medical standards. Several commenters communicated support for using NQF; Hospital Quality Alliance (HQA); Ambulatory care Quality Alliance (AQA); and the American Medical Association-Physician Consortium for Performance Improvement (AMA–PCPI) clinical quality measures. Another commenter suggested that measures that have a related U.S. Preventative Services Task Force (USPSTF) recommendation should follow the USPSTF guidelines and the regulations should allow for clinical quality measures to be updated as the evidence base changes. Another commenter indicated CMS should ensure that all clinical quality measures are endorsed through a stakeholder consensus process. Commenters also questioned why some clinical quality measures in the proposed rule do not have identifiers for example, NQF number and another commenter indicated some of the clinical quality measures titles were different in the clinical quality measure tables. Some commenters also stated that clinical quality measures should be phased in, implementing the clinical quality measures by clinically related sets, and that all CMS proposed clinical quality measures should be NQF endorsed.

Some commenters suggested that CMS should consult with other quality measure stakeholders, such as, NQF, the Hospital Quality Alliance (HQA), and the National Committee for Quality Assurance (NCQA), The Joint Commission (TJC), and Regional Health Improvement Collaboratives to verify the validity, reliability, and appropriateness of proposed clinical measures. In addition when developing, validating and recommending clinical quality measures for the pediatric population, a commenter suggested CMS include consultation with the Child Healthcare Corporation of America (CHCA) or the National Association of Children's Hospitals (NACHRI).

Response: The HITECH Act requires that we give preference to clinical quality measures that are NQF endorsed. NQF is the only organization that we are aware of which is in compliance with the requirements of National Technology Transfer and Advancement Act (NTTAA), to endorse quality measures through voluntary consensus standards. However, the HITECH Act does not require the exclusive use of NQF endorsed measures, nor limit the measures to those produced by any particular developer or adopted or supported by any particular organization, such as those suggested by the commenters. We gave preference to NQF endorsed clinical quality measures in this final rule. However, we do not adopt a policy that would restrict the Secretary's discretion of beyond what is required by the statute. Measures listed in the proposed rule that did not have an NQF identifying number were not NQF endorsed.

With respect to specific organizations, we have received broad input regarding clinical quality measures including from many organizations mentioned by commenters and have considered their comments in determining which clinical quality measures to finalize in this final rule. We also note that, for NQF endorsed measures, the NQF provides a venue for public and member input as a part of the endorsement process. With respect to commenters urging consideration of whether the scientific and medical evidence support the measure, whether the clinical quality measures are evidence-based and consistent with current medical standards, and how the clinical quality measures are maintained, we note that these factors are part of the NQF process, as well as standard measure development processes. We are committed to working with national, State and local associations to identify or develop additional electronically specified clinical quality measures, particularly for pediatric populations, for later stages of meaningful use.

In selecting clinical quality measures for the Medicare EHR incentive program, the Secretary is required to provide for notice in the **Federal Register** with public comment. This provides broad public input which we fully consider. However, as we stated in the proposed rule, we are finalizing the policy that technical specifications for clinical quality measures are developed and finalized through the sub-regulatory process. Further, this requirement does not pertain to the Medicaid EHR incentive program. We expect to develop a process in the future to solicit public input on Medicaid-specific clinical quality measures for future stages of meaningful use, if needed. However, because there are no such Medicaid-specific measures in this final rule, and all measures apply uniformly across both the Medicare and Medicaid EHR incentive program, we have not developed such a process in this final rule.

After consideration of the public comments received, the HITECH Act requires that we give preference to clinical quality measures that are NQF endorsed. However, it does not require the exclusive use of NQF endorsed measures, nor limit the measures to those produced by any particular developer nor be adopted by any particular organization. In this case, all clinical quality measures we are finalizing are NQF endorsed and have current electronic specifications as of the date of display of this final rule. Effective with the publication of this final rule, these specifications are final for clinical quality measure reporting under the HITECH Act beginning with 2011 and 2012. The detailed electronic specifications of the clinical quality measures for EPs, eligible hospitals, and CAHs are displayed on the CMS Web site at *http://www.cms.gov/QualityMeasures/03_ElectronicSpecifications.asp#TopOfPage.*

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). For EPs, when the proposed rule was issued there was no statutory authority to provide PQRI incentive payments for services furnished for 2011 or subsequent years. Since then, the PQRI incentive payment for 2011 has been authorized. We acknowledge there is overlap within the clinical quality measure reporting for EPs in the EHR incentive program with the PQRI incentive program. However, the reporting periods in these two incentive programs are different. Currently, the PQRI has a six and a twelve month reporting period. The reporting period for the HITECH EHR incentive program for the first payment year is 90 days, which does not meet the PQRI reporting requirement of six or twelve month reporting period, as currently provided. However, in the second payment year of the HITECH EHR incentive program the reporting period is one year, and the PQRI reporting period, would be synchronous. The requirement for qualification for PQRI is subject to a separate regulation. Although there may be additional issues beyond the reporting periods, we anticipate efforts to avoid redundant and duplicative reporting in PQRI of the same clinical quality measures as required in the EHR incentive program. We envision a single reporting infrastructure for electronic

submission in the future, and will strive to align the EHR incentive program and PQRI as we develop the reporting framework for clinical quality measures to avoid redundant or duplicative reporting. Further, we also note that the Affordable Care Act (Pub. L. 111–148) requires that the Secretary develop a plan to integrate the EHR incentive program and PQRI by January 1, 2012. In doing so we expect to further address the issue of redundant and duplicative reporting. For eligible hospitals and CAHs, for the EHR incentive program, we are finalizing one set of 15 clinical quality measures for both Medicare and Medicaid. For Stage 1 (for clinical quality measures Stage 1 is 2011 and beginning in 2012), none of the finalized 15 clinical quality measures for eligible hospitals and CAHs are currently included in the RHQDAPU program, and therefore there is no issue of redundant and duplicative reporting based upon the HITECH Act. Nevertheless, clinical quality measures in the EHR incentive program for eligible hospitals and CAHs were electronically specified for use in the RHQDAPU program with the anticipation to place these measures in RHQDAPU once we have completed and implemented the mechanism to accept quality measures through electronic submission. For the future, we do not anticipate having one set of clinical quality measures for the EHR incentive program and another set for RHQDAPU. Rather, we anticipate a single set of hospital clinical quality measures, most of which we anticipate can be electronically specified. We note some of the RHQDAPU quality measures, for example HCAHPS experience of care measures, do not lend themselves to EHR reporting. Similarly, certain outcome quality measures, such as the current RQHDAPU readmission measures, are based on claims rather than clinical data. In the future, we anticipate hospitals that report RHQDAPU measures electronically would receive incentives from both the RHQDAPU and EHR incentive program, in addition to properly reporting any required quality measures that are not able to be derived from EHRs; this is however subject to future rulemaking. Further, in the future, for hospitals that do not report electronically we anticipate that they may only qualify for an incentive through the RHQDAPU program, and not through the EHR incentive program. Again this is subject to future rulemaking. We envision a single reporting infrastructure for electronic submission in the future, and will strive to align the hospital quality initiative programs to seek to avoid redundant and duplicative reporting of quality measures for eligible hospitals and CAHs.

Comment: Many commenters also suggested aligning clinical quality measure reporting across federal agencies (for example, HRSA, CMS) as well as across programs, (for example, PQRI, CHIP, Medicare and Medicaid) to avoid duplicative and redundant quality performance reporting. Additionally, several commenters suggested that similar clinical quality measures and/or quality data efforts included in the proposed rule are included in other clinical quality recognition programs and EPs who successfully report in these programs via a certified EHR should be deemed to have successfully reported in the EHR incentive program. Other commenters suggested using the PQRI reporting process to satisfy the meaningful use requirement under the EHR incentive program for EPs. Another commenter indicated that clinical quality measures employed by this program and others will be valuable if EPs using EHRs have an in-depth understanding of how to leverage the technology and the data they produce to improve care. A number of commenters requested that only clinical quality measures chosen for use in the RHQDAPU program should be considered for implementation in the EHR incentive program for eligible hospitals and CAHs that qualify for both incentives. Additionally, the commenters stated they would like the process for avoiding duplicative reporting clearly defined.

Response: The HITECH Act requires that the Secretary seek to avoid redundant and duplicative reporting, with specific reference to PQRI for EPs and RHQDAPU for eligible hospitals and CAHs. We have sought to avoid duplicative and redundant reporting in the implementation of the HITECH Act as discussed elsewhere in our responses to comments in this final rule. We will seek to align quality initiative programs in future rulemaking.

(2) Other Considerations for the Selection of Clinical Quality Measures for Electronic Submission by EPs, Eligible Hospitals, and CAHs

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, we also proposed applying the following considerations to the selection of the clinical quality measures for electronic submission under the Medicare and Medicaid EHR incentive programs:

- 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 for inclusion in the EHR incentive by the HIT Policy Committee.

We noted in the proposed rule that the Children's Health Insurance Program Reauthorization Act (CHIPRA) of 2009 (Pub. L. 111–3) Title IV, section 401 requires the Secretary to publish a core set of clinical quality measures for the pediatric population. We stated that, to the extent possible, we would align the clinical quality measures selected under the EHR incentive program with the measures selected under the CHIPRA core measure set. Included in the proposed clinical quality measures were nine clinical quality measures pertaining to pediatric providers. Four of these nine measures were on the list of CHIPRA initial core measures that were recommended to the Secretary by the Subcommittee to AHRQ's National Advisory Committee (SNAC). In our proposed rule, we noted that not all CHIPRA initial measures recommended to the Secretary were applicable to EHR technology or to the EHR incentive payment program. For example, some of

the measures are population-based, survey-derived, or not yet NQF endorsed. We stated that new or additional measures for the next iteration of the CHIPRA core set would have EHR extractability as a priority.

Since the publication of the proposed rule, the CHIPRA core measure set has been published in a final rule (see 74 FR 68846 through 68849). In this EHR incentive program final rule, there are four clinical quality measures that are also in the published CHIPRA initial core measure set. These clinical quality measures are shown below in Table 4:

Table 4: Clinical Quality Measures in the EHR Incentive Program Final Rule that are also in the CHIPRA Initial Core Measure Set

Measure Number	Clinical Quality Measure Title
NQF 0024	Weight Assessment Counseling for Children and Adolescents
NQF 0033	Chlamydia Screening for Women
NQF 0038	Childhood Immunization Status
NQF 0002 PQRI 66	Appropriate Testing for Children with Pharyngitis

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. Similarly, the adult quality measures requirements enacted in the ACA will provide another opportunity for CMS to align its quality measures programs for consistency and to maximize use of electronic reporting. As these programs move forward, we will continue to prioritize consistency in clinical quality measure selection for providers when possible.

We solicited comments on the inclusion or exclusion of any clinical quality measure or measures proposed for the 2011 and 2012 payment years, and to our approach in selecting clinical quality measures.

We stated in the proposed rule that 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/steward to make basic changes to a clinical quality measure in terms of the numerator, denominator, and exclusions. We proposed that the clinical quality measures selected for the 2011 and 2012 payment year be supplemented by our technical specifications for EHR submission. We proposed to post the complete clinical quality measures specifications including technical specifications to our Web site and solicited comments on our approach.

We received various comments as to our proposed considerations for selection of clinical quality measures for submission by EPs, eligible hospitals, and CAHs.

Comment: One commenter said that there needs to be longer than nine months for the look back for capturing clinical quality measures data. Several commenters indicated that baseline measurements that have used the clinical quality measure in the past have not been performed. Commenters also recommended the linkage of clinical decision support to clinical quality measures to strengthen quality improvement efforts. A commenter supported our inclusion of measures that address both quality and resource use efficiency. Another commenter indicated support for the clinical quality measures as represented in the proposed rule.

Response: The look back for capturing clinical quality measures is the period of time for which data would be considered as applying to the measure calculation. The look back period for a clinical quality measure and the method of documentation of prior information is defined by the clinical quality measure specification. The clinical quality measures require reporting and not achievement on particular performance thresholds. We agree with the commenters regarding the benefits of linking clinical decision support tools to the clinical quality measures, and anticipate that as EHR technology evolves, many of the clinical quality measures will be supported by clinical decision support tools. We also agree with the benefits of efficiency measures and we expect that in future program years the scope and variety of measures that address these factors will expand.

Comment: Commenters requested a definition for "Eligible Provider and Non-Qualifying Eligible Provider" with respect to the provider's ability to meet meaningful use if there are no appropriate clinical quality measures to report, the application of financial penalties beginning in 2015, and the handling of exclusions. Another commenter stressed the need for detailed information regarding what is included and excluded in the numerator and denominator for each measure so as to ensure that certified EHR technology's programmed analytics capture all patients who meet the relevant criteria and to ensure that clinical quality measures are properly evaluated. Others indicated that reporting measures electronically will reduce administrative reporting costs. Other commenters supported the ability to report "N/A" for clinical quality measures where an insufficient denominator exists. Other commenters urged that CMS not include any clinical quality measures in Stage 1 of Meaningful Use because they believe Stage 1 should focus on the initial implementation of certified EHR systems and its use for patient care, and that EPs must gain experience with their certified EHR technology before attesting to the accuracy and completeness of numerators, denominators and quality calculations generated from these systems.

Response: While some commenters recommended we not include any clinical quality measures in Stage 1 (2011 and beginning in 2012), as previously described for Stage 1 EPs are required to attest to the clinical quality measures calculated results (numerator,

denominator, and exclusions) as automatically calculated by the certified EHR technology. Given that the statutory requirement for clinical quality measures is an element of meaningful use, we believe that providing this information on clinical quality measures is appropriate for Stage 1 (2011 and beginning in 2012). We would expect that the patient for whom a clinical quality measure does not apply will not be included in the denominator of the clinical quality measure. If not appropriate for a particular EP we would expect that either patients would not appear in the denominator of the measure (a zero value) or an exclusion would apply. Therefore reporting "N/A" is not necessary. Exclusion parameters—that is, information on what is included and excluded in the numerator and denominator for a clinical quality measure–are included in the measure specifications. We agree that reporting measures electronically will reduce administrative reporting costs, however as discussed in this final rule we will not require electronic submission of clinical quality measures until 2012. Also discussed earlier in this final rule, we believe collecting clinical quality measure data is an important part of meaningful use.

Comment: A commenter indicated that CMS should take ownership of each of the EP clinical quality measures so that CMS can then adjudicate issues related to the clinical quality measures, instead of referring the EP to the measure owner. One commenter believes that EPs and their specialty societies should be the only owners of EP clinical quality measures.

Response: We are the owner/developer for certain clinical quality measures. More commonly, we use the clinical quality measures developed and owned by others, who are then responsible for the clinical quality measure specifications as endorsed by NQF. Numerous measures have been developed over the years by various organizations and CMS, and therefore we do not believe that specialty societies should be the only owners of EP clinical quality measures. The HITECH Act does not suggest or require that we should be the sole owner/developer of clinical quality measures.

Comment: A commenter questioned whether clinical quality measures would be updated during the bi-annual review process and how much lead time will be given.

Response: The measures for Stage 1 (2011 and beginning in 2012) of meaningful use are finalized in this final rule and will not change during that stage. Additionally, the electronic specifications, as posted on the CMS Web site at the time of publication of this final rule, are final. We intend to expand the clinical quality measures again for Stage 2 of meaningful use, which we anticipate will first be effective for the 2013 payment year. As required by the HITECH Act for the Medicare EHR incentive program, prior to selecting any new clinical quality measure(s) for Stage 2 of meaningful use, we will publish notice of the proposed measure(s) and request and consider public comments on the proposed measures. We note that the Medicaid EHR incentive program does not have the same statutory requirement. If future stages of meaningful use include clinical quality measures specific for Medicaid providers, we will consider a process to receive public input on such measures.

Comment: One commenter suggested that only measures chosen for use in the pay-for-reporting program should be considered for implementation in the EHR incentive program.

Response: We selected clinical quality measures that are broadly applicable for the 2011 and 2012 EHR incentive program. Many clinical quality measures used in other Medicare pay-for-reporting programs are not applicable to all Medicaid eligible providers, such as pediatricians, certified nurse-midwives, and children's hospitals.

Comment: Commenters suggested alignment between measures with vocabulary standards, in order to promote interoperability of clinical data. Stage 1 allows alternative vocabularies for problems, drugs, and procedures; and measures should only be included if alternative specifications using all Stage 1 vocabularies are provided. Commenters recommended incorporating HL7, LOINC, SNOMED, ICD–9, and ICD–10 for data exchange.

Response: Standards for certified EHRs, including vocabulary standards, are included in ONC's final rule (found elsewhere in this issue of the **Federal Register**).

Comment: Commenter recommended that in the beginning stages of implementation of the EHR incentive programs, CMS should base its reporting initiatives on existing industry models to prevent delays, consumer mistrust, and potential legal issues.

Response: We have conducted extensive reviews of industry standards, employed the comments of industry experts and solicited public comments on all proposed processes.

Comment: Many commenters are concerned that there will not be adequate time to communicate and implement the electronic specification for 2011 clinical quality measure requirements. Additionally, one commenter expressed concern that the additional clinical quality measures required for 2011 reporting will not be posted by CMS in time for careful review and assessment, since currently there are only 15 measures electronically specified and posted. Commenters requested clinical quality measures to be posted with implementation guides for each quality reporting metric to ensure successful reporting.

Response: We have limited the requirements for clinical quality measure reporting for eligible hospitals and CAHs to the 15 measures that were electronically specified and posted at the time of publishing the proposed rule. All measures specifications for clinical quality measures selected are final effective upon publication of the EHR incentive program final rule.

d. Clinical Quality Measures for EPs

For the 2011 and 2012 EHR reporting periods, based upon the considerations for selecting clinical quality measures discussed above, we proposed certain clinical quality measures that were identified in the proposed rule (see 75 FR 1874–1889) for EPs. Tables 4 though 19 of the proposed rule divided the clinical quality measures identified in Table 3 into core measures and specialty group measures (see 75 FR 1890 through 1895). The concept of core measures and specialty group measures is discussed below.

We also stated that some measures were in a higher state of readiness than others, and requested comment on each measure's state of readiness for use in the EHR incentive programs. For those measures where electronic specifications did not, at the time of the proposed rule, exist, we solicited comment on how quickly electronic specifications could be developed, and the period of time required from final posting of the electronic specifications for final measures to ensure the effective implementation of the measures. We stated our intention 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. We stated that all of the proposed clinical quality measures included in Table 3 (see 75 FR 1874–1889) meet one or more of the

criteria for the selection of clinical quality measures, discussed in the proposed rule. A large portion of these measures had been through notice and comment rulemaking for PQRI, and nearly all 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, nine of the proposed 90 clinical quality measures listed in Table 3 (*see* 75 FR 1874–1889) (PQRI numbers 1, 2, 3, 5, 7, 110, 111, 112, and 113) had preliminary specifications for electronic submission that had already been developed for the purpose of testing the submission of clinical quality data extracted from an EHR for the PQRI program. The link to the preliminary electronic specifications for nine PQRI clinical quality measures was provided: *http://www.cms.hhs.gov/pqri.*

We stated that 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.

We pointed out that the PQRI clinical quality measures that were proposed largely align with the recommendations of the HIT Standards Committee. However, in addition to proposed clinical quality measures that are currently included in PQRI, we also proposed certain other clinical quality measures that we stated are of high importance to the overall population. Those clinical quality measures are Ischemic Vascular Disease (IVD): Use of Aspirin or another Antithrombotic; IVD: Complete Lipid Profile; IVD: Low Density Lipoprotein (LDL–C) Control, and Blood Pressure Management. Finally, we proposed an array of other measures which address important aspects of clinical quality.

We stated our belief that the proposed clinical quality measures were broad enough to allow for reporting for EPs and addressed high priority conditions. We recognized the importance of integrating the measures into certified EHR technologies for calculation of measures results, and that not all measures would be feasible for 2011 and 2012. We invited comment on the advisability of including the measures for payment years 2011 and 2012. Although we recognized that there are many other important clinical quality measures of health care provided by EPs, we anticipated expanding the set of clinical quality measures in future years and listed a number of clinical quality measures for future consideration in section II.A.3.g of the proposed rule preamble, on which we also invited comment.

Comment: Many of the proposed clinical quality measures received favorable comments and support for inclusion in the final clinical quality measure set. A few examples of measures that were supported for inclusion were measures related to prevention and screening, and diabetes. It was stated by a commenter that the proposed rule includes some similar clinical quality measures. For example, the commenter indicated NQF 0059 and NQF 0575 both deal with hemoglobin A1c control. Others commented that some measures should be eliminated and not utilized in the final set of clinical quality measures for EPs. For example, a few commented that the following two measures should be eliminated, NQF 0052 and NQF 0513 were intended to be implemented at the administrator site level using outpatient hospital claims and not at the individual practitioner level. A number of commenters stated that the specifications for certain clinical quality measures, for example, NQF 0022, NQF 0031, NQF 0032, NQF 0033, NQF 0034, and NQF 0061 were not consistent with current clinical practice guidelines. Another commenter requested clarification for the specifications for NQF 0013 because blood pressures are not routinely monitored for 2-month-old patients. Many commenters provided suggestions for other clinical quality measures not included in the proposed rule.

Response: We appreciate all of the suggestions from the commenters. We are unable to add any clinical quality measures that were not identified in the proposed rule due to language in sections 1848(o)(2)(B)(i)(II) and 1886(n)(3)(B)(i) of the Act requiring a period of public comment for any finalized measures. This requirement does not pertain to the Medicaid EHR incentive program; we expect to develop a process in the future to solicit public input on Medicaid-specific clinical quality measures for future stages of meaningful use, if needed. However, we will consider those additional clinical quality measures recommended by commenters for future inclusion in the clinical quality measure sets.

In regard to suggested changes/revisions and/or elimination of the proposed clinical quality measures, we considered these suggestions when finalizing clinical quality measures in this final rule. In regard to this, we considered these suggestions when evaluating the clinical quality measures for selection in this final rule. Of the clinical quality measures in the proposed rule that we are not finalizing, we removed the measures that do not have electronic specifications by the date of display of this final rule. Additionally, some of the proposed clinical quality measures were recommended for deletion or modification, and therefore were recommended to not be used in the final rule; this is delineated in other comments and responses in this final rule. Further, we are only finalizing clinical quality measures that are electronically specified the date of display of the final rule. The electronic specifications included in the final set of clinical quality measures for EPs are posted to the CMS Web site at: *http://www.cms.gov/QualityMeasures/03_ElectronicSpecifications.asp#TopOfPage.*

Comment: Numerous commenters were concerned about the burden (economic and other) of reporting on the large number of clinical quality measures and the overall quality reporting burden this will add to EPs. Some commenters stated that the use of numerators and denominators for some measures will require manual calculation on the part of the EPs since there are no automated reports that can capture all of the information that must be tabulated. One commenter stated that there are insufficient resources to calculate the denominators of the required measures. Other commenters suggested using the PQRI requirements of reporting only three measures, and others suggested reporting on significantly smaller number of measures.

Response: In response to the many comments received regarding the undue burden associated with reporting on a large number of clinical quality measures, or measures that involve a manual process, we have finalized only those clinical quality measures that can

be automatically calculated by a certified EHR technology. We further limited the measures to those for which electronic specifications are currently available, which we posted as final by the date of display of this final rule. This limitation significantly reduces the number of measures EPs are required to report in 2011 and 2012, thus reducing the EPs' reporting burden as well as addressing commenters' concerns about readiness. Although for 2011, Medicare EPs, eligible hospitals, and CAHs will still need to manually report (attest) to the results automatically calculated by their certified EHR technology, we believe that with the reduction in the number of measures that the burden is reasonable. Additionally, this provides for the reporting of clinical quality measures beyond simply the core clinical quality measures that EPs identify as suitable to report.

Table 5, below, shows the proposed clinical quality measures for submission by Medicare and Medicaid EPs for the 2011 and 2012 payment year as stated in the proposed rule (see 75 FR 1874–1889) for EPs, but that are not being finalized. Table 5 conveys the NQF measure number and PQRI implementation number (that is, the number used in the PQRI program to identify the measure as implemented in PQRI (for the 2010 PQRI measures list see *https://www.cms.gov/PQRI/Downloads/2010_PQRI_MeasuresList_111309.pdf*)), clinical quality measure title and description, and clinical quality measure steward and contact information. The measures listed below in Table 5 do not have electronic specifications finished before the date of display of this final rule, thus we have eliminated these measures for this final rule and will consider the addition of these measures in future rulemaking. Also several measures listed below were only concepts at the time of publication of the proposed rule (that is, Hysterectomy rates, Appropriate antibiotic use for ear infections, Statin after Myocardial Infarction, 30 day Readmission Rate, 30 Readmission Rate following deliveries, and Use of CT Scans). These concept measures were not developed or electronically specified clinical quality measures, nor NQF endorsed; and there was not adequate time to consider these concepts for development for this final rule. Therefore, the concepts listed below will be considered in future rulemaking. Lastly, NQF 0026 has since been retired since publication of the proposed rule.

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TABLE 5: Proposed Clinical Quality Measures for Submission by Medicare or Medicaid EPs for the 2011 and 2012 Payment Year; Included in the Proposed Rule (see 75 FR 1874 through 1889) and Not in the Final Rule

NQF Measure Number & PQRI Implementation Number	Clinical Quality Measure Title & Description	Clinical Quality Measure Steward & Contact Information
NQF 0246 PQRI 10	**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
NQF 0270 PQRI 20	**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
NQF 0268 PQRI 21	**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
NQF 0271 PQRI 22	**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

NQF Measure Number & PQRI Implementation Number	Clinical Quality Measure Title & Description	Clinical Quality Measure Steward & Contact Information
NQF 0239 PQRI 23	**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
NQF 0241 PQRI 33	**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
NQF 0102 PQRI 52	**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
NQF 0069 PQRI 65	**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
NQF 0323 PQRI 81	**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 $Kt/V \geq 1.2$ 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

NQF Measure Number & PQRI Implementation Number	Clinical Quality Measure Title & Description	Clinical Quality Measure Steward & Contact Information
NQF 0321 PQRI 82	**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
NQF 0397 PQRI 86	**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
NQF 0401 PQRI 89	**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
NQF 0103 PQRI 106	**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
NQF 0104 PQRI 107	**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
NQF 0066 PQRI 118	**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

NQF Measure Number & PQRI Implementation Number	Clinical Quality Measure Title & Description	Clinical Quality Measure Steward & Contact Information
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
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
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
NQF 0416 PQRI 127	**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/
NQF 0510 PQRI 145	**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
NQF 0508 PQRI 146	**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

NQF Measure Number & PQRI Implementation Number	Clinical Quality Measure Title & Description	Clinical Quality Measure Steward & Contact Information
NQF 0511 PQRI 147	**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 (for example,, x-ray, MRI, CT, etc.) that were performed	**AMA-PCPI** **Contact Information:** cpe@ama-assn.org
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
NQF 0399 PQRI 183	**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
NQF 0400 PQRI 184	**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
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
NQF 0507 PQRI 195	**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

NQF Measure Number & PQRI Implementation Number	Clinical Quality Measure Title & Description	Clinical Quality Measure Steward & Contact Information
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
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/
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
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/
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/

NQF Measure Number & PQRI Implementation Number	Clinical Quality Measure Title & Description	Clinical Quality Measure Steward & Contact Information
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
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/
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/
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/

NQF Measure Number & PQRI Implementation Number	Clinical Quality Measure Title & Description	Clinical Quality Measure Steward & Contact Information
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/
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/
Not applicable	**Title:** Hysterectomy rates **Description:**	
Not applicable	**Title:** Appropriate antibiotic use for ear infections **Description:**	
Not applicable	**Title:** Statin after Myocardial Infarction **Description:**	
Not Applicable	**Title:** 30 day Readmission Rate **Description:**	
Not Applicable	**Title:** 30 Readmission Rate following deliveries **Description**:	
Not applicable	**Title**: Use of CT scans **Description**: Number of repeat CT scans within 60 days	

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Comment: Some commenters requested that CMS implement feedback reports early in the process that document whether EPs are successfully participating in the PQRI Program, the EHR incentive program, and the e-prescribing program, and that the report communicate whether the information received by CMS for these programs was successfully submitted and received.

Response: As the PQRI and e-prescribing programs are beyond the scope of this rule, we do not address suggestions that we implement feedback reports related to these programs. The criteria to qualify for the EHR incentive payments are based on results automatically calculated by EPs' certified EHR technology, as attested by the EPs. As such, we believe that the EP will be able to determine whether they have reported the required clinical quality measures to CMS or the State, rendering it unnecessary that CMS or the State provide the EP with a feedback report. We expect the system through which EPs, must submit information would indicate successful receipt beginning the first year of Stage 1.

Comment: A commenter indicated that the clinical quality measure that addresses tobacco use and the measure that addresses smoking status apply to different age groups, and stated that they should be consistent. A number of commenters recommended removing smoking status as an objective from meaningful use section of this final rule, and only including it in the clinical quality measures in order to avoid confusion.

Response: We are in agreement that the meaningful use objective and the clinical quality measure address the same topic of smoking. The clinical quality measure requires measurement of a clinical action performed by the EP to address the negative consequences of smoking, whereas the meaningful use objective seeks to make sure smokers are identified. Additionally, the age for recording smoking status for meaningful use is 13 years and older, and the population addressed by the clinical quality measure is 18 years and older, thus they are different with respect to intent of the objective/measure and the age population. For the clinical quality measure, we are keeping the age range at 18 years and older because the measure is currently NQF endorsed with these specifications. We will consider merging these in the future to reconcile the age range.

Comment: Some commenters stated that reporting of ambulatory quality measures should remain voluntary for EPs, based on the view that many process measures do not correlate with outcomes and are not evidence based. A process measure focuses on a process which leads to a certain outcome, meaning that a scientific basis exists for believing that the process, when executed well, will increase the probability of achieving a desired outcome. A commenter stated that EPs serving needy patients, minorities, and populations with lower socioeconomic levels will experience lower performance on many clinical quality measures, and therefore will be deterred from participating in the EHR incentive program.

Response: The EHR incentive program is voluntary. Similar to other Medicare quality measure reporting programs, EPs are not required to satisfy minimum clinical quality performance levels in order to qualify for the EHR payment incentive, but rather merely report on their ambulatory quality measure results. Thus, as currently structured, we do not believe the requirement that EPs report clinical quality measures would deter EPs who serve minority patients or patients of lower socioeconomic status or otherwise disadvantaged from participating in the program.

After consideration of the public comments received, we are finalizing the basic requirement that EPs submit results for clinical quality measures.

This requirement applies to both the 2011 and 2012 reporting periods (and will potentially continue to apply, until CMS issues a subsequent final rule that supplants this final rule). We are limiting the clinical quality measures to those for which electronic specifications are available (posted by CMS on the Web site at the time of display of this final rule.) These measures are listed in Table 6 of this final rule for EPs. They constitute the clinical quality measures "specified by CMS" for the purposes of the ONC final rule (found elsewhere in this issue of the **Federal Register**) and are the measures that certified EHRs are required to be able to calculate. Of these, nine EP measures have preliminary electronic specifications for which we provided links for in the proposed rule. The remaining 35 clinical quality measures for EPs were electronically specified more recently and posted on the CMS Web site by the date of display of this final rule. We are finalizing only those measures for which there are available electronic specifications as of the date of display of this final rule. Although we are not finalizing all of 90 proposed clinical quality measures that were proposed for EPs in Table 3 (*see* 75 FR 1874–1889) of the proposed rule, because of lack of electronic specifications, our intent is to include all of them in our proposed Stage 2 requirements, or to propose alternative measures following a transparent process that includes appropriate consultation with stakeholders and other interested parties. In addition, we plan to add new measures to fill gaps where measures were not previously proposed, such as in behavior and mental health (*e.g.,* depression and alcoholism). Certified EHR technology must be able to calculate each measure numerators, denominators and exclusions for each of the clinical quality measures finalized for the EHR incentive program. Table 6 conveys the applicable NQF measure number and PQRI implementation number (that is, the number used in the PQRI program to identify the measure as implemented in PQRI (for the 2010 PQRI measures list see *https://www.cms.gov/PQRI/Downloads/2010_PQRI_MeasuresList_111309.pdf*)), title, description, the owner/steward, and a link to existing electronic specifications. The NQF number is an identifying number that is associated with the NQF endorsed measure number. All of the clinical quality measures in Table 6 are NQF endorsed and 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. 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 66, 110, 111, 112, 113, 114, 115, and 128 support screening and prevention all of which is a high CMS and HHS priority.

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TABLE 6: Clinical Quality Measures for Submission by Medicare or Medicaid EPs for the 2011 and 2012 Payment Year[4]

NQF Measure Number & PQRI Implementation Number	Clinical Quality Measure Title & Description	Clinical Quality Measure Steward & Contact Information	Electronic Measure Specifications Information	Core Clinical Quality Measure
NQF 0059 PQRI 1	**Title:** Diabetes: Hemoglobin A1c Poor Control **Description:** Percentage of patients 18 - 75 years of age with diabetes (type 1 or type 2) who had hemoglobin A1c > 9.0%.	**National Committee for Quality Assurance (NCQA)** **Contact Information:** www.ncqa.org	http://www.cms.gov/QualityMeasures/03_ElectronicSpecifications.asp#TopOfPage	
NQF 0064 PQRI 2	**Title:** Diabetes: Low Density Lipoprotein (LDL) Management and Control **Description:** Percentage of patients 18-75 years of age with diabetes (type 1 or type 2) who had LDL-C < 100 mg/dL).	**NCQA** **Contact Information:** www.ncqa.org	http://www.cms.gov/QualityMeasures/03_ElectronicSpecifications.asp#TopOfPage	
NQF 0061 PQRI 3	**Title:** Diabetes: Blood Pressure Management **Description:** Percentage of patients 18 - 75 years of age with diabetes (type 1 or type 2) who had blood pressure <140/90 mmHg.	**NCQA** **Contact Information:** www.ncqa.org	http://www.cms.gov/QualityMeasures/03_ElectronicSpecifications.asp#TopOfPage	
NQF 0081 PQRI 5	**Title:** Heart Failure (HF): Angiotensin-Converting Enzyme (ACE) Inhibitor or Angiotensin Receptor Blocker (ARB) Therapy for Left Ventricular Systolic Dysfunction (LVSD) **Description**: Percentage of patients aged 18 years and older with a diagnosis of heart failure and LVSD (LVEF < 40%) 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.gov/QualityMeasures/03_ElectronicSpecifications.asp#TopOfPage	

[4] *** In the event that new clinical quality measures are not adopted by 2013, the clinical quality measures in this Table would continue to apply.

NQF Measure Number & PQRI Implementation Number	Clinical Quality Measure Title & Description	Clinical Quality Measure Steward & Contact Information	Electronic Measure Specifications Information	Core Clinical Quality Measure
NQF 0070 PQRI 7	**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.gov/QualityMeasures/03_ElectronicSpecifications.asp#TopOfPage	
NQF 0041 PQRI 110	**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.gov/QualityMeasures/03_ElectronicSpecifications.asp#TopOfPage	Alternate Core
NQF 0043 PQRI 111	**Title:** Pneumonia Vaccination Status for Older Adults **Description:** Percentage of patients 65 years of age and older who have ever received a pneumococcal vaccine.	**NCQA** **Contact Information:** www.ncqa.org	http://www.cms.gov/QualityMeasures/03_ElectronicSpecifications.asp#TopOfPage	
NQF 0031 PQRI 112	**Title:** Breast Cancer Screening **Description:** Percentage of women 40-69 years of age who had a mammogram to screen for breast cancer.	**NCQA** **Contact Information:** www.ncqa.org	http://www.cms.gov/QualityMeasures/03_ElectronicSpecifications.asp#TopOfPage	
NQF 0034 PQRI 113	**Title:** Colorectal Cancer Screening **Description:** Percentage of adults 50-75 years of age who had appropriate screening for colorectal cancer.	**NCQA** **Contact Information:** www.ncqa.org	http://www.cms.gov/QualityMeasures/03_ElectronicSpecifications.asp#TopOfPage	

NQF Measure Number & PQRI Implementation Number	Clinical Quality Measure Title & Description	Clinical Quality Measure Steward & Contact Information	Electronic Measure Specifications Information	Core Clinical Quality Measure
NQF 0067 PQRI 6	**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	http://www.cms.gov/QualityMeasures/03_ElectronicSpecifications.asp#TopOfPage	
NQF 0083 PQRI 8	**Title:** Heart Failure (HF): Beta-Blocker Therapy for Left Ventricular Systolic Dysfunction (LVSD) **Description:** Percentage of patients aged 18 years and older with a diagnosis of heart failure who also have LVSD (LVEF < 40%) and who were prescribed beta-blocker therapy.	**AMA-PCPI** **Contact Information**: cpe@ama-assn.org	http://www.cms.gov/QualityMeasures/03_ElectronicSpecifications.asp#TopOfPage	
NQF 0105 PQRI 9	**Title:** Anti-depressant medication management: (a) Effective Acute Phase Treatment,(b)Effective Continuation Phase Treatment **Description:** The percentage of patients 18 years of age and older who were diagnosed with a new episode of major depression, treated with antidepressant medication, and who remained on an antidepressant medication treatment.	**NCQA** **Contact Information:** www.ncqa.org	http://www.cms.gov/QualityMeasures/03_ElectronicSpecifications.asp#TopOfPage	
NQF 0086 PQRI 12	**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 been seen for at least two office visits who have an optic nerve head evaluation during one or more office visits within 12 months.	**AMA-PCPI** **Contact Information**: cpe@ama-assn.org	http://www.cms.gov/QualityMeasures/03_ElectronicSpecifications.asp#TopOfPage	

NQF Measure Number & PQRI Implementation Number	Clinical Quality Measure Title & Description	Clinical Quality Measure Steward & Contact Information	Electronic Measure Specifications Information	Core Clinical Quality Measure
NQF 0088 PQRI 18	**Title:** Diabetic Retinopathy: Documentation of Presence or Absence of Macular Edema and Level of Severity of Retinopathy **Description:** Percentage of patients aged 18 years and older with a diagnosis of diabetic retinopathy who had a dilated macular or fundus exam performed which included documentation of the level of severity of retinopathy and the presence or absence of macular edema during one or more office visits within 12 months.	**AMA-PCPI** **Contact Information**: cpe@ama-assn.org	http://www.cms.gov/QualityMeasures/03_ElectronicSpecifications.asp#TopOfPage	
NQF 0089 PQRI 19	**Title:** Diabetic Retinopathy: Communication with the Physician Managing Ongoing Diabetes Care **Description:** Percentage of patients aged 18 years and older with a diagnosis of diabetic retinopathy who had a dilated macular or fundus exam performed with documented communication to the physician who manages the ongoing care of the patient with diabetes mellitus regarding the findings of the macular or fundus exam at least once within 12 months.	**AMA-PCPI** **Contact Information**: cpe@ama-assn.org	http://www.cms.gov/QualityMeasures/03_ElectronicSpecifications.asp#TopOfPage	
NQF 0047 PQRI 53	**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	http://www.cms.gov/QualityMeasures/03_ElectronicSpecifications.asp#TopOfPage	
NQF 0001 PQRI 64	**Title:** Asthma Assessment **Description:** Percentage of patients aged 5 through 40 years with a diagnosis of asthma and who have been seen for at least 2 office visits, who were evaluated during at least one office visit within 12 months for the frequency (numeric) of daytime and nocturnal asthma symptoms.	**AMA-PCPI** **Contact Information:** cpe@ama-assn.org	http://www.cms.gov/QualityMeasures/03_ElectronicSpecifications.asp#TopOfPage	

NQF Measure Number & PQRI Implementation Number	Clinical Quality Measure Title & Description	Clinical Quality Measure Steward & Contact Information	Electronic Measure Specifications Information	Core Clinical Quality Measure
NQF 0002 PQRI 66	**Title:** Appropriate Testing for Children with Pharyngitis **Description:** Percentage of children 2-18 years of age who were diagnosed with pharyngitis, dispensed an antibiotic and received a group A streptococcus (strep) test for the episode.	**NCQA** **Contact Information:** www.ncqa.org	http://www.cms.gov/QualityMeasures/03_ElectronicSpecifications.asp#TopOfPage	
NQF 0387 PQRI 71	**Title:** Oncology Breast Cancer: Hormonal Therapy for Stage IC-IIIC Estrogen Receptor/Progesterone Receptor (ER/PR) Positive Breast Cancer **Description:** Percentage of female patients aged 18 years and older with Stage IC through IIIC, ER or PR positive breast cancer who were prescribed tamoxifen or aromatase inhibitor (AI) during the 12-month reporting period.	**AMA-PCPI** **Contact Information:** cpe@ama-assn.org	http://www.cms.gov/QualityMeasures/03_ElectronicSpecifications.asp#TopOfPage	
NQF 0385 PQRI 72	**Title:** Oncology 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 chemotherapy, prescribed adjuvant chemotherapy, or have previously received adjuvant chemotherapy within the 12-month reporting period.	**AMA-PCPI** **Contact Information:** cpe@ama-assn.org	http://www.cms.gov/QualityMeasures/03_ElectronicSpecifications.asp#TopOfPage	
NQF 0389 PQRI 102	**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	http://www.cms.gov/QualityMeasures/03_ElectronicSpecifications.asp#TopOfPage	

NQF Measure Number & PQRI Implementation Number	Clinical Quality Measure Title & Description	Clinical Quality Measure Steward & Contact Information	Electronic Measure Specifications Information	Core Clinical Quality Measure
NQF 0027 PQRI 115	**Title:** Smoking and Tobacco Use Cessation, Medical assistance: a. Advising Smokers and Tobacco Users to Quit, b. Discussing Smoking and Tobacco Use Cessation Medications, c. Discussing Smoking and Tobacco Use Cessation Strategies **Description:** Percentage of patients 18 years of age and older who were current smokers or tobacco users, who were seen by a practitioner during the measurement year and who received advice to quit smoking or tobacco use or whose practitioner recommended or discussed smoking or tobacco use cessation medications, methods or strategies.	**NCQA** **Contact Information:** www.ncqa.org	http://www.cms.gov/QualityMeasures/03_ElectronicSpecifications.asp#TopOfPage	
NQF 0055 PQRI 117	**Title:** Diabetes: Eye Exam **Description:** Percentage of patients 18 -75 years of age with diabetes (type 1 or type 2) who had a retinal or dilated eye exam or a negative retinal exam (no evidence of retinopathy) by an eye care professional.	**AMA-PCPI** **Contact Information:** cpe@ama-assn.org	http://www.cms.gov/QualityMeasures/03_ElectronicSpecifications.asp#TopOfPage	
NQF 0062 PQRI 119	**Title:** Diabetes: Urine Screening **Description:** Percentage of patients 18 - 75 years of age with diabetes (type 1 or type 2) who had a nephropathy screening test or evidence of nephropathy.	**NCQA** **Contact Information:** www.ncqa.org	http://www.cms.gov/QualityMeasures/03_ElectronicSpecifications.asp#TopOfPage	
NQF 0421 PQRI 128	**Title:** Adult Weight 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.	**CMS/Quality Insights of Pennsylvania (QIP)** **Contact Information:** www.usqualitymeasures.org	http://www.cms.gov/QualityMeasures/03_ElectronicSpecifications.asp#TopOfPage	Core

NQF Measure Number & PQRI Implementation Number	Clinical Quality Measure Title & Description	Clinical Quality Measure Steward & Contact Information	Electronic Measure Specifications Information	Core Clinical Quality Measure
NQF 0056 PQRI 163	**Title:** Diabetes: Foot Exam **Description:** The percentage of patients aged 18 - 75 years with diabetes (type 1 or type 2) who had a foot exam (visual inspection, sensory exam with monofilament, or pulse exam).	**NCQA** **Contact Information:** www.ncqa.org	http://www.cms.gov/QualityMeasures/03_ElectronicSpecifications.asp#TopOfPage	
NQF 0074 PQRI 197	**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	http://www.cms.gov/QualityMeasures/03_ElectronicSpecifications.asp#TopOfPage	
NQF 0084 PQRI 200	**Title:** Heart Failure (HF): Warfarin Therapy Patients with Atrial Fibrillation **Description:** Percentage of all patients aged 18 years 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	http://www.cms.gov/QualityMeasures/03_ElectronicSpecifications.asp#TopOfPage	
NQF 0073 PQRI 201	**Title:** Ischemic Vascular Disease (IVD): Blood Pressure Management **Description:** Percentage of patients 18 years of age and older who were discharged alive for acute myocardial infarction (AMI), coronary artery bypass graft (CABG) or percutaneous transluminal coronary angioplasty (PTCA) from January 1- November 1 of the year prior to the measurement year, or who had a diagnosis of ischemic vascular disease (IVD) during the measurement year and the year prior to the measurement year and whose recent blood pressure is in control (<140/90 mmHg).	**NCQA** **Contact Information:** www.ncqa.org	http://www.cms.gov/QualityMeasures/03_ElectronicSpecifications.asp#TopOfPage	

NQF Measure Number & PQRI Implementation Number	Clinical Quality Measure Title & Description	Clinical Quality Measure Steward & Contact Information	Electronic Measure Specifications Information	Core Clinical Quality Measure
NQF 0068 PQRI 204	**Title:** Ischemic Vascular Disease (IVD): Use of Aspirin or Another Antithrombotic **Description:** Percentage of patients 18 years of age and older who were discharged alive for acute myocardial infarction (AMI), coronary artery bypass graft (CABG) or percutaneous transluminal coronary angioplasty (PTCA) from January 1-November 1 of the year prior to the measurement year, or who had a diagnosis of ischemic vascular disease (IVD) during the measurement year and the year prior to the measurement year and who had documentation of use of aspirin or another antithrombotic during the measurement year.	**NCQA** **Contact Information:** www.ncqa.org	http://www.cms.gov/QualityMeasures/03_ElectronicSpecifications.asp#TopOfPage	
NQF 0004	**Title:** Initiation and Engagement of Alcohol and Other Drug Dependence Treatment: (a) Initiation, (b) Engagement **Description:** The percentage of adolescent and adult patients with a new episode of alcohol and other drug (AOD) dependence who initiate treatment through an inpatient AOD admission, outpatient visit, intensive outpatient encounter or partial hospitalization within 14 days of the diagnosis and who initiated treatment and who had two or more additional services with an AOD diagnosis within 30 days of the initiation visit.	**NCQA** **Contact Information:** www.ncqa.org	http://www.cms.gov/QualityMeasures/03_ElectronicSpecifications.asp#TopOfPage	
NQF 0012	**Title:** Prenatal Care: Screening for Human Immunodeficiency Virus (HIV) **Description:** Percentage of patients, regardless of age, 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:** cpe@ama-assn.org	http://www.cms.gov/QualityMeasures/03_ElectronicSpecifications.asp#TopOfPage	
NQF 0013	**Title:** Hypertension: Blood Pressure Measurement **Description:** Percentage of patient visits for patients aged 18 years and older with a diagnosis of hypertension who have been seen for at least 2 office visits, with blood pressure (BP) recorded.	**AMA-PCPI** **Contact Information:** cpe@ama-assn.org	http://www.cms.gov/QualityMeasures/03_ElectronicSpecifications.asp#TopOfPage	Core

NQF Measure Number & PQRI Implementation Number	Clinical Quality Measure Title & Description	Clinical Quality Measure Steward & Contact Information	Electronic Measure Specifications Information	Core Clinical Quality Measure
NQF 0014	**Title:** Prenatal Care: Anti-D Immune Globulin **Description:** Percentage of D (Rh) negative, unsensitized patients, regardless of age, who gave birth during a 12-month period who received anti-D immune globulin at 26-30 weeks gestation.	**AMA-PCPI** **Contact Information:** cpe@ama-assn.org	http://www.cms.gov/QualityMeasures/03_ElectronicSpecifications.asp#TopOfPage	
NQF 0018	**Title:** Controlling High Blood Pressure **Description:** The percentage of patients 18-85 years of age who had a diagnosis of hypertension and whose BP was adequately controlled during the measurement year	**NCQA** **Contact Information:** www.ncqa.org	http://www.cms.gov/QualityMeasures/03_ElectronicSpecifications.asp#TopOfPage	
NQF 0024	**Title:** Weight Assessment and Counseling for Children and Adolescents **Description:** Percentage of patients 2 -17 years of age who had an outpatient visit with a Primary Care Physician (PCP) or OB/GYN and who had evidence of BMI percentile documentation, counseling for nutrition and counseling for physical activity during the measurement year.	**NCQA** **Contact Information:** www.ncqa.org	http://www.cms.gov/QualityMeasures/03_ElectronicSpecifications.asp#TopOfPage	Alternate Core
NQF 0028	**Title:** Preventive Care and Screening Measure Pair: a. Tobacco Use Assessment, b. Tobacco Cessation Intervention **Description:** Percentage of patients aged 18 years and older who have been seen for at least 2 office visits who were queried about tobacco use one or more times within 24 months b. Percentage of patients aged 18 years and older identified as tobacco users within the past 24 months and have been seen for at least 2 office visits, who received cessation intervention.	**AMA-PCPI** **Contact Information:** cpe@ama-assn.org	http://www.cms.gov/QualityMeasures/03_ElectronicSpecifications.asp#TopOfPage	Core
NQF 0032	**Title:** Cervical Cancer Screening **Description:** Percentage of women 21-64 years of age, who received one or more Pap tests to screen for cervical cancer	**NCQA** **Contact Information:** www.ncqa.org	http://www.cms.gov/QualityMeasures/03_ElectronicSpecifications.asp#TopOfPage	

NQF Measure Number & PQRI Implementation Number	Clinical Quality Measure Title & Description	Clinical Quality Measure Steward & Contact Information	Electronic Measure Specifications Information	Core Clinical Quality Measure
NQF 0033	**Title:** Chlamydia Screening for Women **Description:** Percentage of women 15- 24 years of age who were identified as sexually active and who had at least one test for chlamydia during the measurement year.	**NCQA** **Contact Information:** www.ncqa.org	http://www.cms.gov/QualityMeasures/03_ElectronicSpecifications.asp#TopOfPage	
NQF 0036	**Title:** Use of Appropriate Medications for Asthma **Description:** Percentage of patients 5 - 50 years of age who were identified as having persistent asthma and were appropriately prescribed medication during the measurement year. Report three age stratifications (5-11 years, 12-50 years, and total).	**NCQA** **Contact Information:** www.ncqa.org	http://www.cms.gov/QualityMeasures/03_ElectronicSpecifications.asp#TopOfPage	
NQF 0038	**Title:** Childhood Immunization Status **Description:** Percentage of children 2 years of age who had four diphtheria, tetanus and acellular pertussis (DTaP); three polio(IPV), one measles, ,mumps and rubella (MMR); two H influenza type B (HiB); three hepatitis B (Hep B); one chicken pox (VZV); four pneumococcal conjugate (PCV); two hepatitis A (Hep A); two or three rotavirus (RV); and two influenza (flu) vaccines by their second birthday. The measure calculates a rate for each vaccine and nine separate combination rates.	**NCQA** **Contact Information:** www.ncqa.org	http://www.cms.gov/QualityMeasures/03_ElectronicSpecifications.asp#TopOfPage	Alternate Core
NQF 0052	**Title:** Low Back Pain: Use of Imaging Studies **Description:** Percentage of patients with a primary diagnosis of low back pain who did not have an imaging study (plain x-ray, MRI, CT scan) within 28 days of diagnosis.	**NCQA** **Contact Information:** www.ncqa.org	http://www.cms.gov/QualityMeasures/03_ElectronicSpecifications.asp#TopOfPage	

NQF Measure Number & PQRI Implementation Number	Clinical Quality Measure Title & Description	Clinical Quality Measure Steward & Contact Information	Electronic Measure Specifications Information	Core Clinical Quality Measure
NQF 0075	**Title:** Ischemic Vascular Disease (IVD): Complete Lipid Panel and LDL Control **Description:** Percentage of patients 18 years of age and older who were discharged alive for acute myocardial infarction (AMI), coronary artery bypass graft (CABG) or percutaneous transluminal angioplasty (PTCA) from January 1-November1 of the year prior to the measurement year, or who had a diagnosis of ischemic vascular disease (IVD) during the measurement year and the year prior to the measurement year and who had a complete lipid profile performed during the measurement year and whose LDL-C<100 mg/dL.	**NCQA** **Contact Information:** www.ncqa.org	http://www.cms.gov/QualityMeasures/03_ElectronicSpecifications.asp#TopOfPage	
NQF 0575	**Title:** Diabetes: Hemoglobin A1c Control (<8.0%) **Description:** The percentage of patients 18-75 years of age with diabetes (type 1 or type 2) who had hemoglobin A1c <8.0%.	**NCQA** **Contact Information:** www.ncqa.org	http://www.cms.gov/QualityMeasures/03_ElectronicSpecifications.asp#TopOfPage	

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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, we proposed to require that each EP submit information on two measure groups: a core measures group (Table 4 of the proposed rule see 75 FR 1890), and the subset of clinical measures most appropriate given the EP's specialty (Tables 5 through 19 specialty group measures see 75 FR 1891 through 1895). For the core measure group, we stated our belief that the clinical quality measures were sufficiently general in application and of such importance to population health; we would 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.

We proposed that with the inclusion of measures applicable to targeting children and adolescents and the wide applicability of the measures like Blood Pressure Management, we believed the proposed core set of clinical quality measures and specialty measures was broad enough to enable reporting by all EPs. However, we encouraged commenters to identify the EPs in question and propose specific remedies if the public believed that other EPs would not have sufficient patients in the denominator of these core measures.

Comment: Several commenters requested clarification about the core measures group. Many comments were received regarding the inclusion of a core measure set for EPs. Some commenters favored the inclusion of one or more core measures (for example, preventive care) and others indicated core measures were essential for improving the quality of care. Conversely, numerous commenters suggested eliminating the core measure set for EPs. The primary reason offered by commenters for excluding core measures was that these clinical quality measures were outside their scope of practice and/or not relevant to their specific patient population. A commenter requested that the core set of clinical quality measures be better defined and/or increased for each reporting period. Many commenters indicated the clinical quality measures included in the core measure set are not appropriate to all EPs and specialists (for example, EPs that do not have direct physical access to the patients such as teleradioloists, EPs that do not routinely report blood pressure in patients with diagnosed hypertension, such as dermatologists) and they would not be able to report on these clinical quality measures. Many commenters supported reporting exclusions. A commenter recommended the use of PQRI 128/NQF 0421 Preventive Care and Screening: BMI Screening and Follow-up as a core clinical quality measure. Other commenters indicated these clinical quality measures were important for improving care and the core measure set should be expanded.

Response: After considering the comments, we agree there may be circumstances such that the core clinical quality measures are not applicable for specific patient populations and/or a specific EP's scope of practice. In such circumstances we anticipate that the patients will not appear in the denominator at all or will be excluded. We have defined the core measure set for EPs in Table 7 of this final rule, and these core measures will be required for Stage 1. We expanded the core measures set to include three alternate measures, as well as added PQRI 128/NQF0421 as a required core measure, based on commenters feedback. Although we require all EPs to report the core measures, there is no requirement that the EP have any particular number of patients in the denominator, which could be zero as calculated by the EHR. Therefore we have changed the reporting criteria to require EPs to report on all three core measures (as shown in Table 7, below), and three additional clinical quality measures selected from Table 6 (other than the core or alternate core measures listed in Table 6). The clinical quality measures included in this final rule reflect a subset of measures that were included in the proposed rule (see 75 FR 1874 through 1889). The clinical quality measures included in Table 6 of this final rule were selected from the Tables included in the proposed rule, based on having electronic specifications fully developed by the date of display of this final rule.

Comment: Many commenters indicated that NQF 0022 Drugs to be avoided in the elderly is an inappropriate clinical quality measure and should be removed. The rationale given for removal is that the numerator (at least one prescription for any drug to be avoided in the elderly in the measurement year or at least two different drugs to be avoided in the elderly in the measurement year) tends to be very small. Others considered poly-pharmacy a more significant problem in the elderly than avoidance of specific drugs. A number of commenters indicated this clinical quality measure should include a list of the drugs to be avoided.

Response: We agree with the concerns expressed by the commenters and have removed the measure NQF 0022. Additionally, electronic specifications are not available for this measure by the date of display of this final rule making this measure impractical to use for Stage 1. We will consider this measure in future rulemaking.

After consideration of the public comments received, we are finalizing the requirement that all EPs must submit calculated results for three core measures using the certified EHR technology. However, we are finalizing only two of the clinical quality measures that were proposed as "core measures" in the proposed rule. The other core measures presented in Table 6 of this final rule were selected because they have broad applicability, support prevention, were recommended by commenters, and have electronic specifications by the date of display of this final rule. Insofar as a measure does not apply to patients treated by the EP, this will be reflected in the calculation of the clinical quality measure either by the patient not being included in the denominator for the measure or the patient being excluded. Therefore, it is not necessary for CMS to delineate for a particular specialty which measures may or not apply. We note that to qualify as a meaningful EHR user, EPs need only report the required clinical quality measures; they need not satisfy a minimum value for any of the numerator, denominator, or exclusions fields for clinical quality measures. The value for any or all of those fields, as reported to CMS or the States, may be zero if these are the results as displayed by the certified EHR technology. Thus, the clinical quality measure requirement for 2011 and beginning in 2012 is a reporting requirement and not a requirement to meet any particular performance standard for the clinical quality measure, or to in all cases have patients that fall within the denominator of the measure.

The three core measures that EPs will be required to report are: [NQF 0013: Hypertension: Blood Pressure Management; NQF 0028: Preventative Care and Screening Measure Pair: a. Tobacco Use Assessment b. Tobacco Cessation Intervention; and NQF0421/PQRI 128: Adult Weight Screening and Follow-up]. Insofar as the denominator for one or more of the core measures is zero, EPs will be required to report results for up to three alternate core measures [NQF 0041/PQRI 110: Preventative Care and Screening:

Influenza Immunization for Patients ≥50 Years Old; NQF 0024: Weight Assessment and Counseling for Children and Adolescents; and NQF 0038: Childhood Immunization Status]. We believe this final set of core clinical quality measures provides EPs a greater opportunity for successful reporting. The EP will *not* be excluded from reporting any core or alternate clinical quality measure because the measure does not apply to the EPs scope of practice or patient population. The expectation is that the EHR will automatically report on each core clinical quality measure, and when one or more of the core measures has a denominator of zero then the alternate core measure(s) will be reported. If all six of the clinical quality measures in Table 7 have zeros for the denominators (this would imply that the EPs patient population is not addressed by these measures), then the EP is still required to report on three additional clinical measures of their choosing from Table 6 in this final rule. In regard to the three additional clinical quality measures, if the EP reports zero values, then for the remaining clinical quality measures in Table 6 (other than the core and alternate core measures) the EP will have to attest that all of the other clinical quality measures calculated by the certified EHR technology have a value of zero in the denominator, if the EP is to be exempt from reporting any of the additional clinical quality measures (other than the core and alternate core measures) in Table 6. Thus, EPs are not penalized in the Stage 1 reporting years as long as they have adopted a certified EHR and that EHR calculates and the EP submits the required information on the required clinical quality measures, and other meaningful use requirements as defined in this final rule in section II.A.2.d.1 of this final rule.

Table 7, below, shows the core measure groups for all EPs for Medicare and Medicaid to report.

TABLE 7: Measure Group: Core for All EPs, Medicare and Medicaid

NQF Measure Number & PQRI Implementation Number	Clinical Quality Measure Title
NQF 0013	**Title:** Hypertension: Blood Pressure Measurement
NQF 0028	**Title:** Preventive Care and Screening Measure Pair: a. Tobacco Use Assessment b. Tobacco Cessation Intervention
NQF 0421 PQRI 128	**Title:** Adult Weight Screening and Follow-up
	Alternate Core Measures
NQF 0024	**Title:** Weight Assessment and Counseling for Children and Adolescents
NQF 0041 PQRI 110	**Title:** Preventive Care and Screening: Influenza Immunization for Patients ≥ 50 Years Old
NQF 0038	**Title:** Childhood Immunization Status

We proposed that EPs were to submit calculated results on at least one of the sets listed in Tables 5 and 19 as specialty groups (see 75 FR 1891–1895). The specialty groups were Cardiology, Pulmonary Diseases, Endocrinology, Oncology, Proceduralist/Surgery, Primary Care Physicians, Pediatrics, Obstetrics and Gynecology, Neurology, Psychiatry, Ophthalmology, Podiatry, Radiology, Gastroenterology, and Nephrology.

We recognized that clinical quality measures as specified by measures developers and as endorsed by the NQF were not specific to particular specialties. 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 grouped the proposed measures according to the types of patients commonly treated and services rendered by EPs of various specialties. We did this for purposes similar to measures groups used in PQRI which, however, are based on clinical conditions, rather than specialty types. We proposed that the general purpose of each specialty measures grouping was to have standardized sets of measures, all of which must be reported by the EP for the self-selected specialty measures groups in order to meet the reporting requirements. We expected to narrow down each set to a required subset of three-five measures based on the availability of electronic measure specifications and comments received.

We also proposed to require for 2011 and 2012 that EPs would select a specialty measures group, on which to report on all applicable cases for each of the measures in the specialty group. We also proposed that the same specialty measures group selected for the first payment year would be required for reporting for the second payment year. We invited comment on whether there were EPs who believed no specialty group would apply to them. In accordance with public comments, we noted that we would specify in the final rule which EP specialties would be exempt from selecting and reporting on a specialty measures group. As stated, we proposed, EPs that are so-designated would be required to attest, to CMS or the States, to the inapplicability of any of the specialty groups and would not

be required to report information on clinical quality measures from a specialty group for 2011 or 2012, though the EP would still be required to report information on all of the clinical quality measures listed in the proposed core measure set (see 75 FR 1890).

Comment: Several commenters asked if certain specialties, such as chiropractors, audiologists, allergist and immunology, otolaryngologists, etc., could be exempt from having to report all specific clinical quality specialty measures. Many of these EPs indicated the clinical quality measures included in Table 3 were not relevant to their specific practice and/or patient population. Other commenters requested that specialty groups be created for specialties not included in the proposed rule measure groups, (for example, chiropractors, dentists, dermatologists, infectious disease, pediatric oncology, neurosurgery, interventional radiology, plastic & reconstructive surgery, physical therapists, occupational therapists, eye care specialists, family planning, genetics, ear/nose/throat, and nutritionists providers, etc.). Other commenters indicated that specialty clinical quality measures were specific to a subset of patients, but were not broadly applicable to their specialty for treating other conditions within their specialty area. Other commenters asked that CMS reconsider allowing EPs to attest only and be exempt from reporting if no applicable clinical quality measures specialty group exists for them. Another commenter indicated support of specific measure sets for different clinical specialties. Many commenters supported the elimination of specialty groups altogether as a mandatory set and instead supported the reporting of a fixed number of relevant clinically quality measures regardless of the specialty group. A commenter asked for a definition of "specialist" which is not included in the proposed rule. Several commenters expressed concern about the large number of clinical quality measures in certain measure groups versus other measure groups (for example, the primary care, pediatric and ob/gyn measure groups) as well as the applicability of clinical quality measures assigned to primary care EPs when they do not manage conditions that are typically referred to a specialist for example, ischemic vascular disease. A commenter requested clarification and suggestions on how to select a clinical quality measure group. Several commenters wanted clarification on the proposed EP Specialty Measures Tables (see 75 FR 1874), and whether the EPs are accountable for only the clinical quality measures for their specialty. One comment indicated agreement with CMS regarding requiring EPs to report on the same specialty measure groups for 2011 and 2012 and another commenter indicated that CMS should not delay reporting of clinical quality measures as early adopters of EHRs will be ready to report. A few commenters suggested adding NQF 0033 Chlamydia screening in women to all other appropriate specialty clinical quality measure groups. A commenter indicated that PQRI #112, 113, and NQF 0032 should be removed from the oncology clinical quality specialty measure group as oncologists do not perform routine cancer screenings.

Response: We are appreciative of the detail provided by commenters to the potential inapplicability of the proposed specialty measures groups to various practitioner types or to the inapplicability of certain measures within groups to the specialties designated. Our primary purpose, similar to the core measures, was to encourage a certain consistency in reporting of clinical quality measures by EPs. However, after consideration of the comments we do not believe that the proposed specialty measures groups are sufficient to have a robust set of specialty measures groups. Further, given the lack of electronic specifications or final development of many of these measures, requiring specialty measures groups becomes even more impractical. We expect that electronic specifications will be developed for measures which would allow for a broadly applicable set of specialty measures groups in the future.

After consideration of the public comments received, we removed the requirement for EPs to report on specialty measures groups as proposed. We intend to reintroduce the proposed rule's specialty group reporting requirement in Stage 2 with at least as many clinical quality measures by specialty as we proposed for Stage 1 in the proposed rule. We expect to use a transparent process for clinical quality measure development that includes appropriate consultation with specialty groups and other interested parties, and we expect that electronic specifications will be developed for all of the measures that we originally proposed for Stage 1 or alternative related measures, which would allow for a broadly applicable set of specialty measures groups and promote consistency in reporting of clinical quality measures by EPs. Also, in consideration of public comments received, we are finalizing the requirement (in addition to the core measure requirement) that EPs must report on three measures to be selected by the EP from the set of 38 measures as shown in Table 6, above. As stated previously, in regard to the three additional clinical quality measures, if the EP reports zero values, then for the remaining clinical quality measures in Table 6 (other than the core and alternate core measures) the EP will have to attest that all of the other clinical quality measures calculated by the certified EHR technology have a value of zero in the denominator. In sum, EPs must report on six total measures, three core measures (substituting alternate core measures where necessary) and three additional measures (other than the core and alternate core measures) selected from Table 6.

We also proposed that although we do not require clinical quality measure reporting electronically until 2012, we would require clinical quality reporting through attestation in the 2011 payment year. We solicited 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 was feasible, we solicited comment on which key measures should be chosen for 2011 and which should be deferred until 2012 and why. We discuss comments received regarding the reporting method for clinical quality measures in section II.A.3.h. of this final rule.

f. Clinical Quality Measures for Electronic Submission by Eligible Hospitals and CAHs

Our proposed rule would have required eligible hospitals and CAHs to report summary data to CMS on the set of clinical quality measures identified in Table 20 and 21 of the proposed rule (see 75 FR 1896–1899), with eligible hospitals attesting to the measures in 2011 and electronically submitting these measures to CMS using certified EHR technology beginning in 2012. For hospitals eligible for only the Medicaid EHR incentive program, we proposed that reporting would be to the States. In the proposed rule, for eligible hospitals under both programs, we proposed that they would have to also report on the clinical quality measures identified in Table 21 of the proposed rule to meet the requirements for the reporting of clinical quality measures for the Medicaid program incentive (see 75 FR 1896 through 1900). Tables 20 and 21 of the proposed rule (see 75 FR 1896 through 1900) conveyed the clinical quality measure's title, number, owner/

developer and contact information, and a link to existing electronic specifications where applicable.

We included in the proposed 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 between CMS and ONC to develop interoperable standards for EHR electronic submission of the Emergency Department Throughput, Stroke, and Venous Thromboembolism clinical quality measures on Table 20 of the proposed rule (see 75 FR 1896 through 1899). We also proposed to test the submission of these clinical quality measures in Medicare (see 75 FR 43893). The specifications for the RHQDAPU clinical quality measures for eligible hospitals and CAHs 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 we proposed derived from the RHQDAPU program or were measures we considered important for measuring or preventing adverse outcomes. In addition to risk standardized readmission clinical quality measures, we proposed that non-risk-adjusted readmission rates also be reported. For the proposed rule, we also considered HIT Standards Committee recommendations, including the Committee's recommendation to include a measure on Atrial Fibrillation Receiving Anticoagulation Therapy which was included on Table 20 of the proposed rule Our proposed rule noted that we did not propose one measure recommended by the HIT Standards Committee: Surgery patients who received Venous Thromboembolism prophylaxis within 24 hours period to surgery to 24 hours after surgery end time. We noted that the measure is a current clinical quality measure collected in the RHQDAPU program through chart abstraction for all applicable patients (SCIP–VTE–2), and that the VTE–2 clinical quality measure in Table 20 of the proposed rule (*see* 75 FR 1896 through 1899) was a parallel clinical quality measure to SCIP–VTE–2. SCIP–VTE–2 includes surgical and non-surgical patients, and can be more easily implemented for the EHR incentive program because electronic specifications had been completed. We added SCIP–VTE–2 for future consideration.

Comment: Many commenters recommended reducing the number of eligible hospital clinical quality measures and indicated that such a large number of measures would pose a significant financial and administrative burden on hospitals. Commenters suggested a variety of solutions which include: Eliminating duplication between clinical quality measures and meaningful use objectives and associated measures, reducing the number of clinical quality measures for reporting and allowing organizations to select a limited number of clinical quality measures on which they would like to report.

We received comments supporting many of the measures in the proposed rule including Venous Thromboembolism, Emergency Department, Stroke, RHQDAPU, and measures that are evidence-based that could improve the quality of care. Others recommended additional clinical quality measures, changes to the specifications for clinical quality measures or the elimination of certain clinical quality measures such as risk adjusted re-admission measures or measures not applicable to CAHs. Many commenters supported the process through which the electronic specifications were developed for the Emergency Department Throughput, Stroke and Venous Thromboembolism measures while also pointing out the length of time necessary to adequately develop electronic specifications and test the clinical quality measures. Many commented that the remaining measures had not been electronically specified or had otherwise not completed development and would not be ready in time for the 2011–2012 implementation. Others stated their concerns about duplicate reporting systems and the belief that the HITECH Act reporting requirements should be based on the RHQDAPU program, similar to the conceptual framework of hospitals value-based purchasing plan. Others pointed to measures that are already currently reported in RHQDAPU and the statutory provision that clinical quality measure reporting required for the HITECH Act should seek to avoid duplicative and redundant reporting of measures reported under RHQDAPU.

Response: We are appreciative of the comments supporting many of the clinical quality measure sets and the process utilized for electronically specifying the Emergency Department Throughput, Stroke, and Venous Thromboembolism sets. As we have discussed for the EP measures, we agree that we should limit the required clinical quality measures to those measures for where there are electronic specifications as of the date of display of this final rule. This will allow EHR vendors sufficient time to ensure that certified EHR technology will be able to electronically calculate the measures. Therefore, we are not finalizing those clinical quality measures that either have not been fully developed, are currently only specified for claims based calculation, or for which there are not fully developed electronic specifications as of the date of display of this final rule. Accordingly, we are only finalizing the 15 measures listed in Table 10 of this final rule. We note that none of these measures are duplicate measures which are currently required for reporting in the RHQDAPU program. We therefore do not need to address the issue of duplicate or redundant reporting. We will consider adding, changing, developing, and eliminating duplicative clinical quality measures and meaningful use objectives/associated measures in future rulemaking.

Table 8, shows the proposed clinical quality measures for submission by Medicare and Medicaid Eligible Hospitals for the 2011 and 2012 payment year as stated in the proposed rule (see 75 FR 1896–1899) for EPs, but that are not being finalized. Table 9, shows the proposed alternative Medicaid clinical quality measures for Medicaid eligible hospitals in the proposed rule (see 75 FR 1899–1900). Tables 8 and 9 convey the NQF measure number, clinical quality measure title and description, and clinical quality measure steward and contact information. The measures listed below in Tables 8 and 9 do not have electronic specifications finished before the date of display of this final rule, thus we have eliminated these measures for this final rule and will consider the addition of these measures in future rulemaking. Also several measures listed below were only concepts at the time of publication of the proposed rule (that is, Hospital Specific 30 day Rate following AMI admission, Hospital Specific 30 day Rate following Heart Failure admission, Hospital Specific 30 day Rate following Pneumonia admission, and All-Cause Readmission Index). These concept measures were not developed or electronically specified clinical quality measures, nor NQF endorsed; and there was not adequate time to consider these concepts for development for this final rule. Therefore, the concepts listed

below will be considered in future rulemaking.

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TABLE 8: Proposed Clinical Quality Measures for Submission by Medicare or Medicaid Eligible Hospitals for the 2011 and 2012 Payment Year; Included in the Proposed Rule (see 75 FR 1896 through 1899) and Not in the Final Rule

Measure Number Identifier	Measure Title, Description & Measure Developer
Emergency Department (ED)-3 NQF 0496	**Title:** Emergency Department Throughput – discharged patients Median Time from ED Arrival to ED Departure for Discharged ED Patients **Description:** Median Time from ED arrival to time of departure from the ED for patients discharged from the ED **Measure Developer**: CMS/OFMQ
RHQDAPU AMI-8a NQF 0163	**Title:** Primary PCI Received Within 90 Minutes of Hospital Arrival **Description:** Acute myocardial infarction (AMI) patients with ST-segment elevation or LBBB on the ECG closest to arrival time receiving primary PCI during the hospital stay with a time from hospital arrival to PCI of 90 minutes or less **Measure Developer:** CMS/OFMQ
RHQDAPU PN-3b NQF 0148	**Title:** Blood Cultures Performed in the Emergency Department Prior to Initial Antibiotic Received in Hospital **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 NQF 0142	**Title:** Aspirin Prescribed at Discharge **Description:** Acute myocardial infarction (AMI) patients who are prescribed aspirin at hospital discharge **Measure Developer:** CMS/OFMQ
RHQDAPU AMI-3 NQF 0137	**Title:** Angiotensin Converting Enzyme Inhibitor(ACEI) or Angiotensin Receptor Blocker (ARB) for Left Ventricular Systolic Dysfunction (LVSD) **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 NQF 0160	**Title:** Beta-Blocker Prescribed at Discharge **Description**: Acute myocardial infarction (AMI) patients who are prescribed a betablocker at hospital discharge **Measure Developer:** CMS/OFMQ

Measure Number Identifier	Measure Title, Description & Measure Developer
RHQDAPU AMI-READ NQF 0505	**Title &Description:** Hospital Specific 30 day Risk-Standardized Readmission Rate following AMI admission **Measure Developer:** CMS
Not applicable	**Title:** Hospital Specific 30 day Rate following AMI admission
RHQDAPU HF-READ NQF 0330	**Title &Description:** Hospital Specific 30 day Risk-Standardized Readmission Rate following Heart Failure admission **Measure Developer:** CMS/OFMQ
Not applicable	**Title:** Hospital Specific 30 day Rate following Heart Failure admission
RHQDAPU PNE-READ NQF 0506	**Title &Description:** Hospital Specific 30 day Risk-Standardized Readmission Rate following Pneumonia admission **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 •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

Measure Number Identifier	Measure Title, Description & Measure Developer
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 9: Proposed Alternative Medicaid Clinical Quality Measures for Medicaid Eligible Hospitals; Included in the Proposed Rule (see 75 FR 1899-1900) and Not in the Final Rule

NQF Measure Number	Measure Title, Description & Measure Developer
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-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). **Measure Developer:** CMS/OFMQ
0356	**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 one hour prior to surgical incision. Patients who received vancomycin or a fluoroquinolone for prophylactic antibiotics should have the antibiotics initiated within two 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 two hours prior to incision time. **Measure Developer:** CMS/OFMQ

NQF Measure Number	Measure Title, Description & Measure Developer
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

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Comment: Commenters stated that current health information technology is not capable of electronically collecting or reporting on clinical quality measures. Commenters also stated we should not require reporting on clinical quality measures that cannot easily be derived from EHRs. Other commenters believed the timeline was unreasonable to obtain the functionality required in the EHR system to report on these clinical quality measures and were concerned that there were no vocabulary standards.

Response: We agree with the comment that eligible hospitals should only be required to submit information that can be automatically obtained from certified EHR technology. As we discussed elsewhere, ONC's final rule (found elsewhere in this issue of the **Federal Register**) requires that certified EHR technology must be able to calculate clinical quality measures specified by us in this final rule. Standards for certified EHRs, including vocabulary standards, are included in ONC's final rule (found elsewhere in this issue of the **Federal Register**).

Comment: Commenters recommended that CMS conduct a pilot test of the NQF endorsed HITSP electronic specifications of measures in the proposed rule for Stage 1 prior to their adoption. Commenters requested CMS publish results of the pilot and use this information to inform the setting of Stage 2 and 3 objectives and clinical quality measures. Commenters also requested allowing adequate time for implementation after the pilot test before such measures are considered for certification, and 24 months before requiring them for meaningful use. One commenter stated that the Emergency Department Throughput, Stroke, and Venous Thromboembolism have not yet been thoroughly tested for automated reporting and data element capture. Additional commenters recommended that the measures selected for the eligible hospitals incentive program should be comprehensively standardized and tested in the field to ensure that they are thoroughly specified, clinically valid when the data are collected through the eligible hospitals system, feasible to collect, and are regularly updated and maintained with a well established process.

Response: We agree with the commenters that it is important to allow adequate time for pilot testing and implementation before clinical quality measures should be considered for certification, as well as requiring these measures for meaningful use. Emergency Department 1, Emergency Department 2, and Stroke 3, clinical quality measures for eligible hospitals and CAHs that are included in this final rule, were tested during the January 2010 Connectathon and demonstrated at the HIMSS 2010 Interoperability Showcase. Additionally, as part of the process of certification of EHR technology it is expected that certifying bodies will test the ability of EHR technology to calculate the clinical quality measures finalized in this final rule.

After consideration of the public comments received, eligible hospitals and CAHs will be required to report on each of the 15 clinical quality measures, as shown in Table 10. Requiring eligible hospitals and CAHs to report on each of the 15 clinical quality measures in the EHR incentive program is consistent with the RHQDAPU program, which requires reporting on all applicable quality measures. Eligible hospitals and CAHs will report numerators, denominators, and exclusions, even if one or more values as displayed by their certified EHR is zero. We note that to qualify as a meaningful EHR user, eligible hospitals and CAHs need only report the required clinical quality measures; they need not satisfy a minimum value for any of the numerator, denominator, or exclusions fields for clinical quality measures. The value for any or all of those fields, as reported to CMS or the States, may be zero if these are the results as displayed by the certified EHR technology. Thus, the clinical quality measure requirement for 2011 and beginning with 2012 is a reporting requirement and not a requirement to meet any particular performance standard for the clinical quality measure, or to in all cases have patients that fall within the denominator of the measure. Further, the criteria to qualify for the EHR incentive payments are based on results automatically calculated by eligible hospitals or CAHs certified EHR technology, as attested by the eligible hospital or CAH. As such, we believe that the eligible hospitals or CAHs will be able to determine whether they have reported the required clinical quality measures to CMS or the State, rendering it unnecessary that CMS or the State provide the eligible hospital or CAH with a feedback report, which provides information to eligible hospitals and CAHs as to whether they have reported their required clinical quality measures. We expect successful receipt of Medicare eligible hospitals and CAHs' information, beginning the first year of Stage 1.

We are finalizing Table 10, which conveys the clinical quality measure's title, number, owner/steward and contact information, and a link to existing electronic specifications.

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TABLE 10: Clinical Quality Measures for Submission by Eligible Hospitals and CAHs for Payment Year 2011-2012[5]

Measure Number Identifier	Measure Title, Description & Measure Steward	Electronic Measure Specifications Information
Emergency Department (ED)-1 NQF 0495	**Title:** Emergency Department Throughput – admitted patients Median time from ED arrival to ED departure for admitted patients **Description:** Median time from emergency department arrival to time of departure from the emergency room for patients admitted to the facility from the emergency department **Measure Developer:** CMS/Oklahoma Foundation for Medical Quality (OFMQ)	http://www.cms.gov/QualityMeasures/03_ElectronicSpecifications.asp#TopOfPage
ED-2 NQF 0497	**Title:** Emergency Department Throughput – admitted patients Admission decision time to ED departure time for admitted patients **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	http://www.cms.gov/QualityMeasures/03_ElectronicSpecifications.asp#TopOfPage
Stroke-2 NQF 0435	**Title:** Ischemic stroke – Discharge on anti-thrombotics **Description:** Ischemic stroke patients prescribed antithromboti therapy at hospital discharge **Measure Developer:** The Joint Commission	http://www.cms.gov/QualityMeasures/03_ElectronicSpecifications.asp#TopOfPage
Stroke-3 NQF 0436	**Title:** Ischemic stroke – Anticoagulation for A-fib/flutter **Description**: Ischemic stroke patients with atrial fibrillation/flutter who are prescribed anticoagulation therapy at hospital discharge. **Measure Developer:** The Joint Commission	http://www.cms.gov/QualityMeasures/03_ElectronicSpecifications.asp#TopOfPage
Stroke-4 NQF 0437	**Title:** Ischemic stroke – Thrombolytic therapy for patients arriving within 2 hours of symptom onset **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	http://www.cms.gov/QualityMeasures/03_ElectronicSpecifications.asp#TopOfPage
Stroke-5 NQF 0438	**Title:** Ischemic or hemorrhagic stroke – Antithrombotic therapy by day 2 **Description:** Ischemic stroke patients administered antithrombotic therapy by the end of hospital day 2. **Measure Developer:** The Joint Commission	http://www.cms.gov/QualityMeasures/03_ElectronicSpecifications.asp#TopOfPage

[5] * In the event that new clinical quality measures are not adopted by 2013, the clinical quality measures in this Table would continue to apply.

Measure Number Identifier	Measure Title, Description & Measure Steward	Electronic Measure Specifications Information
Stroke-6 NQF 0439	**Title:** Ischemic stroke – Discharge on statins **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	http://www.cms.gov/QualityMeasures/03_ElectronicSpecifications.asp#TopOfPage
Stroke-8 NQF 0440	**Title:** Ischemic or hemorrhagic stroke – Stroke education **Description:** Ischemic or hemorrhagic stroke patients or their caregivers who were given educational materials during the hospital stay addressing all of the following: activation of emergency medical system, need for follow-up after discharge, medications prescribed at discharge, risk factors for stroke, and warning signs and symptoms of stroke. **Measure Developer:** The Joint Commission	http://www.cms.gov/QualityMeasures/03_ElectronicSpecifications.asp#TopOfPage
Stroke-10 NQF 0441	**Title:** Ischemic or hemorrhagic stroke – Rehabilitation assessment **Description:** Ischemic or hemorrhagic stroke patients who were assessed for rehabilitation services. **Measure Developer**: The Joint Commission	http://www.cms.gov/QualityMeasures/03_ElectronicSpecifications.asp#TopOfPage
Venous Thromboembolism (VTE)-1 NQF 0371	**Title:** VTE prophylaxis within 24 hours of arrival **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	http://www.cms.gov/QualityMeasures/03_ElectronicSpecifications.asp#TopOfPage
VTE-2 NQF 0372	**Title:** Intensive Care Unit VTE prophylaxis **Description:** This measure assesses the number of patients who received VTE prophylaxis or have documentation why no VTE prophylaxis was given the day of or the day after the initial admission (or transfer) to the Intensive Care Unit (ICU) or surgery end date for surgeries that start the day of or the day after ICU admission (or transfer). **Measure Developer**: The Joint Commission	http://www.cms.gov/QualityMeasures/03_ElectronicSpecifications.asp#TopOfPage

Measure Number Identifier	Measure Title, Description & Measure Steward	Electronic Measure Specifications Information
VTE-3 NQF 0373	**Title:** Anticoagulation overlap therapy **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) ≥ 2 prior to discontinuation of the parenteral anticoagulation therapy or the patient must be discharged on both medications. **Measure Developer:** The Joint Commission	http://www.cms.gov/QualityMeasures/03_ElectronicSpecifications.asp#TopOfPage
VTE-4 NQF 0374	**Title:** Platelet monitoring on unfractionated heparin **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	http://www.cms.gov/QualityMeasures/03_ElectronicSpecifications.asp#TopOfPage
VTE-5 NQF 0375	**Title:** VTE discharge instructions **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. **Measure Developer:** The Joint Commission	http://www.cms.gov/QualityMeasures/03_ElectronicSpecifications.asp#TopOfPage
VTE-6 NQF 0376	**Title:** Incidence of potentially preventable VTE **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	http://www.cms.gov/QualityMeasures/03_ElectronicSpecifications.asp#TopOfPage

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We proposed that 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 would require eligible hospitals and CAHs to report on all EHR incentive clinical quality measures for which they have applicable cases, without regard to payer. We proposed that Medicare eligible hospitals and CAHs, 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. We also proposed that to demonstrate an eligible hospital or CAH is a meaningful EHR user, the eligible hospital or CAH would be 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 as proposed, we did not require clinical quality reporting electronically until 2012, we would begin clinical quality reporting though attestation in the 2011 payment year. We solicited 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 was feasible, we solicited comment on which key measures should be chosen for 2011 and which should be deferred until 2012 and why.

Comment: We received numerous comments strongly opposed to requiring the reporting of clinical quality measures by eligible hospitals prior to 2013, although some comments favored the reporting in 2011 and 2012. Comments in favor pointed to the importance of quality measurement to achieving improvement in healthcare quality. Those opposed to the reporting of clinical quality measures in 2011 and 2012 cited concerns as to the readiness of EHR technology for automated calculation and reporting of clinical quality measures as well as financial and administrative burden. Many commenters stated that measures should be fully automated and tested prior to implementation, and recommended the process for Emergency Department Throughput, Stroke, and Venous Thromboembolism measures where CMS developed the specifications and has in place a plan to test the submission of such measures for RHQDAPU. Commenters stated their expectation that the testing process would reveal important insights as to potential challenges of electronic submission. Numerous commenters opposed measures already in RHQDAPU and not able to be calculated by the EHR technology. Many commenters stated that electronic data submission should be developed through the RHQDAPU program rather than have a separate quality measure reporting program, such as the EHR incentive program. Further, commenters stated that RHQDAPU should provide the foundation for migration to electronic reporting. Numerous commenters were opposed to having a temporary data collection and reporting process through attestation that would need to be updated or replaced once CMS has the appropriate infrastructure in place. Many commenters stated that requiring hospitals to report summary data through attestation, without the ability for CMS to receive the summary data electronically, creates a dual reporting burden for measures currently in RHQDAPU. Many commenters stated concerns as to the timing of the certification process for EHRs since having a certified EHR is an essential element for quality incentives. Numerous commenters pointed out that only 15 of the proposed measures have electronic specifications currently available.

Response: We are sensitive to and appreciate the many comments urging us not to require the submission of clinical quality measures, through attestation or electronic submission, prior to 2013, based on lack of readiness of many of the proposed measures, fully automating and testing prior to implementation, burden, and the potential duplication of quality measures reporting requirements under the RHQDAPU and the EHR incentive payment programs. Having carefully considered these comments, we have sought to address them while still retaining the important goal of beginning the process of using the capacity of EHRs to promote improved quality of care in hospitals by providing calculated results of clinical quality measures. In terms of readiness, we are limiting the clinical quality measures to those measures having existing electronic specifications as of the date of display of this final rule. Additionally, as recommended by commenters, we will only require hospitals to submit that information that can be automatically calculated by their certified EHR technology. Thus we will require no separate data collection by the hospital, but require submission solely of that information that can be generated automatically by the certified EHR technology; that is, we only adopt those clinical quality measures where the certified EHR technology can calculate the results. Further, we are not adopting any measures which are already being collected and submitted in the RHQDAPU program. Therefore, we are imposing no duplicate reporting requirement on hospitals who participate in RHQDAPU. Through future rulemaking we will seek to align the EHR incentive program with RHQDAPU.

Comment: Some commenters stated that CMS contradicts itself, where the proposed rule states that Medicare eligible hospitals who are also participating in Medicaid EHR incentive program will need to report on all of the Medicaid clinical quality measures and where it says that Table 21 is an alternative set of clinical quality measures if the hospital does not have any patients in the denominators of the measures in Table 20. Many commenters requested clarification of the Medicare and Medicaid reporting.

Response: We agree that the description of the eligible hospital and CAH reporting requirements was unclear. To clarify, our proposal was that if a hospital could submit information on clinical quality measures sufficient to meet the requirements for Medicare that would also be sufficient for Medicaid. However, hospitals for which the Medicare measures did not reflect their patient populations could satisfy the Medicaid requirements by reporting the alternate Medicaid clinical quality measures. Reporting the alternate Medicaid measures would only qualify for the Medicaid program and would not qualify eligible hospitals as to the Medicare incentive program. In this final rule, this clarification is moot, however, because we removed the alternate Medicaid list of clinical quality measures listed in Table 21 (see 75 FR 1896 through 1900) of the proposed rule for eligible hospitals. This was based on the lack of electronic specifications for these measures available at the time of display of this final rule. Hospitals that report information on all 15 of the clinical quality measures, as applicable to their patient population, will qualify for both the Medicare and the Medicaid submission requirements for clinical quality measures. We recognize that many of the measures in the Medicare list would likely not apply to certain hospitals, such as children's hospitals. However, an eligible hospital would meet the clinical quality measure requirement by reporting values for the 15 clinical quality measures, including,

values of zero for the denominator, if accurate. Some value is required for each of the 15 clinical quality measures for eligible hospitals and CAHs. Therefore, for example, a children's hospital would enter zero for the denominator for any of the 15 measures for which they do not have any patients as described in the measure.

After consideration of public comments received, we are finalizing 15 clinical quality measures that eligible hospitals and CAHs will be required to report for Stage 1 (2011 and beginning 2012), as applicable to their patient population. Those 15 clinical quality measures for eligible hospitals and CAHs can be found in Table 10 of this final rule.

g. Potential Measures for EPs, Eligible Hospitals, and CAHs in Stage 2 and Subsequent Years

We stated our expectation that the number of clinical quality measures for which EPs, eligible hospitals, and CAHs would be able to electronically submit information would 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 Stage 2 of meaningful use and beyond for eligible hospitals and CAHs, we also plan to consider other clinical quality measures from the RHQDAPU program which are identified in the FY 2010 IPPS final rule (75 FR 43868–43882). We invited comments on inclusion of clinical quality measures for the 2013 and beyond for the HITECH Act Medicare and Medicaid incentive program. We note that as with the other meaningful use objectives and measures, in the event that we have not promulgated clinical quality measures for the 2013 payment year, the measures for Stage 1 (beginning in 2011) would continue in effect.

For the Stage 2 of meaningful use, we indicated in the proposed rule that we are considering expanding the Medicaid EHR incentive program's 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 measures.
- Dental care/oral health measures.
- Additional behavioral/mental health and substance abuse measures.

The above list does not constitute a comprehensive list of all clinical quality measures that may be considered. We stated that specific measures for Stage 2 of meaningful use and beyond may be addressed by CMS in future notice and comment rulemaking. To assist us in identifying potential clinical quality measures for future consideration for Stage 2 of meaningful use and beyond, we solicited 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.

The following is a summary of comments received regarding the request for public comment on potential measures for EPs, eligible hospitals, and CAHs for Stage 2 of meaningful use and subsequent stages, and our responses.

Comment: A commenter suggested using newly adopted NQF Level 3 measures that incorporate common electronic administrative and clinical data that represent a better measure of the patient's condition. A commenter suggested adding long term care and post acute care measures in the next stage of meaningful use. A few commenters suggested future clinical quality measures be coordinated with Healthy People 2020. Another comment regarding measures included a request for medication measures that evaluate provider intervention. Other commenters indicated CMS should provide a more structured process for the adoption of clinical quality measures such that specialty EPs would have greater input into and ownership of the process. A commenter requested consideration that future clinical quality measures address both quality and resource use efficiency (for example potentially preventable Emergency Department visits and hospitalizations and inappropriate use of imaging MRI for acute low back pain). A commenter requested future clinical quality measures for the following areas: reduce hospital readmissions and to improve medication management, specifically safe and efficient management of heart disease, diabetes, asthma, mental health conditions and hospital procedures. A commenter requested clinical quality measures that will aid in increasing improved patient safety and reduce disparities. A commenter also recommended developing new clinical quality outcomes measures to address overuse and efficiency, care coordination, and patient safety. Some commenters requested the inclusion of HIV testing and reporting for preventive service quality measures. Some commenters stated that this would help to facilitate continued efforts to promote and implement the 2006 CDC Revised Recommendation on HIV testing, especially to non-HIV medical specialties. Some commenters recommended measure development in the areas of community mental health, home health, renal dialysis centers, long term care, post acute care, and nursing homes. A commenter recommended including 3 month treatment of pulmonary emboli (NQF 0593) and deep vein thrombosis (NQF 0434) for the next stage of meaningful use and beyond. A commenter requested including health disparity data in all clinical quality measure analyses. Some commenters also recommended future clinical quality measure development in the following areas: Diabetes, heart disease, asthma, disease screening, chronic disease management, patient safety, nursing sensitive measures, atrial fibrillation, and ethnic disparities. Commenters requested expanding pediatric measures to provide expanded focus on childhood diseases that require hospitalization such as asthma, developmental issues and weight-based medication dosage safety issues. Additional commenters requested measures for blood test for lead levels for children up to 1 year of age and between 1 and 2 years of age, co-morbid conditions and dental utilization. A commenter recommended that only one EP should be accountable for the quality intervention and clinical quality measure such as NQF 0323 Title: End Stage Renal Disease (ESRD): Plan of Care for Inadequate Hemodialysis in ESRD Patient. The commenter indicated that this type of measure could involve more than one provider, for example, nephrologist and a dialysis facility. Because provider clinical practices may vary, practice variations may independently influence patient outcomes. Some commenters suggested future development of measures foster greater use of the clinical information available in EHRs to improve clinical processes and evaluate patient outcomes and suggested use of outcomes measures instead of process measures. Furthermore, commenters support the inclusion of outcomes measures rather than process measures and composite versus individual measures. Several commenters indicated support for the preventive care measures included in

the proposed rule and suggested expanding the set of preventive care measures to include HIV and STD screening and eye care specialty measures. A commenter requested CMS provide information about their strategic plan for future Medicare clinical quality measurement selection, how they will improve care delivery, proposed stages of reporting, goals and metrics.

Response: We are appreciative of the many suggestions and acknowledge the breadth of interest in certified EHR technology being the vehicle for clinical quality measures reporting. We expect to consider these suggestions for future measure selection in the Medicare and Medicaid EHR incentive payment programs.

Comment: We received various comments pertaining to future clinical quality measures applicable principally to the Medicaid population. One commenter urged CMS to include clinical quality measures specific to newborn screening in Stage 1 of meaningful use for pediatric providers.

Response: We agree that newborn screening, both as a clinical quality measure, and from a data standards perspective, is a prime candidate for inclusion in the Stage 2 definition of meaningful use. We affirm our proposed statement about our commitment to work with the measure development community to fill noted gaps. We are appreciative of the many suggestions. We expect to consider these suggestions for immunizations, prenatal screening, infectious disease, etc. in measure selection in future rulemaking.

Comment: A commenter indicated CMS should make explicit the health goals and targets for the HITECH Act investments that are already implied by the proposed clinical measures. Making them explicit allows CMS to set national targets.

Response: In general, the goal with respect to clinical quality measures is to improve healthcare quality as measured by the clinical quality measures. We believe that specific quantitative targets are impractical at this stage given lack of established base level notes and no prior clinical quality measure reporting via certified EHR technology.

Comment: Several commenters asked how CMS plans to develop further measure specifications for clinical quality measures. Another commenter asked for an electronic source for ICD–9 and CPT codes defining the specific conditions or diagnoses or treatments in order to maintain an up-to-date capability.

Response: For many clinical quality measures, clearly defined electronic specifications are not yet available. In general, CMS relies on the measures' stewards to both develop measures and to provide the specifications. Nevertheless, we recognize that many existing measures, some of which are owned and maintained by us or its contractors, do not currently have electronic specifications. We are aware of work currently taking place to fill this gap. We expect to actively work in a collaborative way with measures developers and stewards to help assure the development of electronic specifications for clinical quality measures, but we also expect to engage a contractor to perform work developing electronic specifications which may or may not involve measure developers and stewards. As for CPT codes, these are copyrighted by and are available from the American Medical Association. The National Center for Health Statistics (NCHS) and CMS are the U.S. governmental agencies responsible for overseeing all changes and modifications to the ICD–9 codes.

Comment: Some commenters suggested specific new clinical quality measures which are listed below in Table 11. Several commenters suggested new or revised clinical quality measures or the use of existing measures from other programs.

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Table 11: EP Proposed New Clinical Quality Measures

Measure Number	Clinical Quality Measure Title and/or Description
PQRI 27	Diabetes Mellitus: Diabetic foot and ankle care, ulcer prevention evaluation of footwear; preventive care and screening
PQRI 30	Timely administration of prophylactic parenteral antibiotics
PQRI 76	Prevention of catheter related bloodstream infections CBSI
PQRI 124	HIT: Adoption/use of medical records
PQRI 126	Diabetes Mellitus: Diabetic foot and ankle care, peripheral neuropathy neurological evaluation
PQRI 128	BMI Screening and follow-up
PQRI 130	Documentation and Verification of Current Medications in the Medical Record
PQRI 131	Pain Assessment Prior to Initiation of Patient Treatment
PQRI 148	Back Pain: Initial Visit
PQRI 149	Back Pain: Physical Exam
PQRI 150	Back Pain: Advice for Normal Activities
PQRI 151	Back Pain: Advice Against Bed Rest
PQRI 154	Falls: Plan of care
PQRI 155	Falls: Risk Assessment
PQRI 159	HIV/AIDS: CD4 + Cell Count or CD4 + Percentage
PQRI 160	HIV/AIDS: Pneumocystis jirovecii Pneumonia Prophylaxis
PQRI 161	HIV/AIDS: Adolescent and Adult Patients with HIV/AUDS who are Prescribed Potent Antiretroviral Therapy
PQRI 162	HIV/AIDS: HIV RNA Control After 6 Months of Potent Antiretroviral Therapy
PQRI 193	Perioperative temperature management
PQRI 205	HIV/AIDS: STDs, Chlamydia and Gonorrhea Screenings
PQRI 206	HIV/AIDS: Screening for High Risk Sexual Behaviors
PQRI 207	HIV/AIDS: Screening for Injection Drug Use
PQRI 208	HIV/AIDS: STDs Syphilis Screening
NQF 0021	Therapeutic Monitoring: Annual monitoring for patients on persistent medications
NQF 0039	Flu Shots for Adults Ages 50-64

Measure Number	Clinical Quality Measure Title and/or Description
NQF 0058	Inappropriate antibiotic treatment for adults with acute bronchitis
NQF 0071	Acute Myocardial Infarction: Persistence of Beta-Blocker Treatment After a Heart Attack
NQF 0082	Heart Failure: Patient Education
NQF 0111	Bipolar Disorder: Appraisal for risk of suicide
NQF 0116	CABG: Anti-Platelet Medication at Discharge
NQF 0117	CABG: Beta Blockage at Discharge
NQF 0118	CABG: Anti-Lipid Treatment at Discharge
NQF 0278	Low Birth Weight
NQF 0477	Rate of Very Low Birth Weight Deliveries
NQF 0309	LBP: Appropriate Use of Epidural Steroid Injections
NQF 0602	Migraine: Adults with frequent use of acute medications that also received prophylactic medications
NQF 0613	MI: Use of beta blocker therapy
NQF 0632	Primary prevention of cardiovascular events in diabetics (older than 40 yrs): Use of Aspirin or Antiplatelet Therapy
NQF EC-20-08	Warfarin – INR Monitoring
NQF EC-203-08	Hyperlipidemia (Primary Prevention) – Lifestyle changes and/or lipid lowering therapy
NQF EC-227-08	High Risk for Pneumococcal Disease – Pneumococcal vaccination.
NQF EC-231-08	Diabetes with LDL greater than 100 – Use of lipid lowering agent
NQF EC-232-08	Diabetes with Hypertension or Proteinuria – Use of an ACE Inhibitor or ARB.
NQF EC-238-08	Non-diabetic Nephropathy
NQF EC-252-08	Chronic Kidney Disease with LDL greater than 130
NQF EC-256-08	Male Smokers or Family History of AAA Screening for AAA
NQF EC-262-08	Diabetes and elevated HbA1c – Use of diabetes medications
NQF EC-272-08	Secondary Prevention of Cardiovascular Events – Use of Aspirin or anti-platelet therapy
NQF EC-274-08	Primary prevention of cardiovascular events in diabetics older than 40 yrs – Use of aspirin or anti platelet therapy
NQF EC-281-08	Osteopenia and Chronic Steroid Use – Treatment to prevent Osteoporosis

Measure Number	Clinical Quality Measure Title and/or Description
NQF EC-285-08	Chronic Liver Disease – Hepatitis A vaccination
NQF EC-288-08	Atherosclerotic Disease and LDL greater than 100-use of a Lipid Lowering Agent
N/A	Family Planning - Percent of sexually active clients at risk for unintended pregnancy – screened at least once annually for use of contraceptive method at last intercourse.
N/A	Percent of patients for which EP retrieves and acts on prescription refill data obtained through the e-Rx system
N/A	Percent of patients for which a generic drug has been prescribed
N/A	Provider follow-up on growth chart information where clinically indicated
N/A	Inappropriate Use of Antibiotics in Bronchitis
N/A	Chronic Disease Self Management Goal: Percent of Asthmatics, Diabetics, Diagnosed Hypertension, or Other CVD-Related Illness with a Self-Management Goal/Readiness Plan (4 possible measures)
N/A	Good glycemic control: A1C < 7
N/A	Elective Preterm Induction Rate
N/A	Diabetes Mellitus A1C Frequency: Percent of patients with Diabetes Mellitus with two A1C measures in most recent 12 month period
N/A	Pediatric Type I Diabetes Mellitus Diabetic Retinopathy
NA	Performing a complete lipid panel to assess CVD risk
N/A	Adolescent Preventive Care
N/A	Child Preventive Care
N/A	Preventive Screening Lipid Disorders: Percent of male patients over age 35 who have been screened for lipid disorders, percent of females over age 45 screened if they have risk factors for CAD
N/A	Preventive Care & Screening: Screening for Diabetes
N/A	Cervical Cancer Prevention: Percent of female patients age 9-26 yrs who received three doses of HPV vaccine

Measure Number	Clinical Quality Measure Title and/or Description
N/A	Asthma Action Plan: Percent of asthma patients with a documented asthma action plan that has been developed or updated within the past 6 months.
N/A	Asthma Assessment of Percent of asthma patients who have a documented level of control at last asthma visit
N/A	Asthma Assessment/Spirometry -Percent of asthma patients ages 5 and older who received spirometry in the past 12 months.
N/A	Asthma Assessment of Severity: Percent of Patients who have a Documented Level of Asthma Severity for the Last Asthma Visit

Response: Many of the proposed clinical quality measures are in the existing PQRI program or are NQF endorsed. Others are not. We are appreciative of these many specific suggestions and will retain the comments for future consideration. Prior to including measures in the Medicare EHR incentive payment program, as required by the HITECH Act, we will publish the measures in the **Federal Register** and provide an opportunity for public comment. We will examine all options for soliciting public comment on future Medicaid-specific clinical quality measures, as the **Federal Register** notice requirement does not apply to the Medicaid EHR incentive program.

Comment: Some commenters suggested the following new topics for clinical quality measure development for our program:

Table 12: EP Proposed New Topics

Measure Number	Proposed Clinical Quality Measure Topics
N/A	Measures dealing with overuse e.g, antibiotics and epidural injections and unwarranted procedures-spine surgery, PTCA, hysterectomy, CT, polypharmacy
N/A	History regarding new or changing moles
N/A	Counseling on monthly skin self exam
N/A	Melanoma patients entered into recall system
N/A	Newborn Screening
N/A	Preventing Eye Disease
N/A	Epilepsy
N/A	Health Disparities
N/A	Long Term Care
N/A	Mental Health
N/A	Substance Abuse
N/A	School Health Services for Children
N/A	Newborn Hearing and Bloodspot Screening
N/A	Children at Risk for Developmental Disabilities
N/A	Children with Chronic Disabling Conditions
N/A	Child Health-Related Quality of Life
N/A	Child Specific Health Outcomes
N/A	Lead Poisoning Screening for Children
N/A	Hepatitis A (childhood immunization)
N/A	Hepatitis B and hepatitis immune globulin (for newborns of mothers with chronic hepatitis)
N/A	Functional Status
N/A	Use of epidural injections
N/A	Healthy Weight/Reduction in Obesity
N/A	Population-level lipid test results
N/A	Population-level Blood pressure results
N/A	Population-level Aspirin therapy
N/A	Pharmacologic Prescription for Tobacco Cessation
N/A	Alcohol/Drug Misuse
N/A	Family History for Chronic Diseases Sexually activity status (13+) to trigger screening for STDs
N/A	Screening pregnant women for STDs
N/A	Screening for infectious disease risk factors
N/A	Vaccine Reminders
N/A	STD HIV Screening
N/A	Central Line Placement-Related Pneumothorax for Pediatric Population
N/A	Acute Otitis Externa-Topical Therapy, Pain assessment, and systemic antimicrobial therapy

Measure Number	Proposed Clinical Quality Measure Topics
N/A	Otitis media with effusion (OME)- diagnostic evaluation of tympanic membrane mobility
N/A	NQF Care Coordination Measures
N/A	Additional new pediatric measures
N/A	Radiation dose
N/A	Dental measures/Oral Health
N/A	HRSA Clinical Measures for Health Center Grantee Performance Reviews
N/A	Patient centered quality measures
N/A	Outcomes Measures
N/A	Outpatient Measure core set (NQA/AQA/HQA)
N/A	Nutrition-related measures
N/A	Efficiency Measures
N/A	Patient Engagement Measures
N/A	Decision Support Measures
N/A	New Radiation Oncology measures
N/A	Tobacco Use Assessment
N/A	Tobacco Use Treatment
N/A	Tobacco Use Treatment at Discharge
N/A	Tobacco Use Follow-up
N/A	Preventive Screening: Tobacco Use
N/A	Preventive Screening: Falls in Older Adults
N/A	Preventive Counseling: Breastfeeding
N/A	Preventive Counseling: Use of Folic Acid
N/A	HRSA/BPHC Measures
75, 610, 120, 355, 560, 79, 684, 132, 566, 356	CDS alert responses
N/A	Population health measures
N/A	Identifying patients with paroxysmal atrial fibrillation
N/A	Group practice measures
N/A	Genetic Measures
N/A	Ear, nose, throat measures
N/A	Home health
N/A	ESRD Center measures
N/A	Adherence related measures by therapeutic class
N/A	Medication dosing for certain disease states such as diabetes
N/A	Suboptimal treatment regimens for chronic disease such as diabetes and asthma
N/A	Absence of control therapy in persistent asthma patients
N/A	HEDIS high risk medication use in the elderly measures
N/A	TB Screening
N/A	Patient self report satisfaction

Measure Number	Proposed Clinical Quality Measure Topics
N/A	Prescribing and monitoring of psychotropic medications for children and adolescents with psychiatric illness
N/A	Measure for treatment of ADD and other mood disorders
N/A	Measure immunizations for adolescents including TDaP, HPV, and meningococcal.
N/A	Hepatitis B/immune globulin to newborns to mothers who have chronic hepatitis B infection as recommended by CDC
N/A	Underutilization of medication measures
N/A	Improve active engagement of patients in their care
N/A	Improved care coordination and reduce gaps in care

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Response: We appreciate the suggested measure topics submitted by commenters for potential new clinical quality measures. Any future clinical quality measures developed will be in consideration of the clinical practices particular to EPs and eligible hospitals. We have captured these recommendations and will have them available for consideration in future years.

h. Reporting Method for Clinical Quality Measures for 2011 and Beginning With the 2012 Payment Year

(1) Reporting Method for 2011 Payment Year

As we previously discussed, we proposed to use attestation as a means for EPs, eligible hospitals and CAHs, 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 proposed to require that Medicare EPs and hospitals attest to the use of certified EHR technology to capture the data elements and calculate the results for the applicable clinical quality measures. State Medicaid HIT Plans submitted to CMS will address how States will verify use of certified EHR technology to capture and calculate clinical quality measures by Medicaid EPs and eligible hospitals.

Further, we proposed to require that Medicare EPs, eligible hospitals, and CAHs 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. We expect that States will follow a similar strategy as Medicare for the Medicaid EHR incentive program.

We proposed that attestation will utilize the same system for other attestation for meaningful use objectives, and proposed we would 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 EHR technology.
- 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 of 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.

Again, State Medicaid Agencies will determine the required elements for provider attestations for clinical quality measure reporting, subject to CMS prior approval via the State Medicaid HIT Plan.

For eligible hospitals, we proposed 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 technology.
- 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 of 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.

The following is a summary of comments received regarding the proposed reporting method for clinical quality measures for the 2011 payment year, and our responses.

Comment: The majority of commenters were against requiring attestation for 2011, rather than suggesting modification of the specific attestation requirements. Others commented that reporting should not be delayed to realize quality improvements

and better health outcomes for patients as soon as possible. Many commenters suggested deferral of clinical quality measures submission until CMS can electronically accept data. Commenters indicated that this is consistent with allowing delayed reporting by Medicaid providers until 2012 or beyond. A number of commenters suggested that attestation should be confined to attesting that the EP's had reviewed or selected relevant clinical quality measures.

Response: While we received many comments to delay attestation past 2011, we are finalizing our proposed requirement for EPs and eligible hospitals to attest to the numerators, denominators, and exclusions in their first payment year for the required clinical quality measures as described in section II.A.3.d through f of this final rule. Medicaid providers do not have "delayed reporting of clinical quality measures." The statute and this final rule allow Medicaid providers the option of receiving the EHR Incentive Payment for having adopted, implemented or upgraded to certified EHR technology, in lieu of meeting the meaningful use bar in their first participation year. We expect that most Medicaid providers would choose to adopt, implement or upgrade to certified EHR technology, rather than demonstrating they are meaningful EHR users in their first participation year.

Comment: Some commenters also suggested EPs should only have to attest that the EP is entering the required data elements for clinical quality measure reporting where those fields exist in the certified EHR technology and provide feedback to the vendor where structured data fields are not available. Other commenters indicated the burden of adding numerous new data elements is high and labor intensive.

Response: We considered the suggestion of only requiring attestation of documentation of clinical encounters. While we agree that this could be considered "information on clinical quality measures," however, we do not believe that such information is needed when including the submission of information on clinical quality measures, which is a required element of meaningful use. We also believe that submission of such information would be of limited value. We believe that by limiting the clinical quality measure submission requirement to those results calculated by certified EHR technology, we have limited the potential burden.

After consideration of the public comments received, we are requiring EPs, eligible hospitals, and CAHs to attest to the numerator, denominator, and exclusions for the payment year 2011 at § 495.8. We are finalizing the following requirements for EPs in this final rule for reporting clinical quality measures:

- 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 for all patients included in the certified EHR technology.
- The NPI and TIN of the EP submitting the information at § 495.10.
- 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 applicable patients contained in the certified EHR technology irrespective of third party payer or lack thereof.
- The beginning and end dates for which the numerators, denominators, and exclusions apply (the Medicare EHR reporting period in payment year 1 is 90 days as stated at § 495.4, and for payment year 2 is the beginning and end date of the reporting period as stated at § 495.4. For Medicaid providers, as there is no EHR reporting period for adopting, implementing or upgrading for their first payment year, it is in their second payment year/first year of demonstrating meaningful use that they have a 90-day EHR reporting period. Therefore, it is their 2nd year of demonstrating meaningful use that has a 12 month EHR reporting period. For eligible hospitals and CAHs, we are finalizing the following requirements in this final rule:
- The information submitted with respect to clinical quality measures was generated as output from an identified certified EHR technology.
- The information submitted is accurate to the best of the knowledge and belief of the official submitting on behalf of the eligible hospital or CAHs.
- The information submitted includes information on all patients to whom the measure applies for all patients included in the certified EHR technology.
- The identifying information for the eligible hospital and CAH at § 495.10.
- 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 applicable patients contained in the certified EHR technology irrespective of third party payer or lack thereof.
- The beginning and end dates for which the numerators, denominators, and exclusions apply (the Medicare EHR reporting period in payment year 1 is 90 days as stated at § 495.4, and for payment year 2 is the beginning and end date of the reporting period as stated at § 495.4. For Medicaid providers, as there is no EHR reporting period for adopting, implementing or upgrading for their first payment year, it is in their second payment year/first year of demonstrating meaningful use that they have a 90-day EHR reporting period. Therefore, it is their 2nd year of demonstrating meaningful use that has a 12 month EHR reporting period.

States must implement the same meaningful use requirements, including clinical quality measures, with the exceptions described in section II.A. of this final rule. Therefore, Medicaid EPs and eligible hospitals must submit the same required information described above for clinical quality measures. States will propose in their State Medicaid HIT Plans how they will accept provider attestations in the first year they implement their Medicaid EHR incentive program, and how they will accept electronic reporting of clinical quality measures from providers' certified EHR technology in their second and subsequent implementation years.

(2) Reporting Method Beginning in 2012

In our proposed rule, we proposed that for the 2012 payment year, the reporting method for clinical quality measures would be the electronic submission to CMS of summary information, (that is, information that is not personally identifiable) on the clinical quality measures selected by the Secretary using certified EHR technology. For Medicaid, we proposed that EPs and hospitals eligible only for the Medicaid EHR incentive program must report their clinical quality measures data to States. We proposed that States would 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 we did for payment year 2011, for 2012, we also proposed reporting on all cases to which a clinical quality measures applies in order to accurately assess the quality of care rendered by the particular EP, eligible hospital, or CAH 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 solicited comments on the impact of requiring the submission of clinical quality measures data on all patients, not just Medicare and Medicaid beneficiaries.

The following is a summary of comments received regarding the proposed reporting method beginning in 2012 in regard to the collection of aggregate level data on all patients.

Comment: Several commenters noted that it appears that EPs are supposed to submit clinical quality measures electronically to the States in 2012. The commenters noted that several States have aging Medicaid Management Information Systems that may not be capable of accepting this data/information. The commenters requested clarification about whether CMS expects the States to utilize and report this data immediately.

Response: To clarify, States may propose to CMS in their State Medicaid HIT Plans (See Section 495.332) the means by which they want to receive providers' clinical quality measures, starting with States' second implementation year of their Medicaid EHR incentive program. States are not obliged to receive this data using their MMIS but can consider other options such as but not limited to: An external data warehouse, registries or health information exchanges that include data repositories.

Comment: A commenter asked that we state the authority which provides us the ability to require EPs and hospitals to report on non-Medicare and Medicaid patients.

Response: 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." Likewise, section 1903(t)(6) of the Act states that demonstrating meaningful use may include clinical quality reporting to the States, and may be based upon the methodologies that are used in sections 1848(o) and 1886(n). 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, eligible hospital, or CAH. We believe that the quality of care of our EP, eligible hospitals, and CAHs, as well as the ability to demonstrate the meaningful use of certified EHR technology, is best reflected by the care rendered to all patients, not just Medicare or Medicaid beneficiaries.

Comment: Some commenters recommended patient level data for clinical quality measure reporting while others supported CMS' requirement to submit summary level data for EPs and hospitals. There were several commenters that indicated support for reporting clinical quality measure data on all patients rather than just on Medicare and Medicaid patients. Another commenter stated that CMS should not require hospitals to submit patient level data and that the data should be at the aggregated level for all payment years. Another commenter stated that it is well proven in other disciplines that aggregated clinical data on quality measures can drive improvements in outcomes. Another commenter recommended patient level data that would be useful to State health programs and link information to managed care organizations.

Response: We agree with the commenters that stated that reporting clinical quality measure data for all patients provides a more comprehensive measure of quality. We acknowledge that there are potential advantages to patient level data in measuring quality such as those stated by the commenter. However, for Stage 1 we have elected to require aggregate level data since the EHR standards as adopted by ONC's final rule (found elsewhere in this issue of the **Federal Register**) do not provide standards for the submission of patient level data.

Comment: The commenter requested that CMS should have a process in place to support end-users with on-going help desk support.

Response: We agree with the suggestion for the implementation of a help desk to respond to questions related to the various CMS related questions after implementation of the proposed rule. Information about how we will provide assistance to providers will occur outside this final rule.

Comment: A few commenters asked for clarification regarding the Stage 1 audit process to ensure accuracy for the reporting of clinical quality measures (for example, numerator, denominator, and exception data).

Response: EPs, eligible hospitals, and CAHs are required for 2011 to attest to results as automatically calculated by certified EHR technology. Beginning with 2012, such information will be submitted electronically with respect to these requirements; we expect our audit strategy would be based on verifying that the results submitted accord with how they were calculated by the certified EHR technology.

Comment: We received comments requesting that CMS require that eligible providers report their clinical quality measures data to not only States and CMS, but also to Regional Health Improvement Collaboratives, where such programs exist. The commenters believed that this represents an alternative means for data submission rather than attestation and would allow States and CMS to test this alternative in 2011 or 2012. A commenter requested that CMS interpret the statutory requirement (Sections 1848(o)(2)(B)(iii) and 1886(n)(3)(B)(iii)) to avoid redundant or duplicative reporting of quality measures to include not just other CMS reporting efforts but also to avoid duplicative and redundant reporting with State and/or regional quality measurement and reporting efforts. They therefore requested that for Medicaid, CMS require EPs and hospitals report their clinical quality measures to not only States/CMS but also to Regional Health Improvement Collaboratives, where such programs exist.

Response: Clinical quality measures need to be reported to CMS for the Medicare program. For 2011, we intend to provide a web based tool for attestation. Beginning with 2012 for Medicare, we will provide one or more alternative options for electronic submission which may include intermediaries. For Medicaid, information will go to the States as directed by the States. We believe it would go well beyond the purview of this provision to require additional reporting other than to CMS or the States. To clarify the issue raised by the commenter, sections 1848(o)(2)(B)(iii) and 1886(n)(3)(B)(iii) are tied to the Secretary and Federally-required quality measures reporting programs. However, CMS agrees that State and regional redundancies could be very problematic. We therefore clarify our proposed policy. States must include in their State Medicaid HIT Plans an environmental scan of existing HIT and quality measure reporting activities related to Medicaid. We expect States to include details in their SMHP about how these other on-going efforts can be leveraged and supported under HITECH; and how HITECH will not result in duplicative and/or burdensome reporting requirements on the same providers or organizations.

In the proposed rule, we proposed that Medicare EPs, eligible hospitals, and CAHs would be required to report the required clinical quality measures information electronically using certified EHR technology via one of three methods. The primary method we proposed would require the EP, eligible hospital, or CAH to log into a CMS-designated portal. Once the EP, eligible hospital, or CAH 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 proposed to permit Medicare EPs, eligible hospitals, and CAHs 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, eligible hospital, or CAH who chooses to submit data via an HIE/ HIO network to be a participating member of the HIE/HIO network. Medicare EPs, eligible hospitals, and CAHs would be required to submit their data payload based on specified structures or profiles, such as Clinical Data Architecture (CDA), and accompanying templates. The EPs, eligible hospitals, or CAHs data payload would be an output from their respective certified EHR technologies, in the form and manner specified from their HIE/HIO adopted architecture into the CMS HIE/HIO adopted architecture.

As another potential alternative, we proposed to accept submission through registries dependent upon the development of the necessary capacity and infrastructure to do so using certified EHRs.

We stated in the proposed rule that we intended 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 and CAHs on or before April 1, 2011 for EHR adoption and incorporation and to accommodate EHR vendors.

The following is a summary of comments received regarding the proposed reporting method for clinical quality measures beginning with the 2012 payment year, and our responses.

Comment: A commenter recommended that CMS test a range of reporting options for clinical quality measures to establish uniform and reliable rates of data transmission. Several commenters supported the three data submission methodologies listed in the proposed rule to allow flexibility in the quality reporting mechanisms. Many commenters requested reporting via registries.

Response: We agree with the desirability of considering the three transmission methodologies listed in the proposed rule. The submission through a portal is the only mechanism that is feasible and practical for 2012 electronic clinical quality measure submission. We plan to test HIE/HIO and registry submission for future possible implementation through HITECH.

Comment: A commenter requested clarification as to when CMS would no longer accept data for 2012 for Medicare EPs.

Response: The specific technical mechanism for attestation and electronic submission will be posted on the CMS Web site, and through various educational products in development. We anticipate that the last date for attestation or electronic submission will be two-three months after the close of the applicable EHR reporting period for EPs, eligible hospitals, and CAHs respectively.

Comment: Several commenters requested that CMS continue programs that incentivize advanced patient care for providers who are not eligible for the EHR incentive program and/or who do not become meaningful users of certified EHR technology.

Response: CMS clarifies, based upon the comments, that our efforts to avoid duplicative quality reporting requirements do not necessarily mean the discontinuation of other quality reporting programs. CMS and State Medicaid agencies support several quality reporting programs that are legislatively mandated or approach quality measurement in ways that are not exclusively tied to HIT, or that, are voluntary and/or address emerging or developing quality measure focus areas. We are committed to determining where the EHR incentive program's quality measure reporting can support other quality objectives, where it cannot and how to best align our overall quality measurement efforts across programs.

Comment: Many commenters requested deferring quality measure reporting until 2012 and/or 2013, at which time all measures will be electronically specified and tested. Commenters believed that this was especially important for new clinical quality measures such as Emergency Department Throughput and Stroke, and recommended gradually phasing in or gradually increasing the number of reportable measures and measure sets over time to allow for sufficient testing and harmonization between programs. Some commenters suggested that for Stage 1, eligible hospitals should be required to report only on the 15 measures that have been electronically specified and those that are appropriate for that organization. One commenter requested clinical quality measure reporting should be optional. Also, commenters requested for 2011 and 2012 that hospitals continue to report clinical quality measures through the current pay-for-reporting (RHQDAPU and HOP QDRP) programs or on clinical quality measures that coincide with HEDIS reporting measures including HOS and CAHPS, using the existing approaches, while quality measurement specialists and vendors create valid, reliable, and field-tested e-measures for deployment in the eligible hospitals for 2013. Finally, commenters stated that the proposed timeline may negatively impact credibility of data produced and have potentially negative impact on patient safety.

Response: With respect to comments received regarding the timeline for implementation of the EHR incentive program, we are only finalizing clinical quality measures that are electronically specified by the date of display of this final rule. For eligible hospitals and CAHs, we are finalizing 15 clinical quality measures as listed in Table 10 of this final rule that will be required to report for 2011 and 2012, as applicable to their patient population. Although we understand the suggestion that reporting through RHQDAPU should suffice for the HITECH Act, the difficulty is that HITECH specifically requires that EPs, eligible hospitals, and CAHs use "certified EHR technology" in connection with the submission of clinical quality measures. Thus the HITECH Act introduces a requirement that at least some clinical quality measures be submitted in connection with the use of certified EHR technology, whereas RHQDAPU has no such requirement. We have limited the measures to those that have been electronically specified and that are able to be automatically calculated by the certified EHR technology. These results will be reported by EPs, eligible hospitals, and CAHs. We will seek to align the EHR incentive program and quality reporting programs in future rulemaking.

Comment: A number of commenters urged CMS not to require submission of

clinical quality measures data beyond what a certified EHR can produce. Specifically, commenters stated that no clinical quality measures required for submission in Stage 1 should require a manual chart review. Some commenters also requested allowing submission of clinical quality measures through other EHRs that are not certified.

Response: We have adopted the suggested approach for 2011 and 2012 that limits the required information on clinical quality measures results to that which can be automatically calculated by the certified EHR technology. As to non-certified EHR technology, the HITECH Act incentive program specifically requires the meaningful use of certified EHR technology.

Comment: Several commenters stated that currently the data required to be used in the calculation of clinical quality measures are obtained from EHR discrete fields, free text and paper records. Commenters recommended a uniform reporting structure. Commenters questioned if they would be submitting raw data, numerators and denominators only, if there will be an intermediary file that will allow manual edits to the file prior to submission, and if not will validity be based entirely on discrete electronic data. Commenters asked if sampling will be permitted or if hospitals will be required to report on entire populations. Commenters supported the value of reporting clinical quality measures for all patients, not just Medicare and Medicaid patients, in order to see the whole picture of the patient population which will enhance quality improvement.

Response: As discussed elsewhere, the submission requirement is limited to calculated results of clinical quality measures from certified EHR technology, as specified in this final rule, and as is consistent with the ONC final rule (*see* 75 FR 2014) which requires certified EHR technology to be able to calculate clinical quality measures as specified by CMS.

Comment: Several commenters suggested the clinical quality measures requiring medication administration data be delayed for reporting because they require advanced features of EHR systems with implementation of the features, in particular Electronic Medication Administration Record (eMAR).

Response: The Department has adopted certification criteria for EHR Modules and Complete EHRs, as identified in the Health Information Technology: Initial Set of Standards, Implementation Specifications, and Certification Criteria for Electronic Health Record Technology; Interim Final Rule (75 FR 2014). It has also proposed temporary and permanent certification programs for testing and certifying health information technology in a March 10, 2010 proposed rule (75 FR 11328). The certification of EHRs will assure functionality of the information system to obtain clinical quality data from the EHR.

After consideration of the public comments received, starting in payment year 2012, in addition to meeting requirements for measures on meaningful EHR use and other requirements, Medicare EPs, eligible hospitals, and CAHs will be required to electronically submit clinical quality measures results (numerators, denominators, exclusions) as calculated by certified EHR technology at § 495.8. Medicaid EPs will be required to do so in the State's second implementation year for their Medicaid EHR incentive program. The clinical quality measures will be for all patients, regardless of payer, and will be for the period of the EHR reporting period. Medicare EPs, eligible hospitals, and CAHs will be required to report the required clinical quality measures information electronically using certified EHR technology via one of three methods. The primary method will require the EP, eligible hospital, or CAH to log into a CMS-designated portal. Once the EP, eligible hospital, or CAH has logged into the portal, they will 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, contingent on feasibility, we will permit Medicare EPs, eligible hospitals, and CAHs to submit the required clinical quality measures data using certified EHR technology through a Health Information Exchange (HIE)/Health Information Organization (HIO). This alternative data submission method will be dependent on the Secretary's ability to collect data through a HIE/HIO network and would require the EP, eligible hospital, or CAH who chooses to submit data via an HIE/HIO network to be a participating member of the HIE/HIO network. Medicare EPs, eligible hospitals, and CAHs would be required to submit their data payload based on specified structures or profiles. The EPs, eligible hospitals, or CAHs data payload should be an output from their respective certified EHR technologies, in the form and manner specified from their HIE/HIO adopted architecture into the CMS HIE/HIO adopted architecture.

As another alternative, we will also accept submission through registries dependent upon the development of the necessary capacity and infrastructure to do so using certified EHRs. Finally, qualifying Medicare Advantage organizations for their eligible Medicare Advantage EPs, as well as, Medicare Advantage-affiliated eligible hospitals and CAHs will continue to submit HEDIS, HOS and CAHPS data instead of the clinical quality measures results under this final rule in section II.C.6.

We will 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 and CAHs on or before April 1, 2011 for EHR adoption and to accommodate EHR vendors.

State Medicaid Agencies must follow the same requirements for meaningful use, including clinical quality measures, for example, across all payers and for the entire EHR reporting period for EPs and eligible hospitals. We expect that States will be able to accept the electronic reporting of clinical quality measures by their second year of implementing the EHR incentive program. States will include in their State Medicaid HIT Plan a description of how Medicaid providers will be able to electronically report clinical quality measures, subject to CMS prior approval.

i. Alternative Reporting Methods for Clinical Quality Measures

We proposed several alternative reporting methods to create a dataset of provider-submitted summary data. One such alternative we proposed is the development of a distributed network of EHRs where health information is retained locally in individual EP, eligible hospital, and CAH EHRs and only summary reports are submitted to CMS. Another alternative we proposed is the creation of databases of patient-level EHR data stored at the state or regional level.

The following is a summary of comments received regarding the proposed alternative reporting methods for clinical quality measures and our responses.

Comment: A commenter recommends aggregate reporting necessary for clinical quality measures to be able to be completed in secondary systems such as data warehouses.

Response: For Medicare, we require that the data source be from certified EHR technology. EPs, eligible hospitals

and CAHs may use intermediaries (data warehouses) to submit the EHR-generated clinical quality measure if available, assuming all requirements are met. States may seek CMS prior approval via their State Medicaid HIT Plans for how they expect Medicaid providers to report the required meaningful use data, including clinical quality measures. For example, States may propose that the data, while it originates in the providers' certified EHR technology, may be reported using a health information exchange organization or registry as an intermediary.

Comment: A few commenters communicated that the calculation and submission of quality measures may depend on the use of health information technology systems beyond those used by the EP such as data warehouses or registries that have to manipulate the data received. They indicated the final rule should not exclude the use of additional non-certified EHR technology to assist EPs in satisfying the quality reporting requirements provided the EP uses certified EHR technology to capture the data and to calculate the results.

Response: Certified EHR technology will be required to calculate the clinical quality measure results for the CMS specified measures we finalize in this final rule and transmit under the PQRI Registry XML specification, as provided in the ONC final rule (found elsewhere in this issue of the **Federal Register**).

Comment: Several commenters recommended inclusion of QRDA with PQRI XML for reporting, thus allowing vendors the ability to bypass PQRI XML if they plan to ultimately implement QRDA. There is also concern that switching to QRDA from XML will require duplicative investments. They recommended attestation for 2011 and 2012 as well as allowing use of QRDA in 2012.

Response: Electronic specifications will need to utilize standards that the certified EHR can support. ONC's final rule (found elsewhere in this issue of the **Federal Register**) limits this to PQRI Registry XML specifications. There is no current requirement that a certified EHR be able to produce QRDA.

j. Reporting Period for Reporting of Clinical Quality Measures

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, eligible hospital, and CAH must submit information "for such period" on the clinical quality measures and other measures selected by the Secretary. Therefore we proposed that the reporting period for the clinical quality measures selected by the Secretary be the EHR reporting period.

Another alternative we proposed was a fixed reporting period of four quarterly reporting periods, or two six-month reporting periods. In terms of practice and precedent for other Medicare clinical quality measure reporting programs, all of these programs submit data to us at specific reporting intervals.

The following is a summary of comments received regarding the proposed EHR reporting period for EPs, eligible hospitals, and CAHs.

Comment: Some commenters asked for clarification on whether the EP must continuously report during the "entire payment year" or whether the reporting period for clinical quality measures covers a 12-month period. Other commenters questioned the timing of the requirements associated with the measures—whether the specifications for Stage 1 payment year 1 apply to EPs regardless of when the EPs become first eligible or whether the clinical quality measure specifications follow the calendar year.

Response: The EP only needs to report clinical quality measures once a year, as described at § 495.4. For Medicare EPs, eligible hospitals and CAHs, the EHR reporting period is 90 days for their first payment year. For Medicaid eligible providers, their first payment year in which they demonstrate meaningful use (which may be their second payment year, if they adopted, implemented or upgraded in their first payment year) also has a 90-day EHR reporting period. For Medicare EPs, eligible hospitals and CAHs, in their second payment year, the reporting period is 12 months. For Medicaid EPs and eligible hospitals, in their second payment year of demonstrating meaningful use, they also have a 12-month EHR reporting period. Related to the timing of the requirements, the final clinical quality measure specifications for 2011 and 2012 will be posted at the time of display of this final rule.

Comment: Some commenters requested clarification of the process for reporting in the entire payment year. A commenter requested clarification regarding whether the EP must continuously report during the entire payment year or whether the reporting period for clinical quality measures covers an entire 12-month period. Some commenters pointed out that reporting capability may not be available every day of the year due to information system availability.

Response: Technical requirements for electronic reporting will be posted on the CMS Web site prior to the reporting period. The reporting period refers to parameters of the data captured in the EHR or the services documented in the EHR, not the time when the submission of information regarding clinical quality measures is made. States will dictate for Medicaid EPs and eligible hospitals the timing of submission of their clinical quality measures data via electronic reporting. Submission could be as infrequent as once a year after the close of the reporting period. The reporting period beyond 2011 and 2012 for clinical quality measures will be determined in future rulemaking.

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 final 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

As proposed, in the final rule, we are adopting a common method for demonstrating meaningful use in both the Medicare and Medicaid EHR incentive programs, for the same reasons we have 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 in section II.4.b of this final rule. 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 final rule.

b. Methods for Demonstration of the Stage 1 Criteria of Meaningful Use

Our final regulations, at § 495.8, will require that for CY 2011, EPs demonstrate that they satisfy each of the fifteen objectives and their associated measures of the core set listed at § 495.6(d) and five of the objectives and their associated measures from the menu set listed at § 495.6(e) unless excluded as described in § 495.6(a)(2). (An exclusion will reduce the number of objectives/measures the EP must satisfy by the number that is equal to the EP's exclusions. For example, an EP that can exclude two menu objectives/measures is required to satisfy only three of the objectives and associated measures from the menu set. Similarly, an exclusion will reduce the number of core objectives/measures that apply). We permit only those exclusions that are specifically indicated in the description of each objective and its associated measure (§ 495.6(d) for the core set and § 495.6(e) for the menu set). If an exclusion exists and the EP meets the criteria for it, the EP would report to CMS or the States that fact rather than demonstrating that they satisfy the objective and associated measure. At § 495.8, we will require that for FY 2011, eligible hospitals and CAHs demonstrate that they satisfy each of the fourteen objectives and their associated measures of the core set listed at § 495.6(f) and five of objectives and their associated measures from the menu set listed at § 495.6(g) unless excluded as described in § 495.6(b)(2). As with EPs, all exclusions are specifically indicated, in the description of the objective and associated measures (§ 495.6(f) for the core set and § 495.6(g) for the menu set) and an exclusion will reduce the number of objectives and associated measures an eligible hospital or CAH must satisfy (see above example for EPs). If an exclusion exists and the hospital meets the criteria for it, the eligible hospital or CAH would report to CMS or the States that fact rather than demonstrating that they satisfy the objective and associated measure. Finally, as specified in 495.316(d), for those participating in the Medicaid EHR incentive program, the State may alter the requirements for demonstrating that an EP or eligible hospital is a meaningful user, with regard to four specific objectives and measures. For these objectives and measures, the State may also choose to make a menu-set objective a core objective. Such State additions could increase the core or menu set objectives and measures that must be satisfied.

For payment years beginning in CY 2012 and subsequent years, our final regulations, at § 495.8, will require that for Stage 1 of meaningful use, EPs demonstrate that they satisfy each of the 15 objectives and their associated measures of the core set listed at § 495.6(d), except § 495.6(d)(4) "Report ambulatory quality measures to CMS or, in the case of Medicaid EPs, the states" and 5 of the objectives and their associated measures from the menu set listed at § 495.6(e) unless excluded as described in § 495.6(a)(2). The form and mechanism for excluding an objective and its associated measure is the same for CY2012 and subsequent years as it is for CY2011. The ability for States to add certain requirements is the same for CY 2012 and subsequent years as it is for CY 2011. The EP must 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 final rule. For payment years beginning in FY2012 and subsequent years, our final regulations, at § 495.8, will require that eligible hospitals and CAHs demonstrate that they satisfy each of the fourteen objectives and their associated measures of the core set listed at § 495.6(f), except § 495.6(f)(3) "Report hospital quality measures to CMS or, in the case of Medicaid EPs, the states" and five of the objectives and associated measures from the menu set listed at § 495.6(g) unless excluded as described in § 495.6(b)(2). The form and mechanism for excluding an objective and its associated measure is the same for FY2012 and subsequent years as it is for FY2011. The ability for States to add certain requirements also is the same for FY 2012 and subsequent years as it is for FY 2011. The eligible hospital or CAH must 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 final rule.

Except for the clinical quality measures (for which we require electronic reporting in CY or FY 2012 and subsequent years as discussed above), satisfaction of meaningful use objectives and associated measures may be demonstrated through attestation. Specifically, we will require that EPs, eligible hospitals and CAHs attest through a secure mechanism, such as through claims based reporting or an online portal. For the Medicare FFS and MA EHR incentive programs, CMS will issue additional guidance on this mechanism. For the Medicaid EHR incentive program, the States will include additional information in the State Medicaid HIT plans they submit to CMS to implement the program. We will require that an EP, eligible hospital or CAH 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 reported objectives of meaningful use. We would require 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, eligible hospitals and CAHs. 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, eligible hospitals and CAHs demonstrate meaningful use should work for all provider types. We also believe that uniform means of demonstration for EPs, eligible hospitals and CAHs are preferred 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 could require use of certified EHR technology beyond the capabilities certified according to the ONC FR.

In addition to requiring electronic reporting of clinical quality measures beginning in 2012 in Medicare and Medicaid, we also leave open the possibility 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 require any EP, eligible hospital or CAH to participate in this testing in either 2011 or 2012 in order to receive an incentive payment. 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, eligible hospitals and CAHs who wish to join in our efforts to explore the electronic exchange of information. Any testing should be based on the principle 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 final 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.

Comment: Several commenters submitted comments regarding the methods of demonstration for clinical quality measures.

Response: We summarize and respond to those comments in section II.A.3 of this final rule.

Comment: A few commenters submitted comments regarding section 1848(o)(2)(A) of the Act, which provides discretion to the Secretary to provide for the use of alternative means for meeting the requirements of meaningful use in the case of an eligible professional furnishing covered professional services in a group practice. Some of these commenters suggested that CMS provide such an alternative means in the final rule, while others suggested we consider doing so in future rulemaking.

Response: We did not propose any alternative means in the proposed rule. Given the per EP basis for most of the objectives and their associated measures, we did not believe group reporting would provide an accurate reflection of meaningful use. In addition, as the incentives payments are calculated on a per EP basis it is unclear to us how variance of meaningful use among EPs within the group should be treated. We believe the possible reduction in burden of attesting once per group versus once per EP is outweighed by the less accurate reporting, increased possibility of duplicate payments and decreased transparency. We note that many of the measures rely on data which could easily be stored at a group level such as a patient's demographics or medication lists and any EP with access to that information about a patient in their certified EHR technology and who sees that same patient in the EHR reporting period would receive credit for that patient in their numerator and denominator. Other aspects such as the enabling of drug-drug, drug-allergy checks, using CPOE and eRx could vary widely from EP to EP within the same group. We would also be concerned with EPs in multi-specialty group practices some of whom might be eligible for an exclusion, while others would not be. As requested by commenters we will continue to review this option in future rulemaking, but for this final rule we do not include the option to demonstrate meaningful use at a group level.

While we did not make changes to the demonstration of meaningful use requirements based on the comments above, we did make modifications to other aspects of the Stage 1 definition of meaningful use that required the descriptions of how many and which objectives and their associated measure EPs, eligible hospitals and CAHs to be altered accordingly. These changes are to the first paragraph of this section (II.4.b).

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

In the proposed rule, we said that 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 will not post information on group practices because we will not 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 qualifying MA organizations receiving the incentive payment or payments. We would 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. The HITECH Act did not require Medicaid EPs and eligible hospitals to be identified online so we will not do so.

We did not receive any comments and we are finalizing these provisions as proposed.

b. Program Election Between Medicare FFS/MA and Medicaid for EPs

In the proposed rule, we said 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, if eligible, could receive incentive payments from both Medicare and Medicaid simultaneously). Section 495.10 allows an EP meeting the eligibility criteria for both the Medicare FFS/MA and Medicaid programs to participate in either program. We would also allow an EP to change his or her election once during the life of the EHR incentive programs after making the initial election, for payment years 2014 and

before. We believe this one-time election rule allows 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) continues the availability to the EP of 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.

In the proposed rule, we proposed at 495.10(e)(5), that an EP switching program is "placed in the payment year the EP would have been in, had the EP not switched programs." 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. For the final rule, we are clarifying that the EP is "placed in the payment year the EP would have been in had the EP begun in and remained in the program to which he or she has switched." We have modified 495.10(e)(5) accordingly.

We believe this clarification is necessary in order to address comments we received on non-consecutive payments. As outlined in II.A.1.c and d of this final rule, the definition of first, second, third, fourth, fifth, and sixth payment year differs across the Medicare and Medicaid programs. Section 1848(o)(1)(E)(ii) of the Act requires that the second Medicare payment year be successive to the first payment year and immediately follow it. Similarly, the third payment year must immediately follow the second, and so on. Thus, as explained in II.A.1.c., "if a Medicare EP receives an incentive in CY2011, but does not successfully demonstrate meaningful use or otherwise fails to qualify for the incentive in CY2012, CY2012 still counts as one of the EP's five payment years and they would only be able to receive an incentive under the Medicare EHR incentive program for three more years." The same rule, however, does not apply to the Medicaid EHR incentive program. For that program, EP payments may generally be non-consecutive. If an EP does not receive an incentive payment for a given CY or FY then that year would not constitute a payment year. For example, if a Medicaid EP receives incentives in CY2011 and CY2012, but fails to qualify for an incentive in CY 2013, they would still be potentially eligible to receive incentives for an additional four payment years.

The rules on consecutive payment, discussed above, govern how an EP should be treated after switching from the Medicaid to the Medicare EHR incentive program, or vice versa. As stated above, we believe that an EP that switches from the Medicaid to the Medicare program should be treated in the same manner as if such EP had started in the Medicare program. Payment years that are skipped in the Medicaid EHR incentive program thus become payment years that count against the EP's five years of payment in Medicare. For example, an EP that receives nonconsecutive payment under Medicaid for CYs 2011 and 2013 (but skips CY 2012), and then switches to the Medicare program in CY 2014, is in the fourth payment year in 2014, and is limited to that payment year's limit on incentive payments. Such an EP may receive only one more year of incentive payments under the Medicare EHR incentive program. We believe this rule is equitable, given that, had the EP started in the Medicare program, the EP would not have been able to benefit from non-consecutive payments available under the Medicaid EHR incentive program. We see no reason why EPs that switch from the Medicaid to the Medicare program should be treated differently from those who initially began in the Medicare program, and believe that any other rule might encourage gaming on the part of eligible professionals.

By the same token, an EP that switches from the Medicare to the Medicaid EHR incentive program will not be penalized for non-consecutive payment years accrued while in the Medicare program. For example, an EP that receives nonconsecutive payment under Medicare for CYs 2011 and 2013 (but skips CY 2012), and then switches to the Medicaid program in CY 2014, is in the third year of payment in 2014, and is potentially eligible to receive three additional years of payment under Medicaid (after 2014), for a total of six years of payment. Similar to our rationale described in the paragraph above, we do not believe an EP that switches to the Medicaid program should be treated differently from the EP that initially begins in the Medicaid program, as once the EP switches to the Medicaid program, there is no statutory requirement that the payment year ordering be consecutive.

We believe it is self-evident that an EP switching to a new program is subject to the requirements of such new program. Thus, for example, an EP switching from Medicaid to Medicare might be subject to a higher stage of meaningful use upon moving to the Medicare program. The EP also would be subject to fewer years of payment and to the requirement that no incentive payments may be made after 2016.

Finally, 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 proposed 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. If the EP receives the HPSA bonus available under the Medicare FFS EHR incentive program, this amount could be as much as $4,450. An EP who switches from Medicaid to Medicare could potentially exceed the Medicare threshold in a number of circumstances; however, since they will not be allowed to exceed the Medicaid threshold under any circumstance, we would pay the incentive for which they are eligible for a given payment year in whichever program they are in for that payment year until they exceed the Medicaid threshold. No incentive payments will be made to any EP that would allow the EP to exceed the Medicaid threshold. We anticipate that this would result in a prorated final year incentive payment. Finally, we proposed 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.

Comment: We received comments requesting clarification on when an EP could make their one switch.

Response: As described in our example, the EP could make their one

switch anytime after the receipt of an incentive payment under either the Medicare or Medicaid program. Since this policy would also apply to other program changes (for example, changing from one State to another, or updating registration data elements), we want to clarify when program registration changes can take place. An EP, eligible hospital or CAH sets into motion receipt of the incentive payment when they attempt to demonstrate meaningful use or demonstrate to the State efforts to adopt, implement, or upgrade to certified EHR technology. Therefore, prior to their first successful attempt to demonstrate meaningful use or demonstrate to the State efforts to adopt, implement, or upgrade to certified EHR technology, the EP could change their registration in either the Medicare or Medicaid EHR incentive program as many times as they wish. Furthermore, EPs and hospitals selecting the Medicaid incentive program may also switch freely prior to payment as described here. However, there may only be one payment from one State in any one payment year.

After consideration of the public comment received, we are modifying the provision at § 495.10(e)(2) to "(2) After receiving at least one EHR incentive payment, may switch between the two EHR incentive programs only one time, and only for a payment year before 2015". This modification better reflects our clarification in response to the comment received on the ability to switch between programs. For the final rule, we have made a few other technical changes to § 495.10, in addition to the changes made to § 495.10(e)(2) and (e)(5).

c. Data To Be Collected

In addition to information regarding the demonstration of meaningful use, in § 495.10 of this final rule we would 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 and CAHs, their CCN.

To coordinate with the States to avoid duplication of payments, we would make available to the States through a single National Level Repository (NLR) 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.
- Other information as specified by CMS.

CMS, our contractors, and the States will have access to these data elements through the NLR 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.

Comment: We received comments that some EPs do not use TINs, but rather the EP's Social Security Number (SSN).

Response: In these cases the EP would submit a TIN, which is their SSN. An incorporated EP would have a TIN for the corporation that would be an EIN. The EP's own TIN remains his/her SSN.

Comment: Some commenters requested clarification on whether the business address is the physical location or the mailing address.

Response: We believe that the HITECH Act required reporting of this information to assist the public in identifying meaningful EHR users. We believe the practice location address serves this purpose better than the mailing address. However we will allow EPs to enter an alternate address for posting purposes but will not allow that address to be a post office box.

Comment: Commenters suggested that States would be allowed to determine the requirements associated with Medicaid provider TIN assignments.

Response: We discuss the requirements associated with TIN assignment in 495.10(f) and in the requirements associated with SMHPs in this preamble at section 495.332 SMHPs. States are responsible for making sure the providers are providing an acceptable TIN, consistent with the regulations at 495.10(f), which states that providers may only assign to certain TINs.

We clarified 495.10(f), to reflect this and other changes.

Comment: CMS received numerous comments about the schedule for and State's role in the national single repository where CMS will collect data elements on all registrants.

Response: The technological requirements and systems interfaces are outside this regulation and we look forward to providing additional guidance.

Comment: Some commenters recommended a shorter record retention period that the ten years proposed. Commenters recommended periods ranging from three to eight years. The reasons given for a shorter time period were the cost of record retention, no perceived need for a retention period longer than the incentive period, rapid changes in EHR technology and consistency with other unspecified retention requirements.

Response: After reviewing the comments, we agree with commenters that ten years is longer than necessary to ensure the integrity of the program. In considering a shorter retention period, we believe that there may be cause to look over the entire incentive period. As a Medicaid EP would be eligible for incentives over a six-year period if they successfully receive an incentive each year and that is the longest such period available to any participant in the Medicare and Medicaid EHR incentive programs, we adopt a new retention period of six years for this final rule.

Comment: We received a comment suggesting that Medicare adopt an appeals process similar to the one proposed for Medicaid.

Response: We expect to address Medicare appeals in future guidance.

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). Sections 4101(a) and 4201(a) of the HITECH Act originally defined 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. Following publication of our proposed rule, Congress modified the definition of hospital-based EPs. More specifically, on April 15, 2010, President Obama signed into law the Continuing Extension Act of 2010 (Pub. L. 111–157) which, in Section 5, made the following changes to the Social Security Act as it applies to both the Medicare and Medicare EHR incentives for EPs:

(1) Medicare—Section 1848(o)(1)(C)(ii) of the Social Security Act (42 U.S.C. 1395w–4(o)(1)(C)(ii)) is amended by striking 'setting (whether inpatient or outpatient)' and inserting 'inpatient or emergency room setting'.

(2) Medicaid—Section 1903(t)(3)(D) of the Social Security Act (42 U.S.C. 1396b(t)(3)(D)) is amended by striking 'setting (whether inpatient or outpatient)' and inserting 'inpatient or emergency room setting'.

These amendments were effective as if included in the enactment of the HITECH Act.

The above sections indicate 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 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 whether he or she has made a reassignment to the hospital for Part B billing purposes.

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.

Based on section 4101(a) of the HITECH Act (and prior to the amendments in the Continuing Extension Act of 2010), we proposed that an EP would be a hospital-based EP and therefore ineligible to receive a Medicare or Medicaid EHR incentive payment if more than 90 percent of their services are provided in the following place of service (POS) codes for HIPAA standard transactions: 21—Inpatient Hospital, 22—Outpatient Hospital, 23—Emergency Room.

In addition, because of concerns that some primary care EPs who provide services to Medicare and Medicaid beneficiaries would be ineligible for the incentive payments under this proposed definition, in the proposed rule, we asked for comments on whether we should use another method for defining hospital-based EPs. We estimated that under this proposal, 12–13 percent of family practitioners under Medicare would be considered hospital-based. We did not have corresponding data for Medicaid EPs.

Comment: Many congressional representatives, hospital associations, individual providers and other commenters indicated that they believed that the proposal would inappropriately exclude from receiving EHR incentive payments EPs practicing in ambulatory settings such as those that practice in hospital provider-based departments (referred to by most commenters as "outpatient centers and clinics"). They indicated these centers and clinics provide services similar to services furnished by EPs in private offices. Many suggested that this definition may inhibit hospital investments in their outpatient primary care sites. Commenters believe the absence of any EP incentive payment in these settings may discourage hospitals from adopting EHR in ambulatory settings, particularly if doing so requires the purchase of an ambulatory-based EHR system (or an ambulatory component to be added to the hospital's EHR system). This is because the hospital's total incentive payment is based on total inpatient services. A hospital with a large outpatient department will not receive a higher incentive payment as a result of their outpatient services. These commenters indicated that ambulatory care EHRs are very different from inpatient EHRs because of the inherent differences between the types of care provided in each setting. Commenters differed somewhat to the extent that they provided specific alternatives. Some commenters went so far as to suggest that all EPs should be eligible to receive EHR incentive payments, regardless of where they practice.

Response: The changes to the hospital-based definition that are included in the Continuing Extension Act of 2010 (Pub. L. 111–157) discussed above address commenters concerns about ambulatory settings. These changes have been incorporated into the final rule. An EP will be a hospital-based EP and therefore ineligible to receive a Medicare (or Medicaid) EHR incentive payment if more than 90 percent of their Medicare (or Medicaid) services are provided in the following two place of service (POS) codes for HIPAA standard transactions: 21—Inpatient Hospital, 23—Emergency Room.

Comment: Some commenters argued that the proposed rule failed to make a critical distinction between hospital-based EPs who primarily use an EHR paid for and maintained by the hospital and those that did not. Some commenters suggested that an EP should be eligible for an EHR incentive payment if he or she had contributed 15 percent or more toward the cost of acquiring or maintaining the certified EHR. Some commenters requested that CMS change the definition of a hospital-based EP to read: "An EP who furnishes 90 percent or more of his or her covered professional services in the CY preceding the payment year in a hospital setting and primarily through the use of the qualified electronic health records of the hospital." The commenters believed that Congress's intent was to exclude only those EPs using qualified EHRs of the hospital, and that their approach would allow separate EHR incentive payments for EPs who have developed cutting-edge, patient centered EHR modules, thereby allowing for a clinical specificity not currently available in more generalized, hospital-wide EHR systems. Commenters stated that these EHR technologies are currently used in hospital settings and interoperate with hospital systems, but are paid for and primarily maintained by physician groups who see patients in hospital settings. The commenters indicate that these physician groups continue to invest in their EHRs through improvements, ongoing maintenance, and support staff employed to ensure optimal use of such technology. The commenters indicated that many early health IT champions, including hospital-based anesthesiologists, radiologists, pathologists, hospitalists, emergency medicine physicians, and neonatal physicians would be negatively affected by the proposal. These comments would apply to EP services provided in all hospital settings, including inpatient, outpatient, and emergency rooms.

Response: The statute, as now amended, indicates that hospital-based EPs are those who furnish substantially all their services in an inpatient or emergency room setting, such as a pathologist, anesthesiologist, or emergency physician, and who do so using the facility and equipment, including qualified electronic health care records, of the hospital. While commenters focused on the statutory language: "* * * including qualified electronic health care records of the hospital", they did not address the

broader meaning of the section which also includes the requirement that hospital-based EPs are those who furnish services "using the facility and equipment", including qualified electronic health care records of the hospital. We believe both phrases together are intended to provide an explanation of why hospital-based EPs are to be excluded from receiving EHR incentive payments (that is, that they would typically use the facilities and equipment, including the EHR, of the hospital and that therefore it would represent double payment if both hospitals and hospital-based EPs were to be paid incentives). We do not believe that the intent of this language was to require CMS to evaluate each EP as to whether they are using the EHR of the hospital. Further, the commenters did not address the significance of the next sentence of the statute, which clearly indicates that: "The determination of whether an eligible professional is a hospital-based eligible professional shall be made on the basis of the site of service * * *". Since Congress directed that site of service must be the determinant of whether an EP is hospital-based, we could not use individualized determinations of whether an EP is using the EHR of the hospital to deliver his or her services. Also, the subsequent legislation in the Continuing Extension Act of 2010 is consistent with the interpretation that the determination of whether an EP is hospital-based is based on the place where the EP furnishes services, as that subsequent legislation further limited hospital-based to those EPs providing substantially all services in the emergency room or inpatient hospital settings. Furthermore, our final policy is that eligible hospitals must demonstrate meaningful use based upon all applicable cases in the inpatient (21) and emergency department (23) site of service codes. Therefore, there would be duplication in measuring meaningful use for the purposes of making EHR incentive payments in the scenario proposed by these commenters.

The HITECH Act does not define the term "hospital" for purposes of establishing a definition of hospital-based EPs for Medicare and Medicaid. However, 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, clearly EPs that practice primarily in inpatient hospital settings, as referenced in section 1861(e) of the Act, would be considered hospital-based EPs.

We will 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://www4.cms.gov/PlaceofServiceCodes/Downloads/posdatabase110509.pdf.*

From this code set, we would consider the use of the following POS codes to determine whether an EP is a hospital-based eligible professional for Medicare:

- 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.
- 23—Emergency Room, Hospital—is a portion of a hospital where emergency diagnosis and treatment of illness or injury is provided.

Comment: Most commenters were supportive of the proposal to define "substantially all" of his or her covered professional services in a hospital setting as EPs who furnish at least 90 percent of his/her services in a hospital setting. However, some commenters expressed concerns that this threshold will be too high starting in 2015 when the time comes to determine which EPs should be subject to penalties for failure to become meaningful users of certified EHR technology. A few commenters misunderstood the proposal and requested that a hospital-based EP be defined as one who provides at least 90 percent of his or her services, defined as encounters and not as charges.

Response: 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. 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. Consistent with the statute, we proposed to make this determination on the basis of services performed by each EP, not the charges for each EP. We are finalizing the proposed definition of "substantially all" as furnishing at least 90 percent of services in a hospital setting. We believe a 90 percent threshold certainly would qualify as "substantial."

Comment: Representatives of surgeons asked that CMS make an accommodation to the hospital-based definition to account for services paid under a global fee.

Response: The determination of whether or not an EP is hospital-based is determined individually for each EP. A global fee is a single payment for a bundle of services, some of which could be performed in a hospital such as major surgery or hospital visits, whereas some could be performed in an office such as follow-up visits, CMS does not have data, for the place of service for services performed by individual EPs when the services are paid as part of a global fee. We considered possibilities for using national level estimates for individual services typically performed under global fees as proxies for services provided by individual EPs. However, this would add significant additional operational complexity to the determination of hospital-based status and we have not pursued this approach.

Comment: Some commenters requested that CMS establish a process by which EPs could know in advance of a payment year whether CMS considered them as being hospital-based and therefore ineligible for an incentive payment.

Response: To the extent practical, we intend on establishing a process whereby the EP would know his/her hospital-based status during the registration period. We plan to provide information to EPs regarding their hospital-based status as early as possible (that is, no later than early in each payment year). As indicated in the proposed rule, we will make a 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. In the proposed rule we indicated that we would use claims data from the prior calendar year to make hospital-based determinations for EPs. However, in order to provide information regarding the hospital-based status of each EP at the beginning of each payment year, we will need to use claims data from an earlier period. Therefore, we will use claims data from the prior fiscal year (October through September). Under this approach, the hospital-based status of each EP would be reassessed each year, using claims data from the fiscal year preceding the payment year. The hospital-based status will be available for viewing beginning in January of each payment year. For Medicaid purposes, State Medicaid agencies will 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. For purposes of making this determination, States would be permitted to use data either from the prior fiscal or calendar year.

After consideration of the public comments received, we are revising the definition of hospital based EPs in this final rule. An EP will be defined as being hospital-based and therefore 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 two place of service codes 21 (Inpatient Hospital) or 23 Emergency Room, Hospital. We plan to reassess the hospital-based status of each EP for Medicare purposes each year, using claims data from the fiscal year immediately preceding the payment year. Based on preliminary claims data from the first 9 months of 2009, CMS currently estimates that, under this final definition of hospital-based EPs, about 14 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.

7. Interaction With Other Programs

In the proposed rule, we described how 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 in this final 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 final rule, we discuss how we will avoid duplication of reporting requirements for clinical quality measures.

Comment: Some commenters requested more information on efforts to avoid duplication of requirements and highly encouraged CMS to do everything it could in this regard.

Response: We address comments on the avoidance of duplication of requirements in several other areas of this rule where more specifics can be provided.

Comment: Commenters generally supported our proposal to only apply the limitation of participation in multiple programs to the limitation outlined in the HITECH Act.

Response: We continue to believe that providers should be able to participate in every program for which they are statutorily eligible and therefore are maintaining our proposal to only limit Medicare EPs from receiving either the Medicare EHR incentive payment or the Medicare E–Prescribing incentive payment.

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 final 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 will 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 final 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 the Act. As specified under section 1848(o)(1)(A)(i) of the Act, 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 proposed to codify these specifications and definitions in our regulations at 495.102.

Comment: The commenters who expressed concerns about the EP definition under the Medicare program had one overall theme. It is that the definition is too narrow and that it should be more inclusive of other health professionals in order to serve the goals of the HITECH Act. The commenters stated that they believe that the intent of the electronic health records (EHR) legislation is to encompass a wide range of health professionals to incorporate efficient and effective EHR technology. Specifically, these commenters stated that the Medicare EP definition should be expanded to include nonphysician practitioners and health professionals such as physician assistants (PAs), nurse practitioners (NPs), clinical nurse specialists (CNSs), certified nurse-midwives (CNMs), clinical psychologists (CPs), clinical social workers (CSWs), certified registered nurse anesthetists (CRNAs), registered nurses (RNs), occupational therapists (OTs), and credentialed pedorthists who make shoes for diabetic patients. Additionally, we received a comment that the Medicare EP definition should recognize health professionals who provide health support services as members of an interdisciplinary health care team such as a team consisting of diabetes nurse educators, NPs, pharmacists, PAs, dieticians, and case managers.

Representatives of rural health clinics (RHCs), Federally qualified health centers (FQHCs), ambulatory surgical centers (ASCs), outpatient clinics and dialysis facilities commented that their providers should also be included under the Medicare EP definition to qualify for Medicare incentive payments. These providers believe that they are a key set of contributors that will implement and meaningfully utilize electronic health care record program modules that directly benefit their patient populations. Alternatively, one of these commenters recommended that provider eligibility should be determined by type of service provided rather than by location of service and should include non-physician clinicians and providers.

The sub-theme of the comments that we received on the Medicare EP definition is that the definition of an "eligible provider" that qualifies for EHR incentive payments should be a common definition for the Medicare and Medicaid programs. The commenters believe that a uniform definition of an EP would be more administratively efficacious for the Medicare and Medicaid programs considering that EPs are permitted to switch participation between the Medicare and Medicaid incentive programs one-time after the initial payment year.

An organization representing pathologists expressed concern that the Medicare EP definition, as currently drafted would subject certain pathologists to payment incentive penalties for not being meaningful EHR users if the pathologists performed less than 90 percent of their professional services in any inpatient or outpatient setting in the prior year. All EPs have to report on all Core Measures and a subset of clinical measures that pathologists could not meet in their day-to-day practice given the nature of pathology's scope of practice. Accordingly, this organization recommended that CMS ensure that pathologists who are currently defined as Medicare EPs be considered as "non-qualifying" EPs, that are exempt from future meaningful user penalties.

Response: While we appreciate the comments that we received on the Medicare EP definition, we are unable to expand or alter this statutory definition or consolidate it with the Medicaid program EP definition as suggested by the commenters. Under the EHR incentive payment program, the law provided a separate Medicare EP definition rather than giving the Secretary authority or discretion to determine who is a Medicare EP or, who is an EP for both the Medicare and Medicaid programs.

Comment: A commenter requested clarification of the method used for determining Medicare incentives for EPs practicing in a rural health clinic.

Response: The amount of the EHR incentive payment is based on the estimated allowed charges for all covered professional services furnished by an EP during the payment year, subject to the maximum payment amount for the payment year for the EP. For EPs that practice in an RHC, EHR incentive payments are based on the amount of covered professional services that are not part of the RHC package of services and are billed by the EP through the physician fee schedule.

Comment: A commenter suggested that the definition of allowable charges be amended to include the RHC schedule of services, or allow providers who use UB92 and HCFA 1500 forms to be eligible for the EHR incentive payment.

Response: The allowed charge is the amount that Medicare determines to be reasonable payment for a provider or service under Part B, including coinsurance and deductibles. RHC services furnished by an EP are not considered covered professional services for purposes of the Medicare EHR because they are not billed or paid under the physician fee schedule.

After consideration of the public comments received on the term, "eligible professional" for the Medicare program, we are adopting the Medicare EP definition in our regulations at § 495.100 that state that a Medicare EP is a physician as defined under § 1861(r) of the Social Security Act. That is, a Medicare EP is 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 and a doctor who is legally authorized to practice their profession under State law.

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.

Comment: One commenter believes that the methodology for determining the incentive payments under the incentive program does not offer each EP an equal incentive, despite being held to the same standards of adoption and implementation.

Response: We are uncertain why the commenter believes that the methodology for determining the incentive payments under the incentive program does not offer each EP an equal incentive to adopt EHR technology. However, the payment methodology in the statute for EPs (as well as the methodologies for hospitals and CAHs) is quite prescriptive, and offers no discretion for us to adopt revisions designed to enhance incentives for adoption. For EPs, the HITECH Act defines the incentive payment amount as, "an amount equal to 75 percent of the Secretary's estimate * * * of the allowed charges under this part of all such covered professional services furnished by the eligible professional during such year."

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). This section of the PHS Act refers to geographic HPSAs, which are areas that have been designated by the Secretary as having 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 proposed that for an EP to be considered as "predominantly" furnishing covered professional services in a geographic HPSA, more than 50 percent of the EP's covered professional services must be furnished in a geographic HPSA. We stated that 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. Our data indicates that most physicians furnishing services in a HPSA furnish 100 percent of their covered services in a HPSA, and only very few furnish services in both HPSA and non-HPSA areas.

To determine whether an EP has furnished more than 50 percent of his/her covered professional services in a geographic HPSA, we proposed 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. We proposed to make the incentive payment to the EP based on an EP's estimated allowed charges for the relevant payment year.

We proposed that 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. 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. 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(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 Medicare-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 will apply these same rules for the 10 percent EHR HPSA payment limit increase provided under section 1848(o)(1)(B)(iv) of the Act.

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.

Comment: We received a comment stating that many EPs who work in a HPSA do so only on a part-time basis and that most would not qualify for the 10 percent increase in the payment limit based on the proposed threshold of furnishing more than 50 percent of his/her covered professional services in a geographic HPSA. The commenter suggested that an EP should be able to qualify for the ten percent increase in the payment limit if at least 25 percent of his/her covered services during an EHR reporting period are furnished in a HPSA.

Response: The statute states that the annual payment limit be increased by ten percent for EPs who predominantly furnish services in a geographic HPSA. We continue to believe that "more than fifty percent" correctly reflects the

meaning of the word "predominantly" as used in this statute. As noted above, our data also indicate that most physicians furnish all of their services either in a HPSA or outside of a HPSA, and only very few furnish services in both HPSA and non-HPSA areas.

Comment: Several commenters requested that Federally Qualified Health Centers (FQHCs) be eligible to receive the ten percent increase in the payment limit for EPs who predominantly furnish services in a HPSA since the FQHC is a legal entity that bills Medicare and receives payment for services provided by physicians.

Response: The 10 percent increase in the payment limit applies to EPs who predominantly furnish services in a geographic HPSA. FQHCs and RHCs are not eligible for the ten percent increase in the payment limit because they do not meet the definition of EP as specified in section 1848(o)(5)(C) of the Act. Please see others sections of the regulation that discuss the criteria to be considered an EP. Additionally, we wish to restate that FQHCs are not entitled to any Medicare or Medicaid incentive payments under this program.

Comment: A commenter suggested that "predominantly" be defined as the location where the EP provides the most services, so that an EP who sees patients in more than two locations could receive the increase in the payment limit if he/she provided more care in the HPSA location than any other location. The commenter also suggested that if this is too difficult to administer, we should accept an attestation from the EP.

Response: We are aware that many physicians, especially in rural areas, furnish services in more than one location, and appreciate the commenter's interest in making the HPSA payment limit increase available to these EPs. If we were to accept this recommendation, then an EP who worked in three locations at forty percent, thirty percent, and thirty percent time respectively, would be eligible for the HPSA payment limit increase if the first location was in a geographic HPSA. If the EP worked in four locations at thirty percent, twenty-five percent, twenty five percent, and twenty percent time respectively, he/she would be eligible for the HPSA payment limit increase if the first location was in a geographic HPSA. We considered this suggestion and concluded that lowering the threshold for services furnished in a HPSA would be inconsistent with the intent of the HPSA payment limit increase, which is to provide an incentive to promote the use of EHR by EPs who practice predominantly in HPSAs. Also, if an EP who worked in more than two locations and furnished services in a HPSA only thirty or forty percent of his/her time was eligible for the HPSA payment limit increase, this would be unfair to an EP who worked in two locations and spent forty-five percent of his/her time in a HPSA and fifty-five percent time in a non-HPSA, because this EP would not be eligible for the HPSA payment limit increase even though he/she spent more total time in a HPSA.

Comment: A commenter stated that the proposed HPSA payment limit increase was being applied inconsistently because an EP would still get the payment limit increase if the designation was removed mid-year, and would not get the payment limit increase if the designation was added mid-year.

Response: Section 1848(o)(1)(B)(iv) of the Act authorizes us to apply the provisions of the HPSA bonus program to the implementation of the EHR HPSA payment limit increase. The HPSA bonus is paid to physicians who furnish Medicare-covered professional services in an area that is designated as a geographic HPSA as of December 31 of the prior year. They are authorized to receive the HPSA bonus throughout the current year, even if the area loses its designation as a geographic HPSA during the current year. Physicians furnishing Medicare-covered professional services in an area that is not designated as a geographic HPSA as of 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 proposed to use the same methodology for the HPSA EHR program, and believe that this is consistent with the statute.

After consideration of the public comments received, we are finalizing these provisions as proposed.

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 proposed to make a single, consolidated, annual incentive payment to EPs. Payments would be made on a rolling basis, as soon as we ascertained that an EP had 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, we proposed that EPs would be 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. We proposed to preclude an EP from reassigning the incentive payment to more than one employer or entity. To implement this requirement, we proposed 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 was associated with more than one practice, we proposed that EPs would select one tax identification number to receive any applicable EHR incentive payment.

As mentioned above, we 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. We proposed to add a new part 495.10(e) and (f) to permit reassignment of the incentive payment with certain limitations. The following is a summary of the comments we received and our responses.

Comment: Several commenters, including one representing Rural Health Clinics, requested clarification of the statement in the proposed rule (75 FR 1910) that an eligible professional (EP) is allowed to reassign his/her EHR incentive payment to an employer or other entity to which the EP has reassigned his/her payments for Medicare covered services. The commenters believe that the HITECH Act requires in such cases that any Medicare EHR incentive for which the EP qualifies must be paid to such employer or other entity. The commenters reference the phrases from the HITECH Act, "shall be paid" to an eligible professional (or to an employer or facility in cases described in the reassignment provisions of the Social

Security Act). In addition, the commenters referenced the phrase regarding the transfer of an EP's Medicaid EHR incentive which states that "such incentives are paid directly to such provider (or to an employer or facility to which such provider has assigned payments)". The commenters interpret these phrases to mean that an EP's EHR incentive payments (both Medicare and Medicaid) must be paid to an employer or other entity to which the EP has reassigned payments for his/her services.

Response: We do not agree with the commenters' conclusions regarding to whom the payments must be made. As we stated in the proposed rule, Section 1842(b)(6) of the Act allows, but does not require reassignment to an employer or entity with which the physician has a valid contractual arrangement allowing the employer or entity to bill for the physician's services. The HITECH Act provisions cited by the commenter similarly do not require that the EHR incentive payment be made pursuant to a reassignment, but provide that the payment may be made directly to the EP or to the employer or other entity. A physician reassigns payment based on the scope of his or her employment or contractual arrangement. Based upon our interpretation of the applicable provisions, we are finalizing our proposal at § 495.10(f) to permit EPs 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.

We are taking this opportunity to remind the public that if the EP wishes to reassign his or her incentive payment to the employer or entity with which the EP has a contractual arrangement, the parties should review their existing contract(s) to determine whether the contract(s) currently provides for reassignment of the incentive payment or if the contract(s) needs to be revised. Reassignment of the incentive payment must be consistent with applicable Medicare laws, rules, and regulations, including, without limitation, those related to fraud, waste, and abuse. For Medicaid, a discussion of reassignment of the incentive payment is found in section II.D.3.e of this final rule "Entities Promoting the Adoption of Certified EHR technology."

Comment: Several commenters stated that the rationale and objectives of the HITECH Act provisions regarding transfer of the EP's EHR incentives are merely to align EHR incentives and EHR costs. Therefore, they believe that the HITECH Act provisions support their view that Congressional intent was to prevent windfall EHR incentives to EPs who incur no EHR-related costs. The commenters also asserted that CMS's failure to address this issue will require entities that employ or contract with EPs to enter into negotiations and a separate agreement transferring the EP's EHR incentive payments to the employer or other entity.

Response: We do not agree with the commenters' statement that the Congress intended to prevent windfall EHR incentives to EPs who incur no EHR-related costs. 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. The provisions are not focused solely upon the costs associated with the EHR technology. Rather, as we stated in the proposed rule (75 FR 1849), it focuses upon the adoption, implementation, upgrade, or meaningful use of the technology.

However, we do agree that some entities may have to review and/or negotiate current contractual arrangements to address the transfer of the incentive payments. The first payment year for the incentive payment is CY 2011, which we believe should afford parties sufficient time to reach a new agreement. For Medicaid, a discussion of reassignment of the incentive payment is found in section II.D.3.e of this final rule "Entities Promoting the Adoption of Certified EHR technology."

Comment: Several commenters supported our proposal that if an EP has reassigned his or her payments for services to more than one employer or entity, that only one of those employers or entities should receive the EP's EHR incentive payments for a particular EHR Reporting Period (75 FR 1910). The commenters do not believe that EPs should decide which employer or entity should receive his or her EHR incentive payment. Rather, the commenters stated that such payments should automatically be paid to the employer or entity that has received for the reporting period the largest percentage of the EP's Medicare or Medicaid payments for services.

Response: We are not persuaded to adopt the commenters' suggestion. We believe that the suggestion by the commenters would create administrative complexities for both CMS and EPs with little benefit. Many of these obstacles would be similar to those described in the proposed rule when discussing the possibility of making proportional EHR incentive payments (75 FR 1911). Therefore, we are finalizing our proposal to revise § 495.10(e) to preclude an EP from reassigning the incentive payment to more than one employer or entity. In cases where the EP is associated with more than one practice, EPs must select one TIN to receive any applicable EHR incentive payment.

Comment: The commenters also state that if an EP has incurred out-of-pocket costs in connection with an EHR provided by an employer or other entity to which the EP has reassigned payments for his or her services, the EP should be permitted to keep an amount of his or her EHR incentives equal to the amount of such costs incurred.

Response: The statute does not address this issue. It simply provides that the incentive payments are to be made directly to the EP or to an employer or other entity to which the EP has reassigned the incentive payment. Reassignment of the incentive payment must be consistent with applicable Medicare laws, rules, and regulations, including, without limitation, those related to fraud, waste, and abuse. We believe that any cost-sharing or subsequent distribution of the incentive payment, such as in the manner described by the commenter, should be resolved between the parties.

Comment: Several commenters urged CMS to clarify that any reassignment of the EP's EHR incentive payment should not constitute a financial arrangement within the meaning of the physician self-referral law, or remuneration within the meaning of the federal anti-kickback statute.

Response: The physician self-referral law prohibits a physician from making a referral for designated health services to an entity with which the physician or a member of the physician's immediate family has a financial relationship, unless an exception applies. For purposes of the physician self-referral law, a financial arrangement includes ownership or investment interests and compensation arrangements. The statute defines a "compensation arrangement" to mean any arrangement involving remuneration, direct or indirect, overt or covert, in cash or in kind. A reassignment of an EP's EHR payment would constitute remuneration, and we note that reassignment generally occurs in the context of an existing compensation arrangement (for example, employment). There are many potentially applicable exceptions for compensation arrangements that involve a physician's reassignment of Medicare payments.

Similarly, with respect to the anti-kickback statute, absent compliance with a safe harbor, a determination of whether a reassignment constitutes prohibited remuneration would be made on a case-by-case basis and we therefore decline to issue any statement regarding the application of the anti-kickback statute to a reassignment. For additional information regarding the anti-kickback statute, please refer to the OIG's Web site at *http://oig.hhs.gov.*

Comment: One commenter representing American Indian and Alaska Native health providers urged CMS to require that the HITECH/EHR Meaningful Use provider incentive payments be reassigned to the Tribal outpatient clinics, because the Tribal clinics developed the infrastructure not the EPs themselves, and purchased electronic medical record systems to complement the current Registration Patient Management Systems (RPMS) of the Indian Health Service. In addition, the commenter noted that many tribal outpatient clinics have employment contracts with their EPs. Thus, the commenters urged CMS to require that incentive EHR payments should be included in employment contracts to help protect the EP as employee and the Tribe as the employer.

Response: As stated above, section 1848(o)(1)(A) of the Act provides that the EP's incentive payment shall be paid to the eligible professional (or to an employer or other entity with which the physician has a valid contractual arrangement allowing the employer or other entity to bill for the physician's services). We recognize that some tribes purchased EHR systems based upon criteria established by the Indian Health Service. However, after careful consideration, we believe that the same standards concerning the incentive payments should apply. The EP and the Tribal outpatient clinic should jointly resolve whether the EP's EHR incentive payment will be reassigned to the Tribal outpatient clinic or made directly to the EP. Similarly, any decision by the Tribal outpatient clinic concerning whether to include language in its employment contract (or in the alternative, whether any pre-existing contract already requires reassignment of the payment), is a matter of contract interpretation that should be resolved by the parties themselves. This discussion is also addressed in the Medicaid section of this rule at II.D.4.a.3.

Comment: One commenter expressed concern about the potential tax consequences associated with an EP's reassignment of the EHR incentive payment by an independent contractor to a larger organization. The commenter recommended that a 1099 independent contractor should consult with his/her tax advisor before agreeing to reassign incentive payments and to ensure that the election to reassign is made before payment is sent from CMS or the State Medicaid Agency.

Response: The commenter's recommendation falls outside the scope of our authority. This is a matter for the 1099 independent contractor EP to consider.

Comment: Many national and state medical associations expressed concern regarding the proposed requirement that the EP must identify a Tax Identification Number (TIN) to which the EP's incentive payment should be made. They assert that this will not work for physicians who do not have a TIN, and are enrolled in Medicare or Medicaid through their Social Security Number (SSN). Therefore, the commenters recommend that CMS accept the SSN in lieu of the TIN, so that all eligible physicians are able to participate in the Medicare and Medicaid EHR incentive programs.

Response: We recognize that many physicians are enrolled in Medicare or Medicaid through their Social Security Number (SSN). Therefore, we are revising our proposal at § 495.10 that 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. In finalized § 495.10(c), we provide that the TIN may be the EP's Social Security Number (SSN) to which the EP's incentive payment should be made. We note that if the physician is part of a group with more than one owner or organization that is incorporated, they would have a TIN for the corporation that is not the EP's SSN.

Comment: Some commenters recommended that the employer or entity to which an EP reassigns payment for covered services, should be deemed authorized to provide, on the EP's behalf, any documentation necessary for the EP to qualify for EHR incentive payments.

Response: We believe that this should be resolved by the parties themselves. There is nothing in the statute that requires an EP's employer or other entity to which an EP reassigns payment to provide any necessary documentation for an EP to qualify for EHR incentive payments. Rather, the finalized regulatory provision at § 495.8 provides that an EP must demonstrate that he or she satisfies each of the applicable objectives and associated measures under § 495.6. If the parties wish to have the necessary documentation furnished by the employer or entity, they should resolve this pursuant to an employment or contractual agreement. We are finalizing our proposal because we believe that making a single, consolidated payment would be the least administratively burdensome for both CMS and EPs. In addition, we believe a single, consolidated payment would reduce the possibility of fraud and duplicate payments. Several of these issues related to reassignment of payment are also addressed in the Medicaid section. See II.D.3.e.

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 do not apply to hospital-based EPs.

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.

Comment: Some commenters believed that when an EP's performance leads to a negative financial impact under Medicare payment policy, it would be unfair and overly punitive for them to face a separate and potentially more significant financial impact—whether through a denial of funding and/or ARRA's penalties. Further, some commenters indicated that they interpreted these requirements to mean that Medicaid participants would or would not experience fee-schedule adjustments if they are not meaningful users by the end of 2014.

Response: We will reduce payments as specified under the statute. Under sections 4101(b) and (c) of the HITECH Act, we are required to pay EPs less than 100 percent of the fee schedule and to make downward adjustments to MA-affiliated EPs for their professional services if they are not meaningful users of certified EHR beginning in CY 2015. Under sections 4102(a), (a)(2), and (c) of the HITECH Act, we are authorized to pay eligible hospitals a reduced annual payment update, provide downward payment adjustment to CAHs for cost reporting periods, and provide downward payment adjustment to MA-affiliated hospitals respectively, if they are not meaningful users of certified EHR technology beginning in FY 2015. The Medicare fee schedule adjustments will impact any EP or subsection(d) hospital that is not a meaningful user by the end of 2014. The adjustments are not authorized under Medicaid, but the adjustments will still apply to Medicaid EPs who are also Medicare EPs and also to Medicaid acute care hospitals that are also subsection(d) hospitals. We are finalizing these provisions as proposed.

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. In the proposed rule, we proposed a new § 495.104 to implement this provision. As we noted in the proposed rule, section 1886(n)(6)(B) of the Act defines "eligible hospitals" for purposes of the incentive payments provision, as "subsection (d) hospitals," referring to the definition of that term 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," we proposed that incentive payments for meaningful users of certified EHR technology would 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 hospitals located in the 50 states. Therefore we proposed that incentive payments for meaningful users of certified EHR technology would be available under this provision to acute care hospitals located in the State of Maryland. The statutory definition of a subsection (d) hospital also does not apply to hospitals and hospital units excluded from the IPPS under section 1886(d)(1)(B) of the Act, such as psychiatric, rehabilitation, long term care, children's, and cancer hospitals. We also proposed that, for purposes of this provision, we would provide incentive payments to hospitals as they are distinguished by provider number in hospital cost reports. We proposed that incentive payments for eligible hospitals would be calculated based on the provider number used for cost reporting purposes, which is the CMS Certification Number (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 final rule.

Comment: We received numerous comments on our proposal to identify all individual hospitals eligible for incentive payments based on the provider number used for cost reporting purposes (the CCN of the main provider). These commenters, including national and regional hospital associations, hospital systems, and hospitals with multiple campuses, objected to the proposed policy on various grounds. Many of these commenters pointed out that there is no standard policy that defines the specific types of facilities to which a single CCN applies. As a result, a single CCN could encompass multiple hospitals within a hospital system in some cases, while in other cases multiple hospitals within a system could have separate CCNs. These commenters therefore maintained that our proposed policy would unjustifiably lead to disparate treatment of hospital systems based solely on whether the system had one or more provider numbers. Commenters also maintained that, because the Medicare and Medicaid payment incentives are calculated using a per-hospital base amount, plus a capped per-discharge amount per hospital, identifying individual hospitals solely by CCN would result in distributing payments in a manner that does not foster widespread EHR adoption and use. The for this argument regarding limited EHR adoption and use is that multi-campus systems with a single CCN would receive only one base payment, and would be more likely to reach the discharge cap. Some commenters also argued that linking incentive payments only to a single CCN would not accurately reflect the pattern of costs required for deploying EHR systems across all sites in a hospital system. For example, even hospital sites that are part of the same system often require significant variations in their EHR systems, accommodating local policies and processes, as well as different legacy systems, physician preferences, clinical protocols, and other variables. Some commenters cited as a precedent our policy with regard to hospitals with one CCN, but multiple sites spanning more than one wage index region. CMS has instructed such hospitals to report wage data for each site separately on the cost report, and pays for discharges under the wage index that applies where the service is provided, that is, under a different wage index for each site.

These commenters recommended various approaches to recognizing and verifying the status of separate hospitals under one CCN number. Many of them

recommended that we adopt a "multi-pronged approach that allows a "hospital" to be defined in ways that acknowledge the varied organizational structures of multi-hospital systems, including by a distinct CCN, a distinct emergency department, or a distinct hospital license." Commenters recommended that we indentify and verify the distinct hospitals within hospital systems either by revising the cost report or by developing an attestation process similar to the process employed under § 413.65 of the regulations to verify provider-based status. Commenters also recommended that we either collect the data necessary for determining payment amounts (for example, discharge counts) directly from each hospital within a system with a single provider number, or develop a method of allocating discharges, bed days, and other relevant data among the hospital campuses represented in a hospital cost report under a single CCN.

Finally, a number of the commenters advocating a different approach contended that our proposed policy ran counter to the intent of the EHR incentive provision, which is to promote broader adoption of EHR systems. These commenters argued in various ways that recognizing each campus of a multi-campus hospital for separate payment was most consistent with the statute because it would provide a greater overall level of funding for EHR efforts, especially to hospital systems that have elected to enroll multiple campuses under a single Medicare provider agreement, and thus support diffusion of EHR systems more broadly. One of these commenters did, however, acknowledge that "in most circumstances the term 'subsection(d) hospital' under the Medicare Program includes all of a hospital system's inpatient facilities that operate under a single provider number," before going on to argue that CMS has both the authority and the obligation under the HITECH Act to diffuse EHR incentive payment more broadly by treating each facility under a hospital system as a separate hospital, regardless of whether any of the facilities share a single provider number.

Response: We appreciate the commenters' concerns, but we continue to believe that our proposal represents the best policy approach in determining what constitutes an "eligible hospital." In the absence of clear direction from the statute to the contrary, we believe that the most appropriate policy is to interpret the terms in subsection (d) "acute care hospital" and "children's hospital" in the light of existing Medicare and Medicaid program policies and precedents. It is quite true, as a number of the commenters noted, that hospital systems have considerable latitude (although not unlimited) in choosing whether to obtain one CCN for all their facilities, or to obtain separate CCNs for some or all of their facilities. However, once a hospital has sought and obtained a single CCN for two or more facilities, that hospital has chosen to represent itself to CMS as a single hospital, including for purposes of payment, cost reporting, and satisfying the conditions of participation. Such systems submit unified cost reports integrating data (including charges, discharges, bed days, and other relevant data) from every facility under the single CCN. For purposes of DSH and IME payments under the IPPS, both eligibility for payment and the applicable payment amounts are determined on the basis of this integrated data. Most significantly, the Medicare conditions of participation require that a system with a single CCN establish and maintain a single governing structure, medical staff, nursing staff, and record services. Section 482.2 states that a "hospital must have an organized medical staff that operates under by-laws approved by the governing body." Section 482.21(e) states that the governing body must ensure, among other matters, that "the hospital-wide quality assessment and performance improvement efforts address priorities for improved quality of care." In addition, § 482.24 states that the hospital must have "a medical record service that has administrative for medical records.". For these reasons, we believe that recognition of the decision made by each hospital or hospital to represent and organize itself as a single entity under one CCN, or as two or more distinct entities under separate CCNs is a strength, rather than a weakness, of our proposed policy. Each institution that has exercised available latitude to obtain one CCN for all their facilities not only represents itself as a single hospital, but also agrees to conduct itself in significant ways as a single hospital.

We also do not agree with those commenters who argue that our policy of applying different wage indexes to the campuses comprising a hospital system operating under a single CCN warrants our treating each campus as a separate eligible hospital for purposes of the EHR incentive payment program. Our policy for these few cases when a multi-campus hospital spans two or more wage index areas does not amount to recognizing that each campus is a separate hospital for payment purposes, but rather to accounting for the fact that, in these few cases, one hospital is located in two wage index areas. In these cases, it is appropriate to pay, and to account for wages, on the basis of where each discharge occurs rather than on the basis of where, for example, the main campus of a hospital may be located.

With regard to the disparate treatment argument advanced by a number of commenters, we acknowledge that, under our proposed policy, a single hospital system with two campuses will receive (all other things being equal) lower incentive payments than the combined incentive payments of two-single-campus hospitals with the same number of discharges. However, an equivalent disparate treatment situation would arise under the policy advocated by these commenters. Under the policy of recognizing each campus of a multi-campus system as a separate hospital, a single-campus hospital would received lower incentive payments than a multi-campus hospital with the same number of discharges, despite the fact that both hospitals have a single CCN and are recognized for administrative and financial purposes, and for purposes of the conditions of participation, as a single hospital.

Example: Hospital A is a multicampus hospital with 30,000 discharges and a Medicare share of 50 percent. Hospital A's discharges are evenly split between its two campuses. Hospital B is a single campus hospital with 30,000 discharges and a Medicare share of 50 percent. During the first year of the transition, each campus of Hospital A would receive a separate incentive payment determined on the following manner:

($2,000,000 base amount + [(15,000 − 1,149) × $200] discharge-related amount) × .5 Medicare share × 1.0 transition factor = ($2,000,000 + $2,770,200) × .5 × 1.0 = $2,385,100

Hospital A's total payment would therefore be $4,770,200. In contrast, Hospital B would receive a single payment determined in the following manner:

($2,000,000 base amount + [(23,000 − 1,149) × $200] discharge-related amount) × .5 Medicare share × 1.0 transition factor = ($2,000,000 + $4,370,200) × .5 × 1.0 = $3,185,100

Hospital B would thus receive a payment that is $1,585,100 smaller than Hospital A's total payment for the same number of discharges.

The change in policy recommended by these commenters will therefore replace one equity issue with another. We see no reason to privilege one of these arguments over the other, and

therefore we believe that the decision on a final policy ought to turn on the other considerations that we discuss.

Finally, we cannot agree with the commenters that determining the appropriate policy on this question should turn on which alternative produces the greatest overall level of spending on EHR systems. Many decisions could result in lower potential payments to some or all potential meaningful users of EHR payments. Congress deliberately chose to limit incentive payments based on the statutory formula (using the current statutory and regulatory definition of "subsection (d) hospital"), and further limited the amount of incentive payments available to large hospitals by not increasing incentive payments above 23,000 discharges.

After consideration of the public comments received, we are finalizing our policy as proposed. 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 CMS Certification Number (CCN) of the main provider (also referred to as OSCAR number). Payments to eligible hospitals will be made to each provider of record.

b. Incentive Payment Calculation for Eligible Hospitals: Initial Amount

Section 1886(n)(2) of the Act, as amended by 4102(a) of the HITECH Act, 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. We proposed to implement the "initial amount" within the formula as that term is defined in the statute.

Comment: Several commenters requested that we identify the sources of the discharge data we plan to employ for purposes of determining the discharge related amount. These commenters also requested confirmation of their understanding that no type of discharge, regardless of source of payment, would be excluded from the discharge count for this purpose. Commenters specifically cited nursery discharges and discharges from non-PPS areas of a hospital as examples of discharges that should not be excluded under the statutory language, which they believe requires the inclusion of all patient discharges regardless of type of patient within the inpatient areas of the hospital.

Response: We cannot agree with the commenters that the statutory language includes all patient discharges within the inpatient areas of the hospital. Rather, the statutory language clearly restricts the discharges to be counted for purposes of determining the discharge-related amount to discharges from the acute care portion of the hospital. As we discussed in the proposed rule, 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."

The phrase "total discharges for the eligible hospital (regardless of any source of payment)" limits the count of discharges to the acute care inpatient discharges. This is because of the reference to "eligible hospital." "Eligible hospital" is defined in section 1886(n)(6)(B) of the Act for purposes of the incentive payments provision, as "a subsection (d) hospital," referring in turn to the definition of that term 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," excluding hospitals that are not paid under the IPPS in accordance with section 1886(d)(1)(B) of the Act, such as psychiatric, rehabilitation, long term care, children's, and cancer hospitals. However, 1886(d)(1)(B) also specifies that the "term 'subsection (d) hospital * * * does not include a psychiatric or rehabilitation unit of the hospital which is a distinct part of the hospital (as defined by the Secretary)." Therefore, the term "eligible hospital" for purposes of the incentive payments provision does not extend to the excluded units of the hospital. The term does, of course, include the inpatient portion of the hospital that receives payment for Medicare purposes under the inpatient PPS. The phrase "regardless of any source of payment," however, indicates that the count of "total discharges" for this purpose should include not only patients for whom Medicare is the source of payment, but also patients for whom payment is received from Medicaid or any other source of payment. Accordingly, in the revised cost report form that is currently pending and which will be finalized in time for the 2011 payment year, CMS Form 2552–10, Hospital and Hospital Health Care Complex Cost Report, we have included a cell for entry of "Total hospital discharges as defined in section 4102 of AARA," in the new Worksheet E–1, Part II, "Calculation of Reimbursement for Settlement for HIT." This new cell is derived from line 14, from "Worksheet S–3, Part I column 15." In turn, this cell from Worksheet S–3, Part I, column 15 incorporate all discharges from the inpatient, acute care portion of the hospital, regardless of payment source. In this final rule, we have also revised the definition of "eligible hospital" in § 495.100 of the regulations, as well as the specification of "initial amount" in § 495.104(c)(3) of the regulations, in order to clarify this point.

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. We proposed, for purposes of administrative simplicity and timeliness, 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 that is prior to the FY that serves as the payment year as the basis for making preliminary incentive payments. Similarly, we proposed that 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 of proposal: 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, 2009 through June 30, 2010, 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.

Commenters raised several issues with regard to our proposals regarding the timing of the cost reports to be used for purposes of determining preliminary and final incentive payments. Each of these issues embraces the use of several data elements, including discharge counts, bed days, and other factors employed in the payment calculations. For purposes of simplicity, we will address these issues in general terms in this section. As we will note at several junctures below, this discussions of these issues, however, are applicable to the cost report data for other elements of the computation.

Comment: Several commenters called our attention to timing issues with regard to the cost reporting periods that we proposed to use for purposes of determining preliminary and final incentive payments. These commenters noted that, if we finalize our proposal to use data 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, hospitals with cost reporting periods on the October-to-September cycle would face a delay of two months or longer after potentially qualifying as a meaningful user before receiving a preliminary incentive payment. Specifically, for hospitals on this cycle, the cost report that would be used for determining interim payments for the first payment year (the October 1, 2009 through September 30, 2010 cost report) would not be due until February 28, 2011, two months after the hospital may have been able to qualify as a meaningful user (January 1, 2011). For hospitals on the September-to-August cycle, the delay could be one month. The commenters pointed out that over one-fifth of subsection (d) hospitals have cost reporting periods beginning on September 1 or October 1. The commenters therefore recommended that we employ discharge and other data from a hospital's most recently filed cost report as the basis for determining the hospital's preliminary incentive payment once the hospital has qualified as a meaningful user.

Response: We agree with these commenters, and in this final rule we are therefore adopting the policy that we employ discharge and other data from a hospital's most recently filed 12-month (see discussion below) cost report as the basis for determining the hospital's preliminary incentive payment once the hospital has qualified as a meaningful user. However, the precise timing of payments, especially during the first payment year, may be affected by other factors such as the timeline for implementing the requisite systems to calculate and disburse the payments. We are adopting the policy recommended by the commenters in order to avoid any unnecessary delays in making interim payments due merely to the timing of cost reporting periods.

Example: FY 2011 begins on October 1, 2010 and ends on September 30, 2011. For an eligible hospital with a cost reporting period on the October-to-September cycle, we would employ the relevant data from the hospital's most recently submitted cost reporting period in order to determine the incentive payment for the hospital during FY 2011. If the hospital qualifies for incentive payments on January 1, 2011, this would probably be the cost report for the period running from October 1, 2008 through September 30, 2009. However, we would also employ the October 1, 2009 through September 30, 2010 cost report, if that cost report is submitted before the point when preliminary incentive payments can be calculated.

Comment: A number of commenters also raised concerns about our proposal to determine final incentive payments at the time of settling the cost report for the hospital fiscal year that ends during the payment year, and to be settled on the basis of the hospital discharge and other data from that cost reporting period. These commenters pointed out that the pending CMS Form 2552–10 will not be effective in time for all hospitals and CAHs to complete the new S–10 worksheet, Hospital Uncompensated Care and Indigent Care Data, reporting charity care for their cost reporting period ending during the payment year. The effective date of the new cost report will be for cost reporting periods beginning on or after May 1, 2010 (as opposed to February 1, 2010 date anticipated in the proposed rule). For purposes of our proposal for determining final incentive payments, including the Medicare share/charity calculation, the first cost reporting period for which the new cost report will be available is the period running from May 1, 2010 through April 30, 2011. This means that, for cost reporting periods ending in FY 2011 before April 30, hospitals will not be able to complete the new S–10 worksheet to report charity care charges. Therefore, these commenters recommended that we revise our proposed policy, so that final incentive payments will be determined at the time of settlement for the cost reporting period beginning in the payment year. In this way all hospitals, regardless of their cost reporting cycle, will have adequate time to submit the revised cost reports in time for determining final incentive payments.

Response: We agree with these commenters, and in this final rule we are therefore adopting the policy that we determine final incentive payments at the time of settling the 12-month (see discussion below) cost report for the hospital fiscal year that begins after the beginning of the payment year, and to be settled on the basis of the hospital

discharge and other 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 through June 30, we would employ the relevant data from the hospital's cost reporting period ending June 30, 2009 in order to determine the preliminary incentive payment for the hospital during FY 2011 (or June 30, 2010, if that cost report was filed prior to the calculation). However, final payments would be based on hospital discharge data from the cost report beginning on July 1, 2011 and ending June 30, 2012, and determined at the time of settlement for that cost reporting period.

Comment: Several commenters requested that we explain how the occurrence of non-standard cost reporting periods will be taken into account in determining the appropriate cost reporting periods to employ for determining preliminary and final EHR incentive payments. Non-standard cost reporting periods run for periods shorter than the standard 12-month cost reporting periods (for example, 3 months, 6 months), and are typically employed to accommodate the circumstances of hospitals in several distinct situations, such as newly constructed hospitals, changes of ownership, and reorganization of a single multicampus hospital into multiple separate providers. In these cases, one non-standard cost reporting period may be employed before the hospital resumes (or begins) cost reporting on a 12-month cycle. One commenter recommended that we account for these situations by adopting three changes to our proposed regulations:

- For purposes of determining preliminary incentive payments, employ the most recently submitted 12-month cost reporting period that ends in the year prior to the payment year, in order to account for those situations in which the most recent cost reporting period ending prior to the payment year is a non-standard period.
- For purposes of determining final incentive payments, employ the first 12-month cost reporting period that begins after the start of the payment year, in order to account for those situations in which the cost reporting period ending during the payment year is a non-standard period.
- Provide that a hospital may address the CMS regional office responsible for its payment area for determination of the appropriate cost reporting period to employ for calculating preliminary or final incentive payment in cases that are not anticipated by the rules adopted in the final regulation.

Response: We acknowledge that we failed to address the circumstances of non-standard cost reporting periods in the proposed rule, and we agree with the commenters that it is only appropriate to do so. Non-standard cost reporting periods are not likely to be truly representative of a hospital's experience, even if methods were to be adopted for extrapolating data over a normal 12-month cost reporting period. This is because these periods are often quite short (for example, 3 months), which makes it questionable to extrapolate the data over a full cost reporting period. In addition, these abbreviated periods often capture the experience of a hospital during a period of transition (for example, change of ownership), which often renders the data highly unrepresentative. We also agree with the logic of the policy revisions proposed by the commenter cited above, subject only to the necessity of adapting the recommendations slightly to the revisions, as discussed above, we are also adopting to our proposals for identifying the cost reporting periods to be employed in determining preliminary and final EHR incentive payments.

After consideration of the public comments we receive with regard to the use of cost reporting periods for preliminary and final incentive payment determinations, we are adopting the following policies in this final rule.

- For purposes of determining preliminary incentive payments, we will employ discharge and other relevant data from a hospital's most recently submitted 12-month cost report once the hospital has qualified as a meaningful user.
- For purposes of determining final incentive payments, we will employ the first 12-month cost reporting period that begins after the start of the payment year, in order to settle payments on the basis of the hospital discharge and other data from that cost reporting period. In this final rule, we are revising section 495.104(c)(2) of the regulations accordingly. We are not adopting the recommendation to allow the CMS regional offices to make a determination about the appropriate cost reporting period in situations not anticipated by these rules because we believe that these two rules cover all possible situations. For example, even in complicated cases involving non-standard cost reporting periods, the cost reporting period for a hospital adjusts to a standard 12-month cycle within a brief period.

c. Incentive Payment Calculation for Eligible Hospitals: Medicare Share

As previously discussed, the initial amount must be multiplied by the eligible hospital's Medicare share and an applicable transition factor to determine the incentive payment to an eligible hospital for a 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 eligible hospital's 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 proposed, for each eligible hospital during each 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 FY that ends during the FY prior to the FY that serves as the payment year as the basis for preliminary payment. We also proposed that 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.

As a result of the changes we are making to these proposed policies in response to the comments discussed in the previous section, in this final rule we are adopting the following policies for employing data on the eligible hospital's Medicare fee-for-service and managed care inpatient bed days, total inpatient bed-days, and charges for charity care from the hospital in making preliminary and final EHR incentive payment determinations:

- For purposes of determining preliminary incentive payments, we will 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 a hospital's most recently submitted 12-month cost report once the

hospital has qualified as a meaningful user.

• For purposes of determining final incentive payments, we will employ the first 12-month cost reporting period that begins after the start of the payment year, in order to settle payments on the basis of the hospital's Medicare fee-for-service and managed care inpatient bed days, total inpatient bed-days, and charges for charity care data from that cost reporting period.

Section 1886(n)(2)(D) of the Act, as amended by section 4102 of the HITECH Act, defines the numerator and denominator of the Medicare share fraction for an eligible hospital 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 proposed 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 proposed 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 CMS Form 2552–96, Hospital and Hospital Health Care Complex Cost Report. We stated that 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.

Comment: A number of commenters pointed out an apparent contradiction between the cost report sources from which we proposed to derive the "the estimated number of inpatient-bed-days * * * attributable to individuals with respect to whom payment may be made under part A" (lines 1, 6 through 9, 10, and 14 in column 4 on Worksheet S–3, Part I of CMS Form 2552–96,), and our statement that "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." These commenters supported our proposal to employ the data from those lines of the cost report, on the grounds that these cost report lines "adequately capture the necessary data." However, as the commenters pointed out, the data on the identified lines do include patient days in units not paid under the inpatient PPS. These commenters also contended that the relevant statutory language ("*inpatient*-bed-days * * * attributable to individuals with respect to whom payment may be made *under part A*"; emphasis supplied) would seem to include patient days in units not paid under the inpatient PPS.

Response: We agree with the commenters that our citation of the specific cost report sources from which we proposed to derive "the estimated number of inpatient-bed-days * * * attributable to individuals with respect to whom payment may be made under part A" was not consistent with our statement 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." In this case, our error was in the specific cost report lines that we cited, rather than in our statement that the relevant statutory language ("*inpatient*-bed-days * * * attributable to individuals with respect to whom payment may be made *under part A*") includes "all patient days attributable to Medicare inpatients, excluding those in units not paid under the IPPS and excluding nursery days." As in the case which we discussed above with regard to counting "total discharges," the relevant statutory language directs that the numerator and denominator of the Medicare share fraction incorporate inpatient bed-day counts for the eligible *hospital,* and, as discussed in our section on total discharges, "eligible hospital" is defined with reference to section 1886(d)(1)(B) of the Act, which specifically excludes from the definition psychiatric or rehabilitation units that are a distinct part of the hospital. Specifically, the "Medicare share" is to be "specified * * * for an eligible hospital." The numerator of the Medicare share fraction is further defined as "the sum (* * * with respect to the eligible hospital) of—

"(I) 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

"(II) the estimated number of inpatient-bed-days (as so established) which are attributable to individuals who are enrolled with a Medicare Advantage organization under part C."

Finally, the denominator of the Medicare share fraction includes "the estimated total number of inpatient-bed-days with respect to the eligible hospital." Therefore, the inpatient-bed-day counts included in the Medicare share fraction for purposes of the incentive payments provision do not extend to inpatient-bed-days in excluded units of the hospital, but only to inpatient-bed-days in the acute care portion of the hospital that receives Medicare payment under the inpatient PPS. In this final rule, we are revising section 495.104(c)(4) of the regulations in order to clarify this point.

Since the publication of the proposed rule, we have adopted various changes to the Medicare cost report, including changes designed to accommodate the appropriate computation and final settlement of EHR incentive payments for qualifying hospitals. These changes are included in the pending cost report form, CMS Form 2552–10. In this revised form, the relevant Medicare inpatient days are entered in line 2 of the new Worksheet E–1, Part II, "Calculation of Reimbursement for Settlement for HIT." This new line is defined as the sum of lines 1 and 8 through 12, from Worksheet S–3, Part I, column 6 of CMS Form 2552–10. These lines include all patient days attributable to Medicare inpatients, excluding those in units not paid under the IPPS, and excluding nursery days.

Comment: Several commenters also contended that our proposed exclusion of nursery days from the determination of "*inpatient*-bed-days * * * attributable to individuals with respect to whom payment may be made *under part A*" is inappropriate. These commenters maintained that the statutory language is broad enough to include all inpatient days associated with Medicare eligible individuals without restriction based on the type of Part A patient.

Response: In excluding nursery days from the count of Medicare inpatient bed days, we are following the precedent of not counting such days for purposes of the direct medical education, indirect medical education, and disproportionate share adjustments under the Medicare IPPS. As in the case of the term "subsection (d)" hospital, we believe that, in the absence of clear direction from the statute to the contrary, the most appropriate policy is

to interpret terms such as "inpatient bed-days" in the light of existing Medicare program policies and precedents. Under our policies for the direct medical education, indirect medical education and disproportionate share adjustments, a bed must be permanently maintained for lodging inpatients in order to be included in available inpatient bed and inpatient bed day counts. We exclude the days provided to newborns (except for those in intensive care units of the hospital) because healthy newborn infants are not provided with an acute level of hospital care. (This is not the case with newborns assigned to intensive care units, who are included in the counts for those units.) For these reasons, nursery days are explicitly excluded from:

- The counts of Medicare inpatient hospital days and total inpatient hospital days for purposes of direct graduate medical education payments under section 413.75(b) of the regulations, where the definition of Medicare patient load reads: "Inpatient days in any distinct part of the hospital are included and nursery days are excluded."
- The counts of bed days for purposes of the Medicare indirect graduate medical education adjustment under section 412.105(b): the "count of available bed days excludes bed days associated with * * * (5) Beds or bassinets in the healthy newborn nursery * * *."
- The count of beds for purposes of the Medicare DSH adjustment under section 412.106(a)(i) of the regulations: "The number of beds in a hospital is determined in accordance with § 412.105(b)."

We note that, in addition to excluding nursery days from the numerator of the Medicare share fraction, these days are excluded for the same reasons from the count of total inpatient bed days in the denominator of the Medicare share fraction. We therefore do not believe that excluding these days would result in disadvantage to hospitals in determining their Medicare share fractions for purposes of calculating EHR incentive payments. (See our discussion of the cost report data employed to determine total inpatient bed days in the denominator of the Medicare share fraction, below.)

Comment: Other commenters maintained that swing bed days should also be included in the determination of "inpatient bed-days * * * attributable to individuals with respect to whom payment may be made under part A."

Response: Once again, as in the case of the term "subsection(d)" hospital, we believe that, in the absence of clear direction from the statute to the contrary, the most appropriate policy is to interpret terms such as "inpatient bed-days" in the light of existing Medicare program policies and precedents. We are therefore also following the precedent of Medicare payment adjustments in excluding certain swing bed days from the count of Medicare inpatient days. As in these cases, swing bed days are excluded when the swing bed is used to furnish SNF care, because only the days used for inpatient hospital care will be included in the count of "inpatient bed-days * * * attributable to individuals with respect to whom payment may be made under part A." Otherwise, we would be including non-inpatient bed-days in the count.

Comment: One commenter objected that, for purposes of the Medicare inpatient day count in the Medicare share, we appeared to be proposing to use only paid Medicare days. This commenter argued that all eligible Medicare days should be counted in order to reflect a hospital's true Medicare utilization. The commenter also maintained that the statute's reference to days "attributable to individuals with respect to whom payment may be made under part A" requires inclusion of all days when a beneficiary was eligible for Medicare, on the grounds that this language "does not require actual payment by Medicare." The commenter further noted that the other factor in the numerator of the Medicare share fraction requires inclusion of all patient days associated with individuals enrolled in a Part C Medicare Advantage plan, and maintained that there "would be no rational basis for Congress to include all enrolled Part C days, quite clearly regardless of whether they are paid, but to limit part A days to those paid by Medicare."

Response: We assume that, by the term "unpaid" Medicare days, the commenter is referring to days provided to Medicare entitled beneficiaries for which the services are non-covered, such as the cases in which a beneficiary has exhausted coverage of inpatient hospital services, or in which the services are not covered under a national or local coverage determination. We do not agree with the commenter that these days ought to be included in the count of "*inpatient*-bed-days * * * attributable to individuals with respect to whom payment may be made *under part A*." Indeed, we believe that the best reading of this statutory language suggests the opposite of what the commenter maintains: In cases of non-covered days, payment may not be made under Part A, and therefore these days should not be included in a count of days "attributable to individuals with respect to whom payment *may be* made *under part A*." We agree with the commenter that the language for the other factor in the numerator of the Medicare share fraction ("inpatient-bed-days attributable * * * to individuals who are enrolled with a MA organization under Part C") is more inclusive. However, we must assume that the difference in the statutory language is meaningful. Therefore, we are finalizing our proposal not to include days provided to Medicare entitled beneficiaries for which the services are non-covered in the count of Medicare inpatient days. It is important to note that we do include such "non-paid" days for purposes of other Medicare payment provisions, where it is appropriate to do so under the governing statutory provisions. For example, for purposes of the Medicare DSH adjustment the relevant statutory language requires inclusion of days associated with individuals who are "entitled" to benefits under Medicare Part A, rather than days for which "payment *may* be made under part A."

After consideration of these comments, we are finalizing our proposals with regard to the data to be used to determine the "inpatient bed-days * * * attributable to individuals with respect to whom payment may be made under part A" in the numerator of the Medicare share fraction. Accordingly, we will derive this information from Worksheet E–1, Part II, line 2 of the pending Medicare cost report, Form CMS–2552–10, which is defined as the sum of lines 1 and 8 through 12 in column 6, Worksheet S–3, Part I of the pending cost report. As we have just discussed, we are revising the cost report data sources from which we are deriving this information in order to be consistent with the statutory requirement. We are also revising § 495.104(c)(4)(ii)(A)(2) of the regulations to clarify this point.

Comment: One commenter inquired about the status of inpatient-bed-days attributable to individuals enrolled in the 1876 Medicare cost plan operating under "billing option 2," under which the section 1876 cost contractor pays hospitals for Part A benefits, and then claims reimbursement from CMS. The cost-contractor pays Part A benefits for its 36,000 enrolled Medicare beneficiaries to contracted hospitals in one State. The commenter maintained that a reasonable interpretation of the statutory language suggests that the inpatient bed days for these

beneficiaries should be counted in the numerator of the Medicare share fraction. The commenter requested clarification concerning the inclusion of these days in the data sources we proposed to employ, or the development of an appropriate remedy in order to ensure that they are counted. Another commenter noted that Worksheet S–3, Part I, column 4, line 2 in the Medicare cost report, CMS 2552–96, has historically been completed primarily by teaching hospitals, based on patient days reported on Provider Statistical and Reimbursement (PS&R) Report Type 118. The commenter further stated that there have been many situations in which non-teaching hospitals reporting days on this cost report line have the days removed by the Medicare fiscal intermediary or Medicare administrative contractor (MAC), as PS&R Report Type 118 contains no patient day data for non-teaching hospitals. The commenter recommended that we clarify our plans with regard to PS&R Report Type 118 and allow the form to populate with accurate data for all hospitals submitting no-pay bills for Medicare beneficiaries who are enrolled in Medicare Advantage (MA) plans and who receive Medicare-covered hospital services. The commenter further noted that, at this time, CAHs and IPPS hospitals that do not receive the DSH adjustment are not required to submit no-pay bills for Medicare Advantage patients.

Response: We agree with the commenters that all these days should be counted in the numerator of the Medicare share fraction. With respect to MA plan enrollees, these patients are already included in the "estimated number of inpatient-bed-days attributable * * * to individuals who are enrolled with a MA organization under Part C." In order for the data on the inpatient days attributable to individuals enrolled in MA plans to be included on the Medicare cost report, the hospital must submit a "no-pay" bill to the Medicare contractor. We have issued instructions clarifying that hospitals must submit no-pay bills for inpatient days attributable to individuals enrolled in MA plans. Specifically, CR 5647, dated July 20, 2007, required all hospitals paid under the inpatient prospective payment system (IPPS), inpatient rehabilitation facility prospective payment system (IRF PPS), and long term care hospital prospective payment system (LTCH PPS) to submit informational only Medicare Advantage claims. Furthermore, CR 6821, dated May 5, 2010, provided that applicable IPPS, IRF PPS and LTC hospitals will be given one final opportunity to comply with the requirement to submit FY 2007 informational only claims. In addition, these hospitals are required to attest in writing to their Medicare contractor that they have either submitted all of their Medicare Advantage claims for FY 2007 or that they have no Medicare Advantage claims for that fiscal year. After consideration of the comments, we are finalizing our proposals for determining the "inpatient bed-days * * * attributable to individuals with respect to whom payment may be made under part A" and the "estimated number of inpatient-bed-days attributable * * * to individuals who are enrolled with a MA organization under Part C." However, we are modifying the language of § 495.104(c)(4)(ii)(A)(1) regarding the counting of inpatient bed-days attributable to individuals with respect to whom payment may be under part A to clarify that this count includes days attributable to enrollees under section 1876 cost contracts where payments for Part A benefits are made by the section 1876 contractor. We intend to derive this information from Worksheet E–1, Part II, line 3 of the pending Medicare cost report, Form CMS–2552–10, which is derived from line 2 in column 6, Worksheet S–3, Part I of the pending cost report. This data source on the revised Medicare cost report is the equivalent of the source we cited in the proposed rule.

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 hospital's 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 proposed 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 proposed to 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. We noted that 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.

Comment: Several commenters noted, regarding our proposal concerning Medicare inpatient days in the denominator of the Medicare share fraction, an apparent contradiction between the cost report sources from which we proposed to derive "estimated total number of inpatient-bed-days with respect to the eligible hospital during such period" (lines 1, 6 through 9, 10, and 14 in column 6 on Worksheet S–3, Part I), and our statement that "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 ." These commenters supported our proposal to employ the data from those lines of the cost report, on the grounds that these cost report lines adequately capture the necessary data. However, as the commenters pointed out, the data on the identified lines do include patient days in units not paid under the inpatient PPS. And these commenters contended that the relevant statutory language ("the estimated total number of inpatient-bed-days with respect to the eligible hospital during such period") would seem to include patient days in units excluded from the inpatient PPS.

Response: As in the case of the equivalent issue with regard to Medicare inpatient bed days, we agree with the commenters that our citation of the specific cost report sources from which we proposed to derive the "the estimated total number of inpatient-bed-days with respect to the eligible hospital during such period" was not consistent with our statement that the data entered on these lines in the cost "include all patient days attributable to inpatients, excluding those in units not paid under the IPPS." And as in the case of Medicare inpatient-bed-days, our error was in the specific cost report lines that we cited, rather than in our statement that the relevant statutory language ("the estimated total number of inpatient-bed-days with respect to the eligible hospital") includes "all patient days attributable to inpatients, excluding those in units not paid under the IPPS.". As we have discussed in connection with counting discharges and Medicare inpatient-bed-days, the relevant statutory language directs that the denominator of the Medicare share fraction incorporate inpatient bed-day counts for the eligible hospital. Therefore, the inpatient-bed-day counts included in the Medicare share fraction for purposes of the incentive payments

provision do not extend to inpatient-bed-days in excluded units of the hospital, but only to inpatient-bed-days in the acute care portion of the hospital that receives payment for Medicare purposes under the inpatient PPS.

We are finalizing our proposal for determining the count of total inpatient-bed days in the denominator of the Medicare share fraction as including all patient days attributable to inpatients, excluding those in units not paid under the IPPS. Accordingly, we will derive this information from Worksheet E–1, Part II, line 4 of the pending Medicare cost report, Form CMS–2552–10, which is defined as the sum of lines 1and 8 through 12, in column 8, Worksheet S–3, Part I of the pending cost report. As we have just discussed, we are revising the cost report data sources from which we are deriving this information in order to be consistent with the statutory requirement. In this final rule, we are also revising § 495.104(c)(4)(ii)(B)(1) to clarify this point.

As we noted above, the denominator of the Medicare share fraction also includes 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 hospital's charges during such period." We discuss the data sources and methods for calculating the charges and charity care portions of this formula in the next section.

d. Incentive Payment Calculation for Eligible Hospitals: Charity Care and Charges

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 a greater charity care 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.

For the purposes of this final rule, we 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 proposed 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. Line number 19 of the revised Worksheet S–10, as proposed, has changed to line number 20 based on the pending OMB approved final Form CMS–2552–10. Only the line number has changed as the instructions are the same for line 19 as proposed and for line 20 in the pending final OMB approved Worksheet S–10. Thus, the charity care charges used to calculate the final Medicare share is reported on line 20 of the pending final OMB approved Worksheet S–10.

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 20 of the pending final OMB approved 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 20, we may question the accuracy of the charges used for computing the final 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 line 20 of the pending final OMB approved Worksheet S–10, then we proposed to deem the portion of the denominator described in section 1886(n)(2)(D)(ii)(II) of the Act to be 1.

In the proposed rule, we specifically solicited 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.

Comment: Some commenters requested that CMS clarify the definition of charity care. One commenter believed the CMS incorrectly indicated that Medicare does not reimburse for charity care. The commenter believed this statement is inconsistent with section 312 of the Provider reimbursement Manual (PRM).

Response: Section 1886(n)(2)(D)(ii)(II) of the Act defines charity care charges to compute the Medicare share as such term is used for purposes of hospital cost reporting under Medicare. Thus, we are adopting our proposed definition of charity care as part of uncompensated and indigent care described for Medicare cost reporting purposes in the

Medicare cost report instructions as described above.

In addition, we believe that our statement is correct in that Medicare does not pay for charity care in accordance with the regulations and manual instructions. Specifically, section 413.89(b)(1) of the Medicare regulations defines bad debts as 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. Section 413.89(b)(2) of the Medicare regulations defines charity allowances as reductions in charges made by the provider of services because of the indigence or medical indigence of the patient. Cost of free care (uncompensated services) furnished under a Hill-Burton obligation are considered as charity allowances. Furthermore, section 413.89(g) states that charity allowances have no relationship to beneficiaries of the Medicare program and are not allowable costs. These charity allowances include the costs of uncompensated services furnished under a Hill-Burton obligation.

Also, section 312 of the PRM states that, for Medicare bad debt purposes, a non-Medicaid beneficiary may be considered indigent or medically indigent and that once indigence is determined and the provider concludes that no improvements in the beneficiary's financial condition exist, the debt may be deemed uncollectible without applying the collection requirements of section 310 of the PRM. We believe that the instructions at section 312 of the PRM specify bad debt amounts that may be allowable under section 413.89 of the regulations and, thus, these instructions are not related to charity care amounts that are not allowable for Medicare.

After consideration of the public comments received, we are finalizing the definition of charity care these provisions as proposed.

Comment: We received some comments asking if CMS will adopt standards to determine if a hospital's charity care policy is sufficient to qualify for the inclusion of charges in the formula for EHR and whether that same policy would suffice to meet the criteria to determine the eligibility for Medicare bad debt.

Response: Currently for bad debt purposes, section 312 of the PRM requires the provider to perform asset/income tests of patient resources for non-Medicaid beneficiaries. These tests will be used to determine if the beneficiary meets the provider's indigent policy to qualify an unpaid deductible and/or coinsurance amount as a Medicare bad debt. The provider is responsible for developing its indigent policy. Currently, the Medicare contractor will determine if the indigent policies are appropriate for determining allowable Medicare bad debt under section 312 of the PRM and § 413.89 of the regulations. We believe that the Medicare contractor will continue to determine if the provider's indigent policy for bad debt purposes is appropriate and can determine if the same policy would be sufficient to use for charity care purposes.

Comment: We received many comments on the use of charity care charge data from line 19 of the revised worksheet S–10, as proposed. Commenters urge CMS to calculate charity care costs by starting with the amount of charges a hospital has written off. Commenters noted that this modification would help streamline and unify charity care reporting across the Federal government (based on the way Internal Revenue Service (IRS)) requires charity care to be reported) ensure consistency of reporting, and avoid significantly increasing hospitals' administrative burden.

Response: As described above, we use charity care charges from line 20 of the pending final OMB approved worksheet S–10 that captures "total initial payment obligations of the patients who are given full or partial discounts, based on the hospital's charity care criteria (measured a full charge), for care delivered during the cost reporting period for the entire facility." Similar comments received on our proposed rule were also received on the Agency Information Collection Activities: Proposed Collection: Comment Request published in the July 2, 2009 **Federal Register** (74 FR 31738). CMS issued a revised package, Agency Information Collection Activities: Submission for OMB Review: Comment Request, in the April 30, 2010 **Federal Register** (75 FR 22810). The comment period for the submission for OMB review ended June 1, 2010. OMB will review the comments received and issue an approved Form CMS 2552 10. The OMB approved Form CMS–2552–10 will be effective for cost reporting periods beginning on or after May 1, 2010.

Comment: Some commenters noted that the Hospital Uncompensated Care and Indigent Care Worksheet S–10 that CMS proposed to revise in the July 2, 2009 **Federal Register** (74 FR 31738) would not be timely (based on the anticipated effective date for cost reporting periods beginning on or after February 1, 2010 as stated in the proposed rule), and therefore, hospitals with cost reporting periods beginning on November 1, 2009, December 1, 2009 or January 1, 2010 would not have the opportunity to report charity care data for the first year of the incentive payment. Commenters further highlighted their concern for available data necessary to be included in interim payments and for final payments for periods that end December 31, 2010. Commenters urged CMS to develop an interim mechanism for hospitals to report the necessary information so that no hospital receives a charity care adjustment of "1" merely because of its cost reporting cycle. Some commenters suggested that CMS use other charity care data. Some commenters suggested that CMS use the current version of the Medicare cost report, Form CMS–2552–96, to determine interim incentive payments.

Response: To calculate the Medicare share, which includes the charges for charity care, we proposed in the proposed rule to employ data from the hospitals fiscal year that ends during the FY prior to the FY that serves as the payment year as the basis for preliminary payment. We further stated that 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. After consideration of the public comments received, we are revising the provision that for purposes of determining preliminary incentive payments, we will employ data on the hospital's/CAH's Medicare fee-for-service and managed care inpatient bed days, total inpatient bed-days, and charges for charity care from a hospital's/CAH's most recently submitted 12-month cost report once the hospital has qualified as a meaningful user. For purposes of determining final incentive payments, we will employ the first 12-month cost reporting period that begins after the start of the payment year, in order to settle payments on the basis of the hospital's/CAH's Medicare fee-for-service and managed care inpatient bed days, total inpatient bed-days, and charges for charity care data from that cost reporting period.

In addition, as described in the proposed rule, hospitals have been required to fill out the worksheet S–10 of the Form CMS 2552–96 since the BBRA of 1999 was enacted. We recognize that the charity care data from the 2552–96 worksheet S–10 may have some limitations because, in some cases, providers failed to complete the worksheet either partially or in its

entirety. Furthermore, in the past CMS did not review the worksheet S–10 because the data had no Medicare payment implications. Thus, in the absence of availability of charity care data from the OMB approved Form CMS 2552–10, a hospital for the purposes of calculating the charity care charges in the interim may use the information from the 2552–96 worksheet S–10; line 22 until the revised worksheet is available. We believe that the Medicare contractor can make a determination if the charity care charges from the 2552–96 are appropriate, and if so, use such charges in determining the preliminary incentive payment amount for hospitals, as described above. Since CAHs were not required to fill out the 2552–96 worksheet S–10, charity care charges may not be available to determine preliminary incentive payments until the revised worksheet is available. However, using data from the first 12-month cost reporting period that begins after the start of the payment year, as described above, hospitals and CAHs will calculate the final incentive payment amount with data from the pending Form CMS–2552–10 Medicare cost report that is effective for cost reporting periods beginning on or after May 1, 2010.

Comment: Several commenters pointed out that we had failed to identify the source of the data for "estimated total amount of the eligible hospital's charges" in the proposed rule. Some of these commenters recommended that we employ Worksheet C, Column 8, line 103 for this purpose.

Response: We did neglect to identify the source of the data for "estimated total amount of the eligible hospital's charges" in the proposed rule. In the final rule, we are providing that, for this purpose, we will employ the data from Worksheet E–1, Part II, line 5 of the revised Medicare cost report, Form CMS–2552–10, which in turn derives this information from line 200 in column 8, Worksheet C, Part I of the pending cost report. We note that line 200 in column 8, Worksheet C, Part I of the revised cost report is the equivalent of 101, Column 8, Worksheet C of the current cost report. We are employing the equivalent of line 101, rather than the equivalent of line 103, as recommended by the commenters, because line 101 (current line 200) includes the charges for observation, and accordingly reflects the "total amount of the eligible hospital's charges" more truly than line 103, which excludes those charges.

e. Incentive Payment Calculation for Eligible Hospitals: 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 one (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, then the applicable transition factor equals three-fourths (¾) for the first payment year (FY 2014), one-half (½) for the second payment year (FY 2015), one-fourth (¼) for the third payment year (FY 2015), and zero thereafter. If a hospital's first payment year is FY 2015, then the applicable transition factor equals (½) for the first payment year (FY 2015), (¼) 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] x [Medicare Share] x [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.

Table13: 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 ¾), 2013 (transition factor equals ½), and 2014 (transition factor equals ¼) 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, 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 ¾), FY 2014 (transition factor equals ½), and FY 2015 (transition factor equals ¼). 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 14: Transition 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

Comment: Several commenters pointed out an apparent inconsistency in the regulation text that we proposed to implement the transition period and applicable transition factors for EHR incentive payments. Specifically, the commenters noted that proposed section 495.104(b)(5) states that hospitals "whose first payment year is FY 2015 may receive such payments for FY 2015 through *2017*" *(emphasis supplied),* while proposed section 495.104(c)(5) states that the transition factors for hospitals "whose first payment year is FY 2015" are:

(A) ½ for FY 2015; and

(B) ¼ for FY *2016.* (Emphasis supplied.)

Response: These commenters are correct. Our proposed section 495.104(b)(5) contained a typographical error. In order to be consistent with the clear requirements of the statute, section 495.104(b)(5) should have stated that hospitals "whose first payment year is FY 2015 may receive such payments for FY 2015 through 2016." In this final rule, we are revising section 495.104(b)(5) of the final regulations accordingly.

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 ¼, ½, and ¾ 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.

In the proposed rule, we noted that specific proposals to implement these payment adjustments for subsection (d) hospitals that are not meaningful EHR users were not being made at that time, but would be subject to future rulemaking prior to the 2015 implementation date. We invited comments on these payment adjustments, and stated any comments received would be considered in developing future proposals to implement these provisions.

We received a few comments on this provision.

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 final 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 final rule.

Comment: We received many comments on the use of the CCN to identify CAHs. Most comments were similar to those received on the use of the CCN for determining incentive payments to eligible hospitals.

Response: We responded to the comments for eligible hospitals elsewhere in this final rule. Our responses to comments received on using the CCN to identify CAHs are the same as the responses for eligible hospital.

After consideration of the public comments received, we are finalizing our policy as proposed. For purposes of this provision, we will provide incentive payments to qualifying CAHs as they are distinguished by the provider number in the CAH's cost reports. Incentive payments for qualifying CAHs 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 qualifying CAHs will be made to each provider of record.

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, or 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 1814(l)(3) of the Act and payment adjustments under section 1814(l)(4) of the Act; (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 proposed 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 proposed 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 proposed 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 proposed to apply the definitions of certified EHR technology, EHR reporting period, meaningful EHR user and qualified EHR in § 495.4 that are discussed elsewhere in this final rule.

In § 495.106(a), we proposed to define a qualifying CAH as a CAH that would meet the meaningful EHR user definition for eligible hospitals in § 495.4, which is discussed in section II A.1. of this final rule if it were an eligible hospital. Also in § 495.106(a), for the purposes of computing the CAH incentive payment, we proposed 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 final rule. We also proposed 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 specified that a qualifying CAH must 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, we proposed under § 495.106(c) that the payment methodology for computing the incentive payment for a qualifying CAH for a cost reporting period during a payment year would be 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 final rule) plus 20 percentage points. However, in no case will the resulting Medicare share for a CAH exceed 100 percent. This payment methodology will be used in place of payment at 101 percent of reasonable costs typically applied under section 1814(l)(1) of the Act and § 413.70(a)(1) 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 final 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 would be 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 proposed § 495.106(d)(3), the interim incentive payment would be subject to a reconciliation process as specified by CMS and the final incentive payment as determined by CMS or its Medicare contractor would be 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 proposed 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 above and in section II.B.4. of this final 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.

Comment: We received many comments requesting CMS to provide a list of those depreciable items that would be used to determine the CAH incentive payment under this provision. The commenters were concerned that certain expenses, such as staff training, associated with an EHR system may not be included in the CAH's incentive payment. We also received comments requesting a further explanation of what documentation will be required to support the reasonable costs incurred by the CAH.

Response: Section 1814(l)(3)(C) of the Act, as amended by the HITECH Act, provides that the costs for which a CAH may receive an incentive payment are reasonable 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. Furthermore, section 1814(l)(3)(A) of the Act, as amended by the HITECH Act, mandates that the Secretary shall compute reasonable costs for the purchase of certified EHR technology 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). As described in the proposed rule, for the purposes of computing the CAH incentive payment, we proposed 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 final rule.

CAHs will incur both depreciable and non-depreciable reasonable costs in a payment year that are associated with implementing and maintaining certified EHR technology. According to the statute, only the reasonable costs for the purchase of certified EHR technology to which purchase depreciation (excluding interest) would otherwise apply are to be included in the CAH incentive payment. Thus, CAHs will not have to depreciate these reasonable costs over the useful life of the EHR asset purchased as such costs will be expensed in a single payment year. Any non-depreciable reasonable costs incurred in that same single payment year that are associated with an EHR system may be paid for under the current Medicare reasonable cost payment system at 101 percent.

Currently, the CAH's Medicare contractor determines if an item purchased is a depreciable asset under Medicare principles or other accounting standards. The Medicare contractor also determines the CAH's reasonable cost for acquiring depreciable assets. For the purposes of computing the CAH incentive payment, we are not changing the Medicare contractor's current responsibilities described above. We, therefore, suggest that CAHs communicate with their Medicare contractors to determine the necessary documentation to support their reasonable costs incurred for the purchase of certified EHR technology and to determine if the items that they purchase are depreciable assets under Medicare principles or other accounting standards.

Comment: We received some comments requesting clarification of how the incentive payments will be computed if an eligible CAH converts to or from an eligible "subsection d" hospital.

Response: If during a payment year an eligible CAH is converted to or from a "subsection d" hospital, the CAH may receive an incentive payment as long as it incurred the reasonable costs of purchasing certified EHR technology in a payment year (or in a previous cost reporting period) when it was a CAH and as long as the affected providers meet the meaningful use criteria described elsewhere in this final rule. When a conversion takes place, the affected CAH and "subsection d" hospital are each required to file a Medicare cost report under section 413.24 of the regulations. For instance, if in month 6 of a cost reporting period that begins January 1, 2011 and ends December 31, 2011, a "subsection d" hospital converts to a CAH, the "subsection d" hospital will file a terminating 6-month cost report (January 1, 2011 to June 30, 2011). If the CAH retains the same year end of December 31, 2011, the CAH will file a 6-month cost report from July 1, 2011 to December 31, 2011. In this instance, the CAH's 6-month cost report would be used to determine if it incurred reasonable costs for the purchase of

certified EHR technology that may qualify for a CAH incentive payment during that period. The "subsection d" hospital's 6 month terminating cost report would be used to determine the possible amount of any incentive payment for that eligible hospital.

After consideration of the public comments received, with the exception of a few minor, technical and conforming changes, we are finalizing the applicable provisions as proposed.

Comment: We received many comments regarding the use of data from the revised Medicare cost report (Form CMS–2552–10) described in the proposed rule to compute the Medicare share portion of the CAH incentive payment. Commenters were also concerned that certain cost report data may not be available at the time of computing a CAH's incentive payment.

Response: As discussed elsewhere in this final rule, we are addressing concerns with data from the revised cost report in a final collection that is currently in the Paperwork Reduction Act clearance process. In addition, we address the timing issues with the revised cost report data elsewhere in this final rule.

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, we proposed that under § 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 would be reduced from 101 percent of its reasonable costs to 100.66 percent. For FY 2016, its reimbursement would be reduced to 100.33 percent of its reasonable costs. For FY 2017 and each subsequent FY, its reimbursement would 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.

Comment: We received some comments requesting further clarification of how CMS will be determining whether a significant hardship exists to warrant an exemption.

Response: We received a few comments on this provision which is not effective until FY 2015. We will take these comments into account when we develop proposals for implementing this provision at a later date.

After consideration of the public comments received, we are finalizing sections 495.106(e) as proposed. We have renumbered proposed section 413.70(a)(6)(iv) as 413.70(a)(7), but are otherwise finalizing section 413.70(a)(6) as proposed.

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 § 413.70(a)(6)(iv) and § 495.106(f), we proposed 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.

Comment: We received some comments requesting clarification of whether CAHs will be able to appeal their incentive payment amounts.

Response: We believe that the limitation of administrative and judicial review does not apply to the amount of the CAH incentive payment. The CAH may appeal the statistical and financial amounts from the Medicare cost report used to determine the CAH incentive payment. The CAH would utilize the current provider appeal process pursuant to section 1878 of the Act.

Accordingly, after consideration of the public comments received, we are finalizing § 495.106(f) as proposed. We have renumbered proposed § 413.70(a)(6)(iv) as § 413.70(a)(7), but are otherwise finalizing the provision as proposed.

4. Process for Making Incentive Payments Under the Medicare FFS Program

As previously discussed in section II.B.1. and 2. of this final 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 proposed 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 methodology set forth in section II.B.1.b. and B.2.b. of this final 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 proposed that the carriers/MACs calculate incentive payment amounts for qualifying EPs, where incentive payments would be disbursed on a rolling basis, as soon as they ascertained that an EP 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. In accordance with section 1848(l)(3)(B) of the Act, we proposed that if a qualifying EP is not eligible for the maximum incentive payment amount for the payment year and if the qualifying EP was also a qualifying MA EP, the qualifying MA organization with which the EP is affiliated would receive the incentive payment for the EP through

the MA EHR incentive program. If the qualifying EP either does not also qualify as a MA EP or he or she qualifies as a MA EP but is not eligible for the maximum incentive payment for the payment year, we proposed that the carriers/MAC would calculate the amount of the qualifying EP's incentive payment and disburse the incentive payment to the qualifying EP in the year following the payment year. The proposed rule also outlined that incentive payments would not be issued to qualifying EPs if an incentive payment was already made under the Medicaid program for the relevant payment year, and as required by section 1848(m)(2) of the Act as amended by section 4101(f) of the HITECH Act, qualifying EPs who received incentive payments from the Medicare EHR incentive payment program would not be eligible to receive an e-prescribing incentive payment. Additionally, we proposed that the incentive payments would be tracked at the qualifying EP's TIN level, and disbursed to the TIN that 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) would be paid at the group practice level's TIN. We proposed 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.

To be clear, we note that financial relationships, including those arising from the reallocation/reassignment of incentive payments, between physicians and their employers/other entities may implicate certain fraud, waste, and abuse laws, regulations, and rules. Therefore, we proposed to include specific safeguards to limit the risk that the allocation/reassignment of incentive payments could raise under those and other applicable laws, regulations and rules. Section II.B.1.d. above finalizes our proposal at § 495.10(f) to permit EPs 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.

Comment: Several commenters expressed concern that the proposed rule contained limited information on how the incentive program for Medicare EPs will be operationalized. They requested additional information on the expected timeframe and process for payments.

Response: The HITECH Act requires that EHR incentive program payments be separately tracked and monitored because these funds cannot be commingled with other Medicare funds. Therefore, to facilitate funds control, payments will be made through a single payment contractor rather than through the carriers/MACs as was originally proposed. Additionally, the Integrated Data Repository (IDR), rather than the carriers/MACs, will be accumulating the allowed charges for each qualified EP's NPI. Payments would be made on a rolling basis, as soon as we ascertain that an EP has successfully demonstrated meaningful use for the applicable reporting period (that is, 90 days for the first year or a calendar year for subsequent years) and the EP's allowed charges has reached the threshold that qualifies an EP for maximum incentive payment, for the relevant payment year. Once this determination has been made, the National Level Repository (NLR) will calculate the EP's incentive payment. The payment will then be made by the single payment contractor. We anticipate that it will take anywhere from 15 to 46 days from the time an EP successfully attests to being a meaningful user to the time an incentive payment is made, and that for FY 2011, incentive payments will be made to EPs who successfully demonstrate that they were meaningful EHR users for the EHR reporting period (that is, 90 days) as early as May 2011. As proposed, we will pay a qualifying EP a single consolidated incentive payment for a payment year, rather than make periodic installment payments. In order to accommodate different attestation dates throughout the first year for EPs, our payment cycle is on a monthly basis as previously described; however, qualifying EPs will receive one single payment per year. In other words, CMS will issue payments as soon as possible after a qualifying EP attested to meaningfully using a certified EHR system, hence the monthly payment cycle; however, an EP will only receive one incentive payment for each year he/she qualifies. For qualifying EPs whose allowed charges for the payment year do not reach the maximum thresholds, the single payment contractor will disburse an incentive payment in the following year.

Comment: One commenter recommended CMS make semi-annual incentive payments for the second and subsequent payment years to ensure physician practices have cash flow to deploy certified EHR systems and train employees how to use the systems.

Response: When the EHR reporting period is a full year, no EPs will have successfully demonstrated that they are meaningful users at the mid-year mark. Therefore, as previously described, qualifying Medicare EPs will receive a single payment per year, issued on a monthly payment cycle. We intend to finalize this provision as proposed; there will be a single successful attestation per year and a single payment following the attestation for qualifying EPs.

Comment: One commenter questioned whether the scopes of work for the MACs/Medicare Carriers would be revised to reflect the additional work that this program will entail.

Response: As previously discussed in the first comment and response, the IDR, rather than the MACs/Medicare Carriers, will accumulate the EPs allowed charges. The MAC/Carrier work related the Medicare EHR incentive program will be within their current scope of work and will be handled through the normal change request process.

Comment: One commenter believes an EP's program selection (Medicare or Medicaid) is tied to the TIN where the EP assigns incentive payments. The commenter recommended CMS permit additional changes in program selection if EPs change their TIN. The commenter believes allowing only one program change in the life of the program is too restricting given that patient mix might change due to a practice being purchased by another TIN or an EP becoming a part-time employee of another TIN.

Response: Section II.A.5.b. of this final rule outlines our policy decision around changing program selections.

After consideration of the public comments received, we are finalizing our policy as proposed. For purposes of this provision, payments will be made through a single payment contractor with the IDR accumulating the allowed charges for each qualified EP's NPI. Payments will be made on a rolling basis, as soon as we ascertain that an EP has successfully 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 then the NLR will calculate the incentive payment. We estimate it will take anywhere from 15 to 46 days from the time an EP successfully attests to being a meaningful user to the time an incentive payment is made.

b. Incentive Payments to Eligible Hospitals

We proposed that the FIs/MACs would calculate incentive payments for qualifying eligible hospitals, and would 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 final 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. We proposed that FIs/MACs would 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 final rule, beginning in 2010, cost reports will capture charity care data which will be used in calculating the Medicare share of the payment. We proposed that the MACs/FIs 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 also proposed 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 would reconcile the incentive payment as necessary at settlement of the cost report. Additionally, incentive payments for qualifying eligible hospitals would be calculated based on the provider number used for cost reporting purposes, which is the CCN of the main provider. Therefore, incentive payments for qualifying hospitals would be disbursed to the CCN rather than the TIN.

Comment: Several commenters expressed concern that the proposed rule contained limited information on how the incentive program for hospitals will be operationalized. They requested additional information on the expected timeframe and process for payments as well as requesting clarification that the incentive payments would be distributed as a "lump sum payment." One commenter requested CMS disburse one lump sum payment at the start of each eligible year for those hospitals that meet all of the meaningful use requirements.

Response: Hospital EHR incentive payments will be calculated by the FIs/MACs; however, to facilitate funds control, payments will be made through a single payment contractor. We will direct the payment contractor to issue to qualifying hospitals, that is those hospitals who successfully demonstrate that they are meaningful EHR users, a single initial payment for the year. We anticipate that payments will be made to qualifying Medicare hospitals beginning in May 2011. No payment will be made prior to an eligible Medicare hospital successfully demonstrating that it was a meaningful EHR user during the EHR period for the relevant payment year. For purposes of determining interim incentive payments, we will 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 a hospital's most recently submitted 12-month cost report once the hospital has qualified as a meaningful user. For purposes of determining final incentive payments, we will employ the first 12-month cost reporting period that begins after the start of the payment year, in order to settle payments on the basis of the hospital's Medicare fee-for-service and managed care inpatient bed days, total inpatient bed-days, and charges for charity care data from that cost reporting period.

Comment: One commenter requested that CMS allow hospitals to make an interim attestation 90 days after the start of the second and subsequent payment years. They suggested the interim attestation would note that they are in compliance with the meaningful use rules and intend to remain in compliance. They requested that CMS instruct the contractor to issue interim EHR payments after receipt of such attestation. The commenter believes this would cut down on the time frame of 21 months between their first and second hospital interim payments.

Response: The reporting period requirements for a hospital's second and subsequent years are 365 days. Due to the year-long reporting period, we do not believe we can allow for an interim attestation that the provider is a meaningful EHR user. Under our definitions at § 495.4, a provider is not a meaningful EHR user unless it has "for an EHR reporting period for a payment year," demonstrated meaningful use "in accordance with § 495.8 by meeting the applicable objectives and associated measures under § 495.6." Thus, we could not determine that the provider is a meaningful user at an interim point in time, and there would be no basis for providing the interim payment.

Comment: One commenter expressed confusion over the term "demonstration period" and questioned if a hospital had to complete the full demonstration period before payments would be made.

Response: We assume the commenter means EHR "reporting period" when using the phrase, "demonstration period." A hospital must demonstrate that it met the requirements for meaningful use for the full EHR reporting period for the relevant payment year before we will direct the payment contractor to issue an incentive payment to the hospital for the payment year. A hospital therefore must complete the full EHR reporting period before demonstrating that it was a meaningful EHR user and before any payments would be made.

Comment: Several commenters recommended that CMS' payment process for eligible hospitals be consistent with its payment process for EPs, and that hospital's initial incentive payment thus be distributed no later than two months after the hospital successfully demonstrates meaningful use. The same commenters requested CMS specify that the final incentive payment be issued no later than two months after the hospital submits its cost report from the FY that ends during the payment year.

Response: We anticipate that for FY 2011, interim incentive payments will be made to eligible hospitals that successfully demonstrate that they were meaningful EHR users for the EHR reporting period for FY 2011 (that is, 90 days) as early as May 2011. The exact timing of when a qualifying eligible hospital receives its interim incentive payment will depend on when the hospital successfully demonstrates that it was a meaningful EHR user; the sooner a hospital successfully demonstrate that is was a meaningful EHR user during the EHR reporting period for the payment year, the sooner it will receive its interim incentive payment. For a Medicare hospital's second and subsequent participation years, after a hospital successfully demonstrates that it was a meaningful EHR user during the EHR reporting period (that is, the federal fiscal year) for the payment year, the hospital will receive the interim incentive payment in the following year; the initial incentive payments will be made on a monthly payment cycle beginning shortly after the hospital is determined to be a meaningful user. To the commenters' point of requesting that we be consistent with the approach to paying EPs, there seems to be confusion around what was proposed as to the timing and distribution of the EP's incentive payment. The proposal for the EP's incentive payment was that EP's

accumulated allowed charges would be based on claims submitted not later than two months after the end of the payment year. The incentive payment for a qualifying EP's second and subsequent payment years was always to be disbursed in the year following the payment year. We did not propose paying an EP within two months of being deemed a meaningful user.

Comment: Several commenters questioned how CMS would treat a hospital that qualified for an incentive payment one year, but did not qualify the next or subsequent years; what is the impact on the stream of incentive payments to the hospital?

Response: An eligible hospital's first payment year is the first year they successfully demonstrate that they were a meaningful EHR user for the EHR reporting period for the payment year. Section 1886(n)(2)(G) of the Act defines the second through fifth payment years for a hospital as each successive year immediately following the first payment year for such hospital. An eligible hospital's second payment year, then, is the year following its first payment year, regardless of whether the eligible hospital qualifies for an incentive payment in the year following its first payment year. Similarly, an eligible hospital's third, fourth, and fifth payment year are the third, fourth, and fifth years, respectively, following the hospital's first payment year, even if the hospital does not receive an incentive payment for one or more of those years.

Comment: Several commenters requested that CMS clarify that EHR incentive payments for which a hospital qualifies or receives under the EHR incentive program (whether directly or pursuant to an assignment, reassignment or other transfer) shall not affect or be taken into account in the calculation or other payments made to the eligible hospital under Medicare, Medicaid, or any other state or federal healthcare program, such as disproportionate share payments, graduate medical education and indirect medical education payments, and payments for un-compensated care payments.

Response: EHR incentive payments will have no bearing on the hospital's Medicare disproportionate share, indirect medical education or direct graduate medical education payments. This discussion is also addressed in the Medicaid section at II.D.4.b.

After consideration of the public comments received, we are finalizing our policy as proposed. For purposes of this provision, Hospital incentive payments will be calculated by the FIs/MACs; however, to facilitate funds control, payments will be made through a single payment contractor. We will direct the payment contractor to issue to qualifying hospitals a single initial payment per year, and expect initial payment may begin as early as May 2011, for those who demonstrate they are meaningful EHR users at the earliest date possible. We estimate it will take anywhere from 15 to 46 days from the time a hospital successfully attests to being a meaningful user to the time an incentive payment is made.

c. Incentive Payments to CAHs

In the proposed rule, CMS proposed that because CAHs are paid on a cost reimbursement basis once a CAH incurs actual EHR costs, it could submit supporting documentation to the FI/MAC for review. The FIs/MACs would determine an incentive payment amount, as discussed in section II.A.3 of the 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.

As discussed in the proposed rule, the FIs/MACs would reconcile the cost report and ensure the EHR expenses are adjusted on the cost report to avoid duplicate payments. Incentive payments for qualifying CAHs would be calculated based on the provider number used for cost reporting purposes, which is the CCN number of the main provider. Therefore, incentive payments for qualifying CAHs would be based on the CCN rather than the TIN.

Comment: Several commenters expressed concern that the proposed rule contained limited information on how the incentive program would be operationalized for CAHs. They requested additional information on the expected timeframe and process for payments to CAHs.

Response: To facilitate funds control, payments will be made through a single payment contractor. In order to receive a HITECH incentive payment, a CAH will have to attest that it is a meaningful user, and submit documentation to its FI/MAC to support the costs incurred for its HIT system. Once the FI/MAC reviews the documentation and the allowable amount is determined, we will direct the payment contractor to release to the CAH a single incentive payment in the next HITECH payment cycle. Payment cycles will begin in May 2011.

Comment: Several commenters requested more information on the timing of the distribution of payments to CAHs once the necessary documentation has been submitted and that recommended CMS be consistent with its proposal on incentive payments for EPs and specify that the CAH's initial incentive payment will be distributed no later than two months after it submits the necessary documentation. The same commenters requested that CMS specify that the final incentive payment be issued no later than two months after the CAH submits its cost report.

Response: CAHs will receive a single initial incentive payment per year with the initial payments beginning in May 2011. Once the FIs/MACs review the documentation and the allowable amount is determined, we will direct the payment contractor to release a single incentive payment in the next incentive payment cycle to qualifying CAHs. We anticipate the initial payments will generally be made within two months of the determination of the allowable amount. The final payment will be calculated on the cost report, and the process to settle the cost report will not be modified for these incentive payments. It will continue to follow the normal final settlement process. For the CAHs' second and subsequent participation years, CAHs will also receive a single initial incentive payment per year and a final incentive payment as described above. With respect to the commenters' request that we be consistent with the proposed approach to paying EPs, there seems to be confusion around what was proposed as to the timing and distribution of incentive payments to EPs. The proposal for EP incentive payments was that an EP's accumulated allowed charges would be based on claims submitted not later than two months after the end of the payment year. The incentive payment for a qualifying EP's second and subsequent payment years was always to be disbursed in the year following the payment year. We did not propose to make incentive payments to an EP within two months of the EP being deemed a meaningful user.

Comment: Several commenters questioned what is considered "necessary documentation" for CAHs to submit in order to receive Medicare CAH incentive payments. The same commenters requested CMS propose and obtain comments on "necessary documentation" and finalize a rule before FY 2011.

Response: The documentation submitted should include information reflecting what was purchased, and support the costs incurred. Such documentation may include invoices, receipts, or other comparable materials.

Comment: One commenter recommended CMS (not the MACs/FIs) should make all determinations regarding CAHs.

Response: The documentation review process for Medicare CAH incentive payments is similar to processes currently performed by FIs/MACs. Also, the data needed to calculate the Medicare Share is on the cost reports, which are submitted to the FIs/MACs. Accordingly, we believe it would be most appropriate for the payment determinations be made by the FIs/MACs, and not by CMS.

After consideration of the public comments received, we are finalizing our policy as proposed. For purposes of this provision, CAH payments will be calculated by the FIs/MACs; however, as discussed above, to facilitate funds control, payments will be made through a single payment contractor. Once the FIs/MACs review the documentation and the allowable amount is determined, we will direct the payment contractor to release to the CAH a single incentive payment in the next HITECH payment cycle. Payment cycles will begin in May 2011.

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 through 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.

5. Preclusion of Administrative and Judicial Review

We did not discuss preclusion of administrative and judicial review in our proposed rule. We are now including a discussion, in order to make the public aware of the preclusion. Also, the sections of this final rule discussing payments to Medicare Advantage (MA) organizations and CAHs both include a description of the preclusion, as well as accompanying regulation text. Therefore, while we believe statutory provisions on preclusion of review are self-implementing, below, we include a discussion of the preclusion of review that applies to EPs and eligible hospitals. We have also added regulation text to maintain consistency with the CAH and MA organization provisions.

For EPs, section 1848(o)(3)(C) of the Act prohibits administrative or judicial review under section 1869, section 1878, or otherwise, of all of the following:

- The methodology and standards for determining EP incentive payment amounts.
- The methodology and standards for determining the payment adjustments that apply to EPs beginning with 2015.
- The methodology and standards for determining whether an EP is a meaningful EHR user, including: (1) The selection of clinical quality measures; and (2) the means of demonstrating meaningful EHR use.
- The methodology and standards for determining the hardship exception to the payment adjustments.
- The methodology and standards for determining whether an EP is hospital-based.
- The specification of the EHR reporting period, as well as whether payment will be made only once, in a single consolidated payment, or in periodic installments.

For eligible hospitals, section 1886(n)(4)(A) of the Act similarly prohibits administrative or judicial review under section 1869, section 1878, or otherwise, of the following:

- The methodology and standards for determining the incentive payment amounts made to eligible hospitals, including: (1) The estimates or proxies for determining discharges, inpatient-bed-days, hospital charges, charity charges, and Medicare share; and (2) the period used to determine such estimate or proxy.
- The methodology and standards for determining the payment adjustments that apply to eligible hospitals beginning with FY 2015.
- The methodology and standards for determining whether an eligible hospital is a meaningful EHR user, including: (1) The selection of clinical quality measures; and (2) the means of demonstrating meaningful EHR use.
- The methodology and standards for determining the hardship exception to the payment adjustments.
- The specification of the EHR reporting period, as well as whether payment will be made only once, in a single consolidated payment, or in periodic installments.

We note that the above listing may summarize or abbreviate portions of the statute. For precise language on the preclusion of judicial review, readers should always refer to the statute.

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.

In § 495.200 we proposed to define "qualifying MA organization." Specifically, in § 495.202(a)(2), we proposed 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 proposed 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 § 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 proposed that the sponsoring MA organization would be required 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.

Although we did not receive any comments on these provisions and are finalizing them as proposed, there is one exception. In order to bring 422.202(a) into conformance with the change we are making to 422.202(b)(1), we are changing the date by which MAOs are required to identify themselves to us from the bidding deadline in June 2010 (for plan year 2011) to the bidding deadline in June 2011 (for plan year 2012).

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 MA 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 final rule, an EP is defined as a physician (under section 1861(r) of the Act).

We said we interpreted "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 said we interpreted "to be a partner of" to mean that the qualifying MA EP has an ownership stake in the entity. Under this interpretation, a professional that contracts with an entity, but who has no ownership stake in the entity, would not be considered a qualifying MA EP.

We said we interpreted "furnishing at least 80 percent" of the entity's "patient care services" to enrollees of the organization to mean at least 80 percent of the qualifying entity'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 proposed to interpret the requirement that a qualifying MA EP furnish at least 80 percent of their professional services covered under Title XVIII to enrollees of the organization to mean 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 said we believed that in establishing the rule that qualifying MA EPs need to furnish at least 80 percent of their 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 said 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 interpreted the requirement to include both Medicare and non-Medicare patient care services. Moreover, we proposed 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 definition of EHR reporting period in section II.A.1.e. of this final rule.) Therefore, we said that over the EHR reporting period, the qualifying MA EP must provide on average 20 hours per week of patient care services. Finally, we interpreted "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 to a Medicare beneficiary.

We considered various methods of determining when at least 20 hour per week, on average, of patient care services would 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 proposed 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.

Comment: A few commenters referenced the Report to Congress required by section 4101(d) of the HITECH Act. The commenters suggested ways in which we could combine original FFS Medicare claims-payment data and MA services provided by EPs in order to arrive at a single, combined EHR payment. One commenter asked whether payments to a provider from a Medicare Advantage plan can contribute to the volume of Allowed Charges for the purpose of calculating maximum Meaningful Use rewards, saying that he believed that they should. Another commenter said that a substantial percentage of senior citizens receive their care from EPs providing services by way of Medicare Advantage plans. The commenter continued that current proposed rules provide incentive payment only to EPs in whose practices 80 percent or more of total services are to Medicare Advantage patients. The commenter concluded that this would exclude many EPs treating our most vulnerable citizens from the opportunity to meaningfully adopt EHRs in their practices and that the 80 percent [MA] practice requirement should be eliminated. Other commenters argued

that the regulation was unclear regarding an exclusion of covered professional services of an EP not employed by an MAO when determining their participation or level of payment because those services are provided to MA beneficiaries. The commenter believed that the Secretary should provide a mechanism, whereby EPs can supplement their record to the appropriate carrier/MAC with their MA charges.

Response: We do not have statutory authority to combine payments across the FFS and MA EHR incentive payment programs. The statutory provision at section 1853(l)(3)(B) of the Act, as added by section 4101 of the HITECH, entitled "Avoiding Duplication of Payments," specifically prohibits us from making payments to EPs for both FFS and MA services. Additionally, had Congress wanted CMS to combine FFS and MA charges it could have included a provision similar to the provision in section 1886(n)(2)(D)(i) of the Act, as added by section 4102(a) of the HITECH Act, where FFS and MA inpatient-bed-days are added together to derive the numerator of the Medicare share fraction. We do not have the authority to eliminate the requirement that an EP provide 80 percent of Medicare services to enrollees of an MA organization, as that requirement is set forth in section 1853(l)(2)(A)(i)(II) of the Act, as added by the HITECH Act, which is clear in requiring that an MA EP provide "80 percent of * * * professional services * * * covered under this title to enrollees of the [MA] organization."

Comment: One commenter recommended that CMS retain its proposal regarding how the 80 percent and the 20 hours per week criteria will be met by MA EPs. Another commenter said that many EPs in Puerto Rico would not qualify for incentives under this test. The commenter said that the single MA organization requirement of 80 percent revenue and 20 hours per week for MA EPs would not be met due to the competition and market changes from year to year. The commenter suggested eliminating the single MA organization requirement. Instead, the commenter said we should change the standards to consider all enrollees of all MA organizations to which an EP furnishes services. The commenter continued by saying that if the requirements are not modified to accept multiple MA organizations, the commenter anticipated several unintended consequences in the Puerto Rico market. First, the commenter said, it would be impossible for providers to meet the single MA organization requirement of 80 percent revenue and 20 hours per week, and therefore, the standard would create disinterest in adopting EHRs in their practice. Second, the commenter said, the single MA organization requirement standard would stymie competition. An unanticipated consequence of the requirement would be providers dropping out of MA plans to consolidate revenue in order to meet the standard from a single MA organization. Third, the commenter concluded, patients would have fewer options to select among MA plans, and to a lesser degree, MA enrollees might be forced to discontinue care with long time MA providers in light of the providers' determination to consolidate revenue under a single MA organization.

Response: As noted above, the 80 percent of Medicare revenue standard is set forth in the statute, and may not be changed by regulation. The 20 hour per week rule is also statutory and based on section 1853(l)(2)(B) of the Act, as added by the HITECH Act. We note, however, that it is not the case that all 20 hours of patient care services per week be provided by an EP to MA enrollees of a single MA organization. Rather, the 20 hours of patient care services to enrollees of a single MA organization can include both Medicare and non-Medicare services and patients.

Comment: One commenter asked CMS to continue to work with Congress to develop an equitable mechanism by which to provide incentives to physicians that provide health care services through participation with more than one MAO.

Response: As previously mentioned in the preamble to this final rule, the statute clearly limits payment related to any specific MA EP to a single qualifying MA organization. Potential changes in the statute are outside the scope of this rulemaking.

After consideration of the public comments received, we are implementing the foregoing provisions as proposed.

As discussed in section II.B. of this final 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 final 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 proposed 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, we proposed that 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.

Comment: We received one comment related to hospital-based MA EPs, and specifically to our proposal in the proposed rule that "similar to the Medicare FFS incentive program, MA incentive payments would also not be available for hospital-based EPs." The commenter noted, however, that unlike the proposed regulatory definition of "Qualifying Eligible Professional (EP)" under the Medicare FFS incentive program, the proposed regulatory definition of "Qualifying MA EP" under the MA EHR incentive program did not expressly exclude hospital-based EPs. The commenter went on to say that if hospital-based MA EPs are excluded from the MA EHR incentive program (for example, because they provide 90% or more of their covered services in the CY preceding the payment year in an outpatient hospital setting), unless there is an exception for MA EPs who are hospital-based in qualifying MA-Affiliated Eligible Hospitals that would not qualify for an incentive payment under the MA Affiliated hospital EHR incentive program payment criteria, Qualifying MA Organizations with MA EPs who are hospital-based in such qualifying MA-Affiliated Hospitals would not qualify for an incentive, with regard to those MA EPs, under any HITECH Act Medicare incentive program. The commenter concluded that this outcome would not be consistent with the objective of the HITECH Act to promote widespread adoption of HIT through the payment of monetary incentives for meaningful use of EHRs. The commenter recommended that if hospital-based MA EPs are excluded from the MA EHR incentive program, then we should include an exception for MA EPs who are hospital-

based in Qualifying MA-Affiliated Eligible Hospitals that would not qualify for an incentive payment (or would only qualify for a very minimal incentive payment) under the MA-Affiliated hospital EHR incentive program payment criteria.

Response: We thank the commenter for pointing out our oversight in not including the hospital-based physician exclusion in the proposed regulation text related to the MA EP EHR incentive program. We will include in regulation text the fact that an MA EP is not a "hospital-based EP," as that term is defined in § 495.4 of this final rule. As to a possible exception for hospital-based EPs who are practicing in MA-affiliated hospitals that do not qualify for incentive payments (or that qualify for very minimal incentive payments), we cannot provide such an exception. MA-affiliated eligible hospitals will receive EHR incentive payments based on the same statutory formula used to make EHR incentive payments to other "subsection (d)" hospitals—see section II.C.3. of this final rule, below. There is no statutory authority nor is there a valid reason to treat MA EPs, in this respect, any differently that other EPs that are hospital-based.

After consideration of the public comment received, we are modifying the regulation text related to the definition of MA EP by the additional of an item 5) to the definition of "Qualifying MA EP" at § 495.200 to add a specific hospital-based MA EP exclusion.

As discussed in the proposed rule, 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 did not propose to define the term "entity," but instead recognized that there exist a range of entities with which MA organizations contract for patient care services, including physician groups, Independent Practice Associations (IPAs), Exclusive Provider Organizations (EPOs), Physician Hospital Organizations (PHOs), and Preferred Provider Organizations (PPOs).

Moreover, we recognized 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, we said, 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.

We said that the qualifying MA organization must attest to the fact that each MA EP is a meaningful user of certified EHR technology in accordance with § 495.4. If all of these conditions are met, such an individual is identified as an MA EP. We proposed to define the term "MA eligible professional (EP)" at § 495.200 as an EP who satisfies all of these conditions.

Finally, we discussed section 4101(d) of the HITECH Act which directed 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. We explained that this rule does not address such individuals, as it is limited to codifying in regulation existing statutory language as discussed herein.

We did not receive any comments on these provisions and are finalizing them as proposed.

c. Qualifying MA-Affiliated Eligible Hospital

We proposed 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 § 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 of the Medicare hospitals discharges (or bed-days) are Medicare individuals enrolled under MA plans offered by such organization. As discussed in section II.A.1. of this final 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 proposed to define "under common corporate governance", as a qualifying MA organization and a qualifying MA-affiliated eligible hospital that have a common parent corporation, where one is a subsidiary of the other, or where 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 an 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 proposed 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 final rule. The term will be used in the same way in computing incentive payments due qualifying MA organizations under the qualifying MA-affiliated eligible hospital incentive payment program.

We note that, as discussed in section II.B.2.b. of this final 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 final rule for the computation of incentive payments to qualifying MA organizations.)

Therefore, we proposed to make EHR incentive payments to qualifying MA-affiliated eligible hospitals under the FFS EHR incentive program. Finally, we said that to the extent 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 proposed to require that qualifying MA organizations seeking reimbursement for qualifying MA-affiliated eligible hospitals submit similar data.

We did not receive any comments on these provisions and are finalizing them as proposed.

2. Identification of Qualifying MA Organizations, MA EPs, and MA-Affiliated Eligible Hospitals

In § 495.202 we proposed to require an MA organization that intended 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 proposed to 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 proposed 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 proposed 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 proposed 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 would seek EHR incentive payments.

In developing the preliminary and final lists of potentially qualifying MA EPs, qualifying MA organizations, we said that qualifying MA organizations must exclude hospital-based MA EPs. We proposed that qualifying MA organizations identify hospital-based MA EPs using the same criteria outlined in section II.A.6 of this final 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 MA-affiliated hospitals, we said that qualifying MA organizations would be required to submit an attestation that these professionals and hospitals meet the criteria to be considered eligible. For example, for hospitals, the qualifying MA organization would need to attest that they are under common corporate governance with the qualifying MA organization and for EPs, the qualifying MA organization would need to attest that the list does not include any hospital-based EPs.

We proposed 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 were sought. We also proposed 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 would be requesting payment under the MA EHR incentive payment program.

We said that 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 proposed 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 proposed to require qualifying MA organizations 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.

Comment: Two commenters contended that requiring MA organizations to provide even a preliminary list of MA EPs by June 2010 (for payment year 2011) would be unrealistic and burdensome, especially when publication of a Final Rule seems unlikely before May 2010 at the earliest. For 2011, any preliminary list will be inaccurate, despite good faith efforts and reasonable due diligence. Moreover, CMS has not stated any justifiable purpose for requiring such a preliminary list.

Response: We agree with the commenters that it would be unnecessarily burdensome and unrealistic to require MA organizations to provide preliminary lists as early as June of 2010 of potential MA EPs for incentive payment year 2011. We will change the timing of this requirement in § 495.202(b)(1) to say that as part of initial bids for plan year 2012 MA organizations will be required to submit preliminary lists in June of 2011 (when bids are due for 2012) of potential MA EPs for incentive payment year 2011. Thus, we will delay the requirement for a full year. The purpose of such preliminary lists is to identify potential MA EPs that have, for instance, registered as FFS Medicare or Medicaid EPs on the National Level Repository. The intent of getting these lists before payment is due, or before a final determination of eligibility can be made, is to help qualifying MA organizations know of any potential conflicts in time to "cure" them before final payment determinations are made.

Comment: One commenter objected to CMS' proposal that MA organizations be required to submit final lists of MA EPs and MA hospitals by the last day of the payment year, including the attestations of meaningful use and accurate payment calculation. The commenter argued that this timing would not allow sufficient time to ensure that data are complete and accurate, especially considering that MA organizations bear the additional burden of having to develop and support internal administrative systems to determine eligibility and to calculate payment (we will calculate FFS EP payments based on claims submitted). The commenter recommended that we extend the deadlines to produce both preliminary and final lists of MA EPs and hospitals. The commenter suggested that MA organizations be given until 90 to 120 days after the close of the payment year to identify and list eligible EPs and hospitals (for example, after 31 December 2011 for plan year 2011).

Response: We agree with the commenter that additional time should be permitted and we are therefore adding a due date in § 495.202(b)(3) for final identification of potentially qualifying MA EPs and MA-affiliated eligible hospitals of 60 days after the close of the payment year. We believe 60 days is reasonable, since it is the same as the time in which FFS EPs have to submit claims for consideration under the Medicare FFS EHR incentive payment program.

After consideration of the public comments received, we are modifying the regulation text related to the timing of both preliminary and final identification of MA EPs and MA-affiliated eligible hospitals. Preliminary

identification of MA EPs and MA-affiliated hospitals for payment year 2011 will need to occur by the bidding deadline in June 2011, and final identification will need to occur within 60 days of the close of the payment year. Accordingly, we are respectively modifying the regulation text at § 495.202(b)(1) and § 495.202(b)(3). We are also modifying the regulation text at § 495.204(b)(2) to be consistent with the change to § 495.202(b)(3), since final identification in § 495.202(b)(3) should occur at the same time as final revenue reporting under § 495.204(b)(2), so calculations of payments due under the MA EP incentive payment program can be finalized. We are also modifying the regulation text at § 495.210(b) and (c) to be consistent with the changes to § 495.204(b)(2) and § 495.202(b)(3), since the deadline for attestations of meaningful use should be consistent with deadlines for revenue reporting for MA EPs, and final identification of MA EPs and MA-affiliated hospitals. Finally, as noted (above) in our discussion of the definition of qualifying MA organizations, we are modifying the date in § 495.202(a)(1) by which MAOs are required to identify themselves to us from the bidding deadline in June 2010 (for plan year 2011) to the bidding deadline in June 2011 (for plan year 2012).

We also proposed 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 proposed 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.

We did not receive any comments on these provisions and are finalizing them as proposed.

3. Computation of Incentives to Qualifying MA Organizations for MA EPs and Hospitals

In § 495.204, we proposed 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 final 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 final rule.)

Sections 1848(o)(1)(D)(i) and 1886(n)(2)(F) of the Act permit us to make incentive payments for a year in installments, although we proposed to make a single lump sum payment with respect to MA EPs. With respect to MA EP incentive payments, we said 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 earned "less than [the] maximum incentive payment for the same period" under the Medicare FFS EHR incentive program. We noted in the proposed rule 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 rather only for services paid under Part B. In a similar manner we proposed 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 said we did 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 proposed, that in calculating qualifying MA EP incentive payments, we would only consider covered professional services provided to enrollees of MA plans offered by qualifying MA organizations and would not include in the calculation any services reimbursed by Medicare FFS.

Comment: Many commenters asked if MA plan beneficiaries and services would be counted in the calculation of FFS EHR incentives and, if so, if it would require separate submissions to each MA plan in the local market.

Response: As we explained in the preamble of the proposed rule, we cannot make MA EP incentive payments for Part B services covered and paid for on a fee-for-service basis under the original Medicare program. We also cannot make MA EP incentive payments to entities other than qualifying MAOs. In short, the Medicare Advantage services provided by EPs that are not qualifying MA EPs—defined in statute and in this rule at § 495.200—are not reimbursable under the EHR incentive payment program.

Comment: Two commenters contended that the proposed Medicare Advantage incentive computation was inconsistent. They said that sections II.C.3. through 5. of this final rule discuss compensation, but the preamble says that the Secretary may substitute a different amount. This discrepancy should be clarified.

Response: We disagree. The statute says that we can substitute an amount "that is similar to the estimated amount that would be payable or based on the fee schedule." It does not say that we can substitute a different amount.

After consideration of the public comments received, we are implementing these provisions as proposed.

We also said that under the Medicare FFS EHR incentive program, an EP's incentive payment could not exceed the annual limits specified under section 1848(o)(1)(B)(i) of the Act. We proposed that similar payment limits apply to qualifying MA organizations for their qualifying MA EPs. 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 proposed 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.

We did not receive any comments on these provisions and are finalizing them as proposed.

We proposed 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 did not receive any comments on these provisions and are finalizing them as proposed.

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 payment data to estimate average annual MA revenue for qualifying MA EPs with respect to a qualifying MA organization. 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 said we believed such a result is contrary to the legal requirement that qualifying MA organizations are to receive 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 be also 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 reporting qualifying MA EP encounters with MA plan enrollees based on the five levels of office visit codes recognized by Medicare FFS.

We said we believed that such a process would be administratively burdensome and difficult to operationalize. Therefore, we proposed an alternative approach, but sought input from interested parties as to which of the 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.

Therefore, in § 495.204(b)(1) through (3) we proposed 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 our proposed 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 said 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 were compensated on a salaried basis, we proposed in § 495.204(b)(4) 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 proposed to require that salaries be prorated to ensure that the amount reported reflects the salary paid for the applicable year, where necessary.

We also said that 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 proposed 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 proposed 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. We said 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 proposed in § 495.204(b)(5) to require qualifying MA organizations to obtain attestations from such EPs and to submit to us 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.

Comment: One commenter recommended that final CMS regulations retain the exact requirements outlined in §§ 495.204(b)(4) and (5). Two commenters said that CMS should allow flexibility in methods MA organizations propose for computing incentive payments so long as the organization's approach is reasonable, straightforward, and fairly equates to the Medicare fee-for-service approach without imposing undue burdens on MA organization systems or compromising EP privacy. The proposed rule describes how incentive payment amounts will be calculated for eligible hospitals and EPs. The proposed rule presents options for a MA payment methodology, but expressly solicits comments from MA organizations about how such a methodology could be designed to fairly approximate the FFS payment calculation. The commenters included recommendations about how MA organizations could be reimbursed and what methodology would be a reasonable proxy for the Part B-based payment applied to FFS physicians, based on the amount of individual physician care provided to MA members. The commenters said that MA EPs who are employed by their organizations are independent physician group practices that contract exclusively with their organizations to meet the health needs of their members, including MA enrollees. Their organizations do not pay the salaries of MA EPs who provide patient care services to their members and patients. They said that CMS has proposed that the organization that directly pays the EP salaries would perform a calculation and attest to the MA organization about the amount of payment. They said that while this would mitigate some of the confidentiality concerns related to sharing salary information with the health plans, salary information would still be potentially exposed to CMS. They said that another disadvantage of using actual salary as a basis for calculating the incentive payment is that this approach potentially introduces unacceptable variability into the estimation of proxy amounts for Medicare services. For example, two MA EPs, whose salaries vary significantly but provide the same Medicare services in a reporting period, would have different proxy amounts. Further, they said, if such EPs were billing under Part B, the amount of Medicare services each billed would be the same, regardless of whether their incomes were the same. These commenters went on to propose an alternative method of computing a proxy Part B amount. They said that as a first step, the MA organization would calculate the percentage of clinic time each physician spends caring for MA members. This MA Practice percentage could be derived by either: (1) Capturing the total scheduled appointment time for MA members for each MA EP and dividing that amount by the total scheduled time for that MA EP (for all appointments); or (2) capturing the number of MA member visits/procedures for each MA EP and dividing that amount by the total number of visits/procedures for that MA EP (for all members). The organization would then calculate the average practice cost by specialty for all specialties identified in the annual American Medical Group Association's ("AMGA") salary survey. The commenters explained that AMGA survey provides the median compensation per physician in most specialties as well as the non-compensation related clinic costs per physician (staffing, supplies, overhead, etc.) in most specialties. Adding specialty specific compensation data (for groups > 100 physicians) to the combined average non-compensation related clinic costs for that specialty (for all sized groups) would provide a surrogate amount for each specialty's total operating costs. This would produce the Average Operating Costs by Specialty. Multiplying each MA EP's MA Practice percentage and the Average Operating Costs by Specialty for that MA EP's practice specialty would produce a surrogate Medicare Part B amount. For each MA EP, the MA organization would be paid an incentive equal to 75 percent of the surrogate Medicare billing amount for that physician, such incentive not to exceed the maximum incentive for each payment year of the program (for example, $18,000 if the first year of participation is 2011).

Response: While we appreciate the thought and effort that went into this proposed alternative method of calculating MA EP incentive payments, we are reluctant to adopt it for the simple reason that where salaries, practice costs, or actual MA EP compensation can be known, we believe it is a better read of statutory requirements to work from that actual compensation and cost data than it would be to allow estimation of both. In many respects the proposed alternative method is similar to the method discussed and disposed of in the proposed rule related to estimating physician compensation based on MA bidding and payment data. Although the commenters' alternative version factors in actual practice time, we believe using AMGA salary survey data would be inferior to using actual physician compensation practice cost information. To the extent actual salary information is unknown or unavailable to the MA organization, we believe it could be provided to us in a manner that would protect the privacy of individual MA EPs and physician groups. Furthermore, the proposal also estimates "non-compensation related clinic costs" based on AMGA data, which is, again, inappropriate, when actual overhead costs might be quite different in a specific MA organization. However, based on the commenters concerns regarding provider privacy and the need to develop a consistent and verifiable method of computing the amount payable to qualifying MA organizations for MA EPs we are modifying the regulation text at § 495.204(b)(5) to say that qualifying MA organizations "may" obtain attestations from qualifying MA EPs and "may" submit such information to us—rather than "must." And, we add a new subparagraph (6) that allows the physician group or other payer to

provide EP reimbursement information directly to us. We also provide assurances that we will use the EP reimbursement data for no other purpose than to compute the MA EP incentive payment due the qualifying MA organization.

Comment: One commenter said that in the proposed rule the 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 would require review and approval by CMS; and that such methodology "could be based on the relative share of patient care hours spent with MA enrollees of the organization or another reasonable method." However, the commenter opined, the proposed rule offers no details about how the review and approval process would be conducted, including dates and timelines for the process. Thus, the commenter recommended that CMS permit flexibility in allowing MA organizations to develop methodologies that will be reasonable in light of organization structure and systems, it is important to provide some guidance about how CMS will review and approve such proposals. CMS should permit, the commenter said, any reasonable payment methodology method that is fair, relatively easy to administer, subject to audit and that provides a reliable approximation of Medicare Part B billing. In addition, the commenter concluded, CMS should provide a simple process for submission and approval of MA payment methodologies.

Response: In the proposed rule at § 495.204(b)(4) we offered flexibility related to the "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," said that the methodology had to be "approved by CMS," and that the amount could include an "additional amount related to overhead." Based on this comment we are adding a new clause (iii) that says that such methodological proposals must be submitted to CMS by June of the payment year, must be auditable by an independent third-party, and that CMS will review and approve or disapprove such proposals in a timely manner.

Comment: One commenter wanted to know what percentage of the incentive payments will go to eligible professionals under Medicare Advantage.

Response: No known percentage of incentive payment will go to eligible professionals under Medicare Advantage, since MA EP payments are made solely to qualifying MA organizations.

In the proposed rule we said that 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 § 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 final rule discusses our methodology for calculating the incentive payment for qualifying eligible hospitals under the Medicare FFS EHR program. As set forth in § 495.204(c)(2), we proposed 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 proposed to require submission of such data to us and adopt the same definition of "inpatient-bed-days" and other terms under the Medicare FFS EHR hospital incentive program specified in § 495.104 of this final rule. In such a case we proposed 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 proposed 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 proposed requiring qualifying MA organizations seeking reimbursement for their qualifying MA-affiliated eligible hospitals to submit similar data.

We said 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 proposed 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.

We did not receive any comments on these provisions and are finalizing them as proposed.

To the extent payments are made to qualifying MA organizations for qualifying MA EPs or qualifying MA-affiliated eligible hospitals, we proposed 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 proposed 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.

We did not receive any comments on these provisions and are finalizing them as proposed.

Finally, as we indicated above in section II.C.2. of this final rule, we are modifying the regulation text at § 495.204(b)(2) to be consistent with the change to § 495.202(b)(3), since final identification in § 495.202(b)(3) should occur at the same time as final revenue reporting under § 495.204(b)(2), in order to ensure that calculations of payments due under the MA EP incentive payment program can be finalized.

4. Timeframe for Payment

For payments to qualifying MA EPs, in § 495.206 we proposed the timeframe 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 proposed 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 final rule.

We proposed 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 proposed 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.

We said that 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 proposed 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 proposed to use the hospital inpatient bed-days data from the hospital FY that ends during the FFY prior to the FY that serves as the payment year. For qualifying MA-affiliated eligible hospitals, we proposed 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) additional 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 final 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 proposed 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.

Comment: Two commenters said that payments to MA organizations will be

delayed every year by an unspecified amount of time. The commenters said that it was understood that CMS is charged by statute to avoid making duplicate payments, however MA organizations should be paid without unspecified delay. A suggested alternative by the commenters was to permit MA organizations to attest that their MA EPs will not seek any payment under the Medicare FFS Incentive Program. Alternatively, the commenters suggested, CMS could use an installment payment system (permitted under statute as stated) for MA organizations. The commenters said that this would permit partial payment until the resolution of the duplicate payment issue and would avoid long delays in paying MA incentives.

Response: We do not agree that MA organization EHR incentive payments are subject to "unspecified delay." Rather, since MA organizations will be paid for MA EPs only if such EPs were not paid the maximum incentive payment under the FFS EHR incentive payment program, and since final claims data will not be available until two months after the close of the payment year—see § 495.102(a)(2)—CMS will not be able to compute MA EP payments until the FFS EHR incentive payment program has completed its calculations. This will occur in the early spring of the year after the close of a payment year. Moreover, MA-affiliated eligible hospitals will receive EHR incentive payments on the same schedule as other "subpart (d)" hospitals. Finally, note that MA EPs are free to leave qualifying MA organizations at any time, and since EPs are also free to register for eligibility under FFS Medicare or Medicaid EHR incentive payments, an attestation by a qualifying MA organization would have little merit. For these reasons we cannot accept the suggestion that qualifying MA organizations receive interim or partial mid-year payments for MA EPs.

After consideration of the public comment received, we are implementing these provisions as proposed.

5. Avoiding Duplicate Payment

We proposed 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 clause (i) of this paragraph 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 said 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. This will occur in the early part of CY 2012. In the MA EHR incentive payment program we proposed to follow the FFS EHR incentive payment program schedule—first computing Medicare FFS incentive payments for EPs and then computing and paying MA EP incentive payments, where appropriate—in all subsequent payment years.

We went on to explain that 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.

We also said that 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 proposed 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 said 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.

Finally, we said that 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 did not receive any comments on these provisions and are finalizing them as proposed.

6. Meaningful User Attestation

We proposed 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 proposed to adopt the definitions of meaningful user under the Medicare FFS program related to EPs and eligible hospitals in § 495.4. We are requiring 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.

In the proposed rule we said 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 EHR incentive program, we proposed 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 final 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.

Comment: The meaningful use criteria make reference to checking eligibility electronically and submitting claims electronically for 80 percent of patients seen. This would not be possible for us because, for most of our visits, there is no insurance company with which to check, and there is no eligibility to submit claims to. We are a capitated system and for most of the patient visits, the concept of checking eligibility and submitting claims in not relevant.

Response: This comment points out the difficulty in adopting FFS Medicare meaningful use measures for qualifying MA organizations, MA-affiliated hospitals and MA EPs. For purposes of determining meaningful use in a Medicare Advantage environment, we agree that submitting claims electronically is not a useful standard in a capitated environment where virtually all patients are members of the same insurance plan.

Comment: One commenter said that given the sensitivity of the data, and the RHQDAPU program specifications, the commenter believes CMS should never request that hospitals submit patient-level data to CMS, but that the data submitted should always be at the aggregated, summary level. The commenter encouraged us to state specifically that this is its intention in FY 2012 and all future years of EHR incentive program reporting. Some other commenters said that their health care delivery systems were based on an integrated care delivery model, where coordination of care is supported through program-wide EHR implementation that enables a patient's medical record to be shared among the members of the patient's care team. The commenters said they believed patient-centric electronic medical record models that integrate clinical information across providers align with goals of ONC's Strategic Plan and reform efforts that seek to enable more patient-centric integration of care. The commenters said that during any given reporting period under the EHR incentive payment program, patients may receive health care services from various providers (for example, the primary care physician, one or more specialists, nurse practitioners, etc.). The commenters said they had adopted program-wide policies and procedures for using their EHR system to promote coordinated delivery of care. Thus, the commenters said they intended to use their EHR system to support the functionality and care delivery criteria of meaningful use for all providers across their organizations. Within their organizations, they said, a single provider is never solely responsible for all the information in a given patient's electronic medical record. In fact, they said, many providers may access the patient's electronic record to view or add information, order tests or medications, review results, etc. They said the shared record makes it extremely difficult to reliably track all the meaningful use criteria to each EP in their organizations without adding additional administrative functionality to their systems that would do nothing to improve patient care. It would be inappropriate and not the intent of the EHR incentive payment program, they said they believed, to add unnecessary redundancy in care delivery (that is, providers re-entering correct demographic information to get "credit" for that measure). They said they intended to participate in the EHR incentive payment program under provisions for Medicare Advantage organizations. They went on to say that since the proposed rule states, "the qualifying MA organization must attest to the fact that each MA EP is a meaningful user of certified EHR technology * * *," they believed such attestation can be based on measuring criteria at a MA organizational level. While they acknowledged that meeting basic eligibility criteria is appropriate on an individual provider level (that is,

the MA EP must meet the same definition for EP under FFS, satisfy minimum hours per week delivering patient care services, not be hospital-based, etc.), they said they should be able to meet meaningful use criteria as a MA organization on behalf of all of their individual EPs, so long as they are able to demonstrate that their EHR system itself meets the criteria and its use is pervasive and consistent throughout their healthcare delivery sites. They recommended that where a patient's electronic medical record is shared among a team of providers within a MA organization, the meaningful use criteria be measured on an organizational versus an individual provider level. As an alternative they proposed that for any provider who treats a given patient, if the criterion is met in that patient's electronic record, all EPs who are members of the patient's care delivery team would receive "credit" for meeting that measure.

Response: We agree with the commenters in large part. We believe that continued reporting by qualifying MA organizations under the HEDIS program is the most appropriate way to protect personally identifiable patient information. We also believe that in integrated care delivery systems, it does not make sense to require specific individuals to enter specific data in order to obtain meaningful user status—especially in a Medicare Advantage environment where we will require only continued HEDIS reporting as a demonstration of meaningful use. Finally, we believe that reporting of clinical quality measures at the MA organization level is the most effective and appropriate means of attaining the ultimate goal of EHR adoption—improved patient outcomes and reduced healthcare costs.

Comment: Some commenters said that the proposed rule states that, "unlike the Medicare FFS EHR Incentive Program, where we will require the reporting of clinical quality measures * * * we will not require qualifying MA organizations to submit clinical quality measures * * * with respect to EPs * * * and with respect to eligible hospitals * * *. [W]e note that qualifying MA organizations sponsoring coordinated care 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." The proposed rule suggests allowing MA organizations to continue reporting these measures, but also considers requiring that MA organizations report those HITECH clinical quality measures that do not overlap with these currently reported measures "and are appropriate for the MA program." We believe this current reporting is both appropriate and sufficient to measure the clinical quality of MA programs and should be deemed to satisfy the clinical quality reporting requirements under the EHR incentive payment program. HEDIS, HOS and CAHPS reporting are well-established and subject to audit. The measures are specifically chosen to capture quality within MA organizations, in particular to measure the clinical quality of the team approach we use to deliver care. While we support consistency across the EHR incentive payment program, we are concerned that requiring MA organizations to create new mechanisms for this additional reporting would be unduly burdensome, especially if these additional measures would have to be reported at the individual provider or patient level. Another commenter said that their considerable experience with developing responses for new measures demonstrated how resource and labor intensive clinical quality measurement can be. For example, the commenter continued, during a recent effort to automate ten TJC (The Joint Commission) measures, we identified 87 data elements, only 37 of which are captured as discrete data. Of the remaining 50 measures, some are captured using discrete data in different places in the EHR, and some are captured using free text (for example, clinical trials and other irregular exclusion criteria) and will require the creation of new documentation tools. We estimate it will take one to two years of work for these ten measures to be fully automated, despite our relatively sophisticated use of data warehousing tools and our high level of automation in the data management process. The burden is especially heavy when measurement elements are ill-defined. Under meaningful use clinical quality reporting, over 120 measures have been proposed. Of these, 94 would be measures not currently calculated or reported on a routine basis. We anticipate a considerable increase in workload to create and maintain these measures. Adding new and duplicate—possibly less reliable—measures and reporting systems will be costly, time-consuming and may not have an incrementally significant impact on improving patient care. While we are not opposed to new metrics (those without similar known specifications), such measures should be field tested prior to becoming requirements; in particular, subject to rigorous testing of the electronic specifications. Such measures should also be supported by robust clinical evidence to show they will impact clinical outcomes. MA organizations should be deemed to have satisfied all clinical quality reporting required in the EHR incentive payment program by meeting their current reporting requirements. If additional measures are required, we recommend staged adoption, beginning with those measures that MA organizations already report or can report in the near future. We recommend eliminating measures that have little or no evidence to link them to improved outcomes. Overall, we strongly recommend that CMS significantly reduce the overall number of clinical quality measures that would be required for meaningful use.

Response: We agree with the commenters and believe that HEDIS, HOS and CAHPS are the appropriate means of reporting measures for both MA EPs and MA-affiliated hospitals. Where appropriate we will consider adding elements to these already existing quality reporting programs. We will consider adding HEDIS elements over time, as experience and clinical data warrant.

Comment: One commenter said one of the five priorities specified by CMS is to improve care coordination. However, the siloed nature of the incentive payments, lack of a robust set of care coordination measures, and the narrow definition of eligible professionals do not fully support this priority. The commenter also said that the current structure of the proposed incentive program, as required by statute, maintains the current siloed structure of Medicare and Medicaid payments. The selected functionality and quality measures in large part do the same. However, this siloed structure does not support or encourage integrated coordinated care across providers and settings. As greater attention is paid to improving care coordination and the quality of care through integrated care models (for example, accountable care organizations, patient-centered medical homes), greater attention should be given to selecting measures that focus on patient-centered episodes of care. Furthermore, consideration should be given to refining the incentive payment structure to foster integration and accountability among and across providers and settings.

Response: We believe that HEDIS reporting and other existing quality reporting programs (that is, HOS and CAHPS) go a long way toward assuring that coordination and integration of care will continue to occur in the Medicare Advantage environment. One of the

purposes of EHR adoption is to facilitate the coordination of care in health care environments where care coordination is not currently perceived to occur. We are asking providers to pick a program through which they are most likely to be eligible for EHR incentive payments. For MA organizations that treat Medicare, Medicaid and dually-eligible patients, EHR incentive payments will be made only under one program (Medicare or Medicaid) with respect to any specific EP. However care coordination should occur regardless of health insurance or EHR incentive payer. After consideration of the public comments received we are not changing our proposed policy to allow qualifying MA organizations to establish meaningful use through attestation and to demonstrate meaningful use through continued HEDIS reporting.

Finally, we proposed 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 proposed 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. In this final rule we are modifying the regulation text at § 495.210(b) and (c) to be consistent with the changes to § 495.204(b)(2) and § 495.202(b)(3), since the deadline for attestations of meaningful use should be consistent with deadlines for revenue reporting for MA EPs, and final identification of MA EPs and MA-affiliated hospitals. We are extending the timeframe for reporting meaningful use to 60 days after the close of the payment year.

7. Posting Information on the CMS Web Site

In the proposed rule we said that 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. We said posted 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 § 495.108.

We did not receive any comments on these provisions and are finalizing them as proposed.

8. Limitation on Review

In the proposed rule we said that 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. We said 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 proposed 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 proposed to codify these requirements in § 495.212(c).

We did not receive any comments on these provisions and are finalizing them as proposed.

9. Conforming Changes

In the proposed rule we said that 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 proposed 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 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.

We did not receive any comments on these provisions and are finalizing them as proposed.

10. Payment Adjustment and Future Rulemaking

In the proposed rule we said that 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 solicited 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.

Comment: Two commenters said that the EHR Incentive Program (the Medicare component) is limited to providers who bill for Part B covered services under traditional FFS Medicare or for MA organizations that provide equivalent services to MA beneficiaries. In addition to incentive payments, the program will impose penalties on providers who do not adopt technology and meet criteria for meaningful use of electronic health records; those penalties will be in the form of percentage reductions in Medicare reimbursements, beginning in 2016. Medicare section 1876 (of the Act) cost contract programs by statute are not eligible for the EHR Incentive Program. The proposed rule does not expressly state whether physicians paid under a cost plan will be required to meet meaningful use criteria to avoid the payment adjustments that will take effect after 2015. CMS should clearly state that those providers who are not eligible to participate in the EHR Incentive Program will not be subject to reductions in payment for not achieving meaningful use, for instance any providers reimbursed under Medicare cost contract arrangements.

Response: While it is true that current statute applies payment adjustments beginning in 2015 only to FFS and MA providers, it is also true that cost plan providers might provide either FFS or MA services to which adjustments would apply. So, while it is true that cost plan payments are unaffected, a blanket statement that cost plan providers are unaffected is not possible.

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 received no additional comments.

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 reasonable 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.

Finally, as required by section 1903(t)(10) of the Act, CMS 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.

Comment: A commenter requested additional discussion in the final rule of the many challenges that exist to adopting electronic health record technology experienced by the Medicaid Transformation Grantees.

Response: The primary challenges faced by the Medicaid Transformation Grantees involved assisting providers to adopt the EHRs and to successfully integrate utilization of the EHRs into their practice workflow. Workflow redesign is unique to each practice based upon practice size, clinical specialty area, practice operation (for example, medical home teams or specialty care) and the providers' hardware and software. In addition, Grantees reported that providers value the EHRs only in so far as the patient data in the EHR is timely and complete. Therefore lagging data feeds or gaps in data from certain sources, such as labs or Part D claims for dual eligibles, were observed to discourage providers from investing their time and effort into learning how to use the EHRs. Many Grantees noted that early negative experiences with workflow or with timely and accurate access to relevant data discouraged providers from using the system. They reported needing to dedicate significant time and resources to provider outreach, technical assistance and training. Some Grantees focused on identifying or developing the right EHR product only to conclude afterwards that their focus needed to be equally, if not more, on supporting their providers' use of the EHR, including fostering health information exchange through interface development. In summary, the Medicaid Transformation Grantees affirmed that the barriers faced by Medicaid providers to EHR adoption and use were not unique to Medicaid. There were several challenges to HIT/EHR implementation that were specific to Medicaid programs that may be useful for States in light of HITECH. These include, integration of HIT into the State Medicaid Management Information System (MMIS); churning

of Medicaid patients on/off Medicaid eligibility; issues of consent with patients with diminished capacity, children and their parents and caregivers, and foster children/wards of the State; costs associated with transaction fees for pharmacy hubs on a statewide scale; and how to calculate return on investment and quality outcomes as a result of HIT programs that are running concurrent with other quality initiatives with the same goals, such as the medical home model, disease management/care coordination and provider pay-for-performance.

While this information is valuable in terms of understanding and addressing the challenges to EHR adoption, we continue to believe that the benefits of meaningful use of EHRs far outweigh the implementation challenges.

2. General Medicaid Provisions

In § 495.320 and § 495.322 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.

We did not receive any comments and we are finalizing these provisions as proposed.

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 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). 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 will 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. for a definition of "hospital-based," and for a thorough discussion of our 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)(A)(iii) of the Act does not define "practices predominantly," we specify that an EP 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 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 § 495.306. Children's hospitals do not have patient volume requirements for Medicaid incentive program participation.

Comment: Commenters expressed confusion about the restrictions on physician assistants' (PAs) participation. Numerous commenters suggested that PAs should be eligible without conditions, particularly the condition that they are practicing in an FQHC or RHC that is "so led by a physician assistant" and/or CMS should exercise flexibility in defining "so led," in order to capture the highest number of PAs. We received specific comments on how to define "so led" to provide the greatest flexibility to PAs. Suggestions included allowing clinics under a larger FQHC to be led by a PA, but not necessarily the entire FQHC. Also, commenters asked that we consider "led" to mean the dominant clinical provider, which is the case for PAs in many RHCs.

Response: As stated in the statute at 1903(t)(3)(B)(v), regarding the program eligibility for PAs, PAs are eligible when they are a "physician assistant insofar as the assistant is practicing in a rural health clinic that is led by a physician assistant or is practicing in a Federally qualified health center that is so led." These conditions on PAs' eligibility apply whether the PA is qualifying because they meet Medicaid patient volume requirements or if they are qualifying because they practice predominantly in an FQHC or RHC. Since this language requiring that a PA must be leading the FQHC or RHC is derived from statute, we have no flexibility to change or remove it.

However, we agree that we have the authority to interpret what it means for a PA to lead an FQHC or RHC, and we believe a PA would be leading an FQHC or RHC under any of the following circumstances:

(1) When a PA is the primary provider in a clinic (for example, when there is a part-time physician and full-time PA, we would consider the PA as the primary provider);

(2) When a PA is a clinical or medical director at a clinical site of practice; or

(3) When a PA is an owner of an RHC.

We agree that FQHCs and RHCs that have PAs in these leadership roles can be considered "PA-led." Furthermore, since RHCs can be practitioner owned (FQHCs cannot), we will allow ownership to be considered "PA-led."

With the exception of this clarification of PA-led, we are adopting this language as proposed. We have not changed our regulatory language, as we consider this clarification to be an interpretation of our regulations as to what it means to be a PA to be leading an FQHC or RHC.

Comment: We received questions about eligibility related to FQHC look-alikes, tribal clinics, and other similar facilities.

Response: As previously mentioned, in accordance with section 1903(t)(2)(B), the only two facilities eligible for incentives are acute care and children's hospitals. However, EPs at facilities such as FQHCs, RHCs, and tribal clinics may be eligible for participation when they practice predominantly at an FQHC or RHC or meet the other patient volume requirements. The statute defines FQHCs at 1905(l)(2)(B) and defines RHCs at 1905(l)(1) by essentially incorporating the definition in 1861(aa).

Comment: Numerous commenters opposed the proposed definition for "hospital-based."

Response: This is a consideration for Medicare and Medicaid and is addressed in II.A.

After consideration of the public comments received, we are making changes under II.A.

(1) Acute Care Hospitals

For purposes of Medicaid incentive payments, we proposed to define an "acute care hospital" as a health care facility where the average length of patient stay is 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 excluded from this proposed definition a category of long-term care hospitals, which are defined for Medicare purposes in regulations at § 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).

Comment: We received numerous comments recommending that CAHs be included in the definition of acute care hospitals for purposes of the Medicaid EHR incentive payment program. Commenters pointed out that the CAHs would qualify on all criteria except for the requirement to have a CCN in the range 0001–0879. CAHs have CCNs in the range 1300–1399. Moreover, many commenters pointed out that, because of their rural location and distance from other hospitals to which they frequently transfer patients, the CAHs would benefit from having electronic records that could be shared with the subsequent provider of care to the patient. Commenters also asked what reimbursement methodology CMS would use if it decided to include CAHs in the Medicaid incentive payment program.

Response: We agree with the commenters that CAHs conform to our definitional criteria for acute care hospital except for the CCN range. Moreover, we recognize the positive impact on quality that may ensue from the CAH's being able to electronically communicate with the hospitals to which it transfers patients. Therefore, in the final rule, we are amending the definition of acute care hospital for purposes of the Medicaid EHR incentive payment program as "those hospitals with an average patient length of stay of 25 days or fewer, and with a CCN that falls in the range 0001–0879 or 1300–1399." This definition will now encompass general short-term hospitals, cancer hospitals, and critical access hospitals that meet the Medicaid patient volume criteria. Since we are including CAHs under the category of "acute care hospital," we are not developing a separate Medicaid incentive payment calculation for CAHs. States will pay the incentive payment to qualifying CAHs using the acute care methodology described at section 495.310(g). In summary, CAHs will be eligible for the Medicaid hospital incentive insofar as they meet the requirements under an acute care hospital described here. While the statute issued specific calculation requirements for CAHs under Medicare, there is no special Medicaid calculation. Like other acute care hospitals, some CAHs may be eligible for Medicare and Medicaid incentives.

We will reflect this definitional change in the final regulation at section 495.302.

Comment: Further guidance was requested on the determination of average length of stay. Commenters questioned whether the average length of stay should be calculated relative to the fiscal year prior to the payment year or relative to the calendar year prior to the payment year. Commenters also questioned whether outliers in terms of extremely long length of stay could be left out of the calculation, and if so, could CMS provide detail on this and any similar exclusions; for example, other exclusions with respect to observation stays.

Response: After consideration of these comments, we believe the best policy is to allow the States to decide whether they will use a fiscal year or calendar year for calculating length of stay, as the State will be in the best position to determine what documentation exists in order to support any length of stay calculation. With respect to outliers, we point readers to the State Operations Manual, page 303, Revision 57, dated January 29, 2010 and we note that these long (and short) stay outliers are included in average length of stay calculations for other purposes, such as reporting statistics to States, Medicare, and other payers. We do not find a basis for excluding outliers from the average length of stay for purposes of the incentive payment. In fact, since acute care hospitals have CCNs in either the 0001–0879 or the 1300–1399 range, and length of stay is one of the definitional criteria for CCNs in these ranges, all of the acute care hospitals are very likely to meet length of stay criteria. Observation stays are considered to be outpatient services and, therefore, cannot be included in average length of stay calculations. This is consistent with the treatment of observation days under Medicare.

In summary we are making no revisions to the regulation as a result of this comment.

(2) Children's Hospitals

For purposes of the Medicaid EHR incentive program, in the proposed rule, we proposed 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 defining "children's hospital" in this way, we: (1) Prevented general acute care hospitals, which could not themselves qualify for the incentive because they did 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) excluded 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) excluded some pediatric specialty hospitals which have CCNs as psychiatric or rehabilitation hospitals.

An alternative definition of a "children's hospital" was also proposed to 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, applied only to those freestanding hospitals within the above mentioned series that exclusively furnish services to individuals under age 21.

This broader definition still: (1) Prevented 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) allowed for participation in the incentive program by the greatest number of children's hospitals, including rehabilitative and psychiatric specialty hospitals; and (3) aligned with Federal efforts aimed at improving healthcare quality for all children, including those with physical and mental diseases/disabilities.

Comment: CMS received several comments on this issue. Specifically, the commenters stated that the proposed rule limited the definition of children's

hospitals to those that provide care to individuals under the age of 21; the commenters stated that children's hospitals actually may provide care to older individuals who have conditions such as congenital cardiac problems, sickle cell disease and cystic fibrosis.

Response: We agree with the commenters that children's hospitals do on occasion treat patients who are over the age of 21, especially if the patient is on a continued course of treatment for a condition that began in childhood, such as those conditions mentioned. Accordingly, in the proposed rule published on January 13, 2010 at section 495.302, we defined a children's hospital for purposes of the HIT incentive payment program as a hospital that is separately certified as a children's hospital, with a CCN in the 3300–3399 series and predominantly treats individuals under the age of 21. We used the term "predominantly" to recognize that not all patients of the children's hospital are in fact under age 21.

This definition addresses the commenters' concerns and we are not revising it in the final rule. The commenter's may have been responding to the alternate definition in which we requested comments. While that alternate definition mentioned specialty hospitals that exclusively treat individuals under the age of 21, we are not adopting that definition in this final rule, as noted in the response to the comment below.

Comment: CMS also received a few comments that supported our proposed definition of children's hospital as those that are separately certified and predominantly treating individuals under 21 years of age. The commenters urged us to adopt this definition rather than the alternate definition discussed in the proposed rule and on which we requested comments.

Response: We agree with the commenters and are adopting the definition that we originally proposed at section 495.302. See the response to the comment below.

Comment: CMS received one comment that recommended use of the alternative definition as providing more opportunity for hospital participation.

Response: We considered the merits of both definitions and we have decided to maintain the definition originally proposed in section 495.302 as representing the clearest definition of a children's hospital. As previously stated, we only intend to include children's hospitals with CCNs within a specific range; this will not include pediatric wings of larger hospitals.

In summary, after considering the comments, we are adopting the definition of children's hospital as originally proposed.

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; our proposed methodologies which follow, are based on this discretion. To establish such patient volume, we proposed that the EP have a minimum of 30 percent of all patient encounters attributable to Medicaid over any continuous, representative 90-day period within the most recent calendar year prior to reporting. There are two statutory 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 medical assistance 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 proposed to use was that the pediatrician have a minimum 20 percent of all patient encounters attributable to Medicaid over any continuous, representative 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 would 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.

Comment: Many commenters requested that CMS consider groups outside of the statute eligible for incentive payments. These facilities and practitioners included: Community mental health centers and other behavioral health providers (including psychiatric clinics); nursing homes, nursing facilities, and skilled nursing facilities; long-term care providers (community and institutional), including home health care providers; pharmacists and pharmacies; social workers; blood centers; provider based departments; professional societies; Medicaid-participating health plans; speech-language pathologists and audiologists; FQHCs, RHCs, tribal providers, and other community clinics; health aides; and podiatrists. The commenters included numerous testimonials, research, and statements to note that these providers are critical partners in improving the quality and coordination of care for the Medicaid population. Some of the commenters acknowledged that this is a statutory issue but assert that exclusion of such providers impacts Medicaid's ability to improve the quality and efficiency of care. Furthermore, some of these commenters based several additional comments upon presumed eligibility. For example, some commenters said that social workers could not afford EHRs and should not be required to participate.

Another group of comments came from health care professionals that sought eligibility for incentives by virtue of early adoption of EHRs but who do not participate in either Medicaid or Medicare. They suggested a third incentive option available for providers that either do not participate with Medicaid/Medicare or would not reach the threshold of patient visits to receive Medicaid incentive payments.

Response: We note that the commenters are correct to recognize that this is a statutory issue. The definition of a "Medicaid EP," at 1903(t)(3)(B) of the Act, lists five types of professionals that are eligible for Medicaid incentive payments: physicians, dentists, certified nurse-midwives, nurse practitioners, and physician assistants practicing in an FQHC that is led by a physician assistant or RHC that is so led. Additionally, the statute at 1903(t)(2)(B) designates acute care hospitals and children's hospitals as the only two types of facilities eligible for the Medicaid incentives. These providers must also meet all other program requirements, including Medicaid patient volume thresholds.

Since the commenters recommend including providers that are not among those explicitly mentioned in the statute, these providers cannot be eligible for the incentive payments.

Additionally, professionals who do not participate in either Medicaid or

Medicare are also not eligible for incentives due to the statutory requirements associated with each program. Specifically, the Medicaid incentives program requires providers to meet Medicaid patient volume thresholds or practice predominantly in an FQHC or RHC, where they must serve needy individuals (as defined at section 495.10). Additionally, the hospital calculations for Medicare and Medicaid are based, in part, on Medicare or Medicaid inpatient bed-days. For Medicare EPs, the incentive is based on the associated Medicare claims. Hence, these professionals cannot meet the statutory requirements for eligibility.

After consideration of these comments, we are maintaining the list of providers eligible for the Medicaid incentive payment program as originally proposed and as identified by statute.

It is worth noting that while the facilities recommended for inclusion by the commenters will not be considered eligible to participate in these incentives, some of the EPs at these facilities may be eligible. One example is that a psychiatrist (physician) or NP is likely to treat individuals at a behavioral health facility. Per our rules at section 495.10, the EP must identify a TIN to which the incentive payment should be made. We believe that, in accordance with 1903(t)(6)(A) of the Act, an EP could reassign payment to a TIN associated with his or her employer or the facility in which she or he works. This facility could be one of those recommended for inclusion by the commenters. Any reassignment of payment must be voluntary and we believe the decision as to whether an EP does reassign incentive payments to a specific TIN is an issue which EPs and these other parties should resolve. Any reassignment of payment must be consistent with applicable laws, rules, and regulations, including, without limitation, those related to fraud, waste and abuse.

We have provided clarifying language at section 495.10(f) to further clarify the reassignment of incentive payments by EPs to specific TINs.

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 define "patient volume" in § 495.302 to be a minimum participation threshold for each individual Medicaid provider (with the exception of children's hospitals). In the proposed rule, we proposed methodologies for estimating the patient volume thresholds and listed them by entity type.

Further, we proposed that States could submit alternative approaches to the established timeframe for estimating patient volume, through their State Medicaid HIT Plans (SMHP) and we would make a determination of whether it was an acceptable alternative.

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 require the 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). In order to remain as consistent as possible between the Medicare and Medicaid EHR incentive programs, States will be required to downward adjust the uncompensated care figure. 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 a Medicaid managed care plan be included. We interpret this to mean that individuals enrolled in 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.

Comment: Commenters recommended that CMS provide flexibility in the specific volume thresholds required for program participation (for example, 30 percent for most EPs, 20 percent for pediatricians) and apply a lower percentage or a minimum number of encounters. Some commenters referenced research stating that practices with a 30 percent patient volume may not be financially viable.

Response: The patient volume thresholds of 30 percent and 20 percent are required by statute and cannot be changed in the rulemaking process.

After consideration of the public comments received, we are not making any changes to these statutory requirements.

Comment: Commenters suggested that CMS define "encounter" and take a menu approach to patient volume to allow States several options, based on their data sources. Some commenters provided specific suggestions for patient volume "menu" items. Some commenters further noted that there were inconsistencies in how we applied "encounter" data. Finally, one commenter noted that we should consider how "encounter" data is applied to EPs that bill services through another provider (for example, PAs that bill through MDs). Other commenters asked for a clarification of how "encounters" would apply to the dually-eligible Medicare/Medicaid beneficiaries. Additionally, several commenters provided specific suggestions for alternative methods making an approximate determination of providers' patient volume by [not using patient volume] and extending the look-back period to two years.

Response: We agree with the approach of offering at least some options to States regarding patient volume. This approach allows States to audit their programs using the data sources available to them, while also including the largest number of providers that may treat Medicaid patients. We believe our new approach will correct the inconsistencies in how we applied "encounter." Furthermore, our new definition of encounter will capture the dually-eligible beneficiaries, as well as individuals who are in a Title XIX-funded 1115 demonstration project. Specifically, the statute at 1903(t)(2) states that Medicaid patient volume will be "attributable to individuals who are

receiving medical assistance under [Title XIX]," and also states that the patient volume calculation for those practicing predominantly in an FQHC or RHC will be "attributable to needy individuals." Needy individual is defined at 1903(t)(3)(F) as "an individual—(i) who is receiving assistance under Title XIX; (ii) who is receiving assistance under Title XXI; (iii) who is furnished uncompensated care by the provider; or (iv) for whom charges are reduced by the provider on a sliding scale basis based on the individual's ability to pay." We believe our final rule definition of "encounter" captures care to all of these individuals.

Additionally, consistent with the statute, we expect providers and States to make estimation in accordance with the methodologies we established here. This estimation would need to be made with reasonable effort, using verifiable data sources by the provider and the State.

Finally, we do not agree with any of the suggestions from commenters that involve using a benchmark number of Medicaid patients or other suggestions that involve a deviation from the statutory language. The statute is clear that Medicaid patient volume must be considered and explicitly specified percentages of caseload mix compositions attributable to either Medicaid and/or "needy" individuals that must be achieved for participation in the incentive program. We also do not agree with allowing the provider to consider a period longer than a year prior to registering because that is not a current, accurate portrayal of the provider's participation in Medicaid.

After consideration of the public comments received, we are revising the patient volume approach to the following two options. The State may choose one of the two options listed below (or both options), or a State-proposed alternative, if approved by CMS. The State's strategy must be submitted for review and approval through the SMHP, in accordance with all requirements at section 495.332.

A Medicaid provider may demonstrate patient volume by:

(1) Having patient encounters within the 90-day period by using the same methodology we proposed in the proposed rule.

This first option preserves the methodology we proposed in the proposed rule, however we clarify "encounter" below. For the Medicaid patient volume, the methodology for estimating patient volume would require calculation of a threshold (represented below) 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 representative continuous 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 methodology for estimating patient volume would require the same calculation, 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 Individual) patient encounters in any representative continuous 90-day period in the preceding calendar year/Total patient encounters in that same 90-day period] * 100

Table 15, below, demonstrates the above-referenced patient volume thresholds. (This same Table appeared in the proposed rule, with a few minor clarifications included in this Table).

TABLE 15: Qualifying Patient Volume Threshold for Medicaid EHR Incentive Program

Entity	Minimum 90-day Medicaid Patient Volume Threshold	
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%	N/A
Children's hospital	N/A	N/A

(2) Having a Medicaid enrollee on the panel assigned to the EP (for example, managed care or medical homes) within that representative 90-day period.

With more than 70 percent of Medicaid and CHIP enrollees receiving care in a managed care delivery system, and additional enrollees in medical homes, we determined that it was necessary to look for flexibility in how we applied these requirements. Under this option, we wanted to capture the EP's panel assignments, as well as any additional unduplicated Medicaid encounters. In other words, we do not intend for the EP to count an assigned patient who was also an encounter more than once.

The methodology for estimating the Medicaid patient volume threshold (represented above) would use as the numerator the individual hospital's or EP's total number of Medicaid patients assigned through a Medicaid managed

care panel, medical or health home program panel, or similar provider structure with capitation and/or case assignment, plus all other Medicaid encounters for that EP. The assignment must be current within the 90-day period and we will consider as a proxy for this an encounter with any patient on the panel within the previous calendar year prior to the representative 90-day period when the patient was on the panel. Note that, as stated above, while the EP may add in encounters with other, non-panel Medicaid patients to the numerator, these encounters must be patients who are not assigned to a panel and would be encounters that occurred during the representative 90-day period. The denominator is all patients assigned to the EP or hospital for the same 90-day period, also with whom the provider had at least one encounter in the prior calendar year as a proxy, as well as any other unduplicated Medicaid encounters during the representative 90-day period.

{[Total (Medicaid) patients assigned to the provider in any representative continuous 90-day period in the preceding calendar year, with at least one encounter taking place during the calendar year preceding the start of the 90-day period] + [Unduplicated (Medicaid) encounters in the same 90-day period]/[Total patients assigned to the provider in that same 90-day period, with at least one encounter taking place during the calendar year preceding the start of the 90-day period] + [All unduplicated encounters in that same 90-day period]} * 100

For the needy individual patient volume for EPs enrolled in managed care and medical homes, the threshold (represented below) would be calculated in the same manner, but with the numerator equal to the EP's total number of needy individuals assigned to the patient panel in any representative 90-day period in the preceding calendar year with at least one encounter within that year.

{[Total (Needy Individual) patients assigned to the provider in any representative continuous 90-day period in the preceding calendar year, with at least one encounter taking place during the year preceding the 90-day period] + [Unduplicated (Needy Individual) encounters in the same 90-day period]/[Total patients assigned to the provider in that same 90-day period, with at least one encounter taking place during the year preceding the 90-day period] + [All unduplicated encounters in that same 90-day period]} * 100

Table 15 demonstrates the above-referenced patient volume thresholds per provider type.

In order to resolve any inconsistencies with the definitions of "encounter," for purposes of EP patient volume, we have allowed the following to be considered Medicaid encounters:

(1) Services rendered on any one day to an individual where Medicaid or a Medicaid demonstration project under section 1115 of the Act paid for part or all of the service; or

(2) Services rendered on any one day to an individual for where Medicaid or a Medicaid demonstration project under section 1115 of the Act paid all or part of their premiums, co-payments, and/or cost-sharing.

For purposes of calculating hospital patient volume, we have allowed the following to be considered Medicaid encounters:

(1) Services rendered to an individual per inpatient discharges where Medicaid or a Medicaid demonstration project under section 1115 paid for part or all of the service;

(2) Services rendered to an individual per inpatient discharge where Medicaid or a Medicaid demonstration project under section 1115 of the Act paid all or part of their premiums, co-payments, and/or cost-sharing;

(3) Services rendered to an individual in an emergency department on any one day where Medicaid or a Medicaid demonstration project under section 1115 of the Act either paid for part or all of the service; or

(4) Services rendered to an individual in an emergency department on any one day where Medicaid or a Medicaid demonstration project under section 1115 of the Act paid all or part of their premiums, co-payments, and/or cost-sharing.

We wanted to adequately reflect what an encounter looked like for a hospital and apply these concepts consistently across the numerous areas of this final rule. We used inpatient discharges and emergency department services for the hospitals because this is consistent with how we will make hospital-based determinations for EPs and how we collect meaningful use information for hospitals. We decided that services rendered on one day would be an encounter. An emergency department must be part of the hospital under the qualifying CCN.

For purposes of calculating *needy individuals patient volume,* we have allowed the following to be considered needy patient encounters:

(1) Services rendered on any one day to an individual where Medicaid or CHIP or a Medicaid or CHIP demonstration project under section 1115 of the Act paid for part or all of the service;

(2) Services rendered on any one day to an individual where Medicaid or CHIP or a Medicaid or CHIP demonstration project under section 1115 of the Act paid all or part of their premiums, co-payments, and/or cost-sharing; or

(3) Services rendered to an individual on any one day on a sliding scale or that were uncompensated.

We understand that multiple providers may submit an encounter for the same individual. For example, it may be common for a PA or NP to provide care to a patient, then a physician to also see that patient. It is acceptable in circumstances like this to include the same encounter for multiple providers when it is within the scope of practice.

We considered whether Medicaid providers or States should pick from the two options provided above. Since States are responsible for auditing the program and must have reliable sources of data, we agree with commenters that it must be States that make a determination as to whether either option will be permitted (or both).

In the proposed rule, we also proposed that if States had an alternative approach for the timeframe in accounting for the methodology, they would be allowed to submit it in the SMHP for review and approval. For the final rule, we are modifying this option. As stakeholders' understanding of the program matures and new technologies become available, there may be new solutions that we did not consider here, but would be a better option for one or several States. To that end, in this final rule we are providing flexibility to consider States' alternative methodologies for measuring not just the timeframe that is used in establishing patient volume, but all of the elements included in the patient volume calculation (except the thresholds established by statute). Therefore, we have revised our final regulations to allow States to offer alternatives regarding the methodology used to establish patient volume, and for the Secretary to adopt these options, so that they may be used by other States as well. An alternative would need a verifiable data source. A State also would need to provide us with an analysis to demonstrate that the methodology being proposed by the State did not result, in the aggregate, in fewer providers becoming eligible than under the two options presented in this final rule. Finally, if a State is reviewed and approved for an alternative

methodology, we will post this alternative methodology on the CMS internet Web site, and allow other States to adopt the methodology as well, thereby ensuring that the alternative is a methodology that is "established by the Secretary." While we believe that States will not submit alternative methodologies until after the first year of the program, allowing for such alternatives will permit the patient volume calculation to evolve along with State and provider experience of the program.

We believe that these solutions will help address issues for providers practicing across State lines, who may have their Medicaid patient volume derived from more than one State. We encourage States to build partnerships, particularly through data sharing agreements. Medicaid providers must still annually re-attest to meeting the patient volume thresholds.

After consideration of the comments, we are revising § 495.302, § 495.306, and § 495.332 regarding patient volume, patient encounters and the associated revisions to the SMHP requirements.

Comment: Commenters asked CMS to include all individuals receiving services through section 1115 demonstrations as eligible encounters.

Response: Although the commenter did not elaborate, we believe the commenter is referring to section 1115 demonstrations under the authority of section 1115(a)(2) of the Act. Our final regulations allow two alternate methods for States to estimate Medicaid patient volume. Under both methods, however, the State must review whether a Medicaid "patient encounter" occurred. Our regulations, at 495.306(e) state that a Medicaid encounter will exist where Medicaid (or a Medicaid demonstration project approved under section 1115) paid for part or all of the service; or where Medicaid (or a Medicaid demonstration project approved under section 1115) paid all or part of the individual's premiums, co-payments and/or cost-sharing. Because our methodology is based upon Medicaid payment for an encounter, and because we believe it will be difficult or impossible for EPs and eligible hospitals to distinguish between payment that is due to patients receiving medical assistance under Title XIX and payment that is due to expansion populations (who are not receiving Title XIX medical assistance), we will allow providers to include in the patient volume calculation individuals who are part of expansion populations under section 1115(a)(2) of the Act. The statute confers broad authority on the Secretary to establish the methodology that is used to estimate the patient volume percentage. Thus, although individuals in section 1115(a)(2) demonstrations are not receiving Title XIX medical assistance, we use our broad authority to allow a methodology that considers these individuals in the estimate that is used. (Limited to Medicaid patient volume determinations, the same reasoning would not apply to CHIP demonstrations or to State-only programs, because no Title XIX funding is received for these projects. However, in calculating Needy Individual patient volume, it is permissible to consider Medicaid or CHIP demonstration projects approved under section 1115.) Our above discussion noting what will be considered a patient encounter includes encounters which were paid for with Title XIX funds under a section 1115 Medicaid demonstration.

Comment: Several commenters asked that CMS allow CHIP patients to be considered in the Medicaid patient volume requirements, particularly for pediatricians.

Response: The requirement that the methodology for estimating Medicaid patient volume is based on Medicaid and not CHIP is related to the statutory language at section 1903(t)(2)(A)(i)–(ii)). Such language requires that the Secretary establish a methodology that can be used to estimate "Medicaid" patient volume for those individuals receiving medical assistance under Title XIX. However, the statute at 1903(t)(2)(A)(iii) allows for an EP practicing predominantly in an FQHC or RHC to consider CHIP patients under the needy individual patient volume requirements.

After consideration of these public comments, we are making no further revisions to this section of the rule.

Comment: Many commenters urged CMS to allow practice- or clinic-level patient volume data to apply to practitioners as a proxy to establish patient volume. This would apply for both Medicaid and needy individual patient volume calculations. The commenters stated that many clinics and group practices do not necessarily track the pay or data per EP and it would be very disruptive to their current practice to begin collecting data like this.

Response: We agree with commenters and acknowledge that it is not our intent to disrupt the practice with new additional burdens, but rather to leverage efficiencies. We will allow clinics and group practices to use the practice or clinic Medicaid patient volume (or needy individual patient volume, insofar as it applies) and apply it to all EPs in their practice under three conditions: (1) The clinic or group practice's patient volume is appropriate as a patient volume methodology calculation for the EP (for example, if an EP only sees Medicare, commercial, or self-pay patients, this is not an appropriate calculation); (2) there is an auditable data source to support the clinic's patient volume determination; and (3) so long as the practice and EPs decide to use one methodology in each year (in other words, clinics could not have some of the EPs using their individual patient volume for patients seen at the clinic, while others use the clinic-level data). The clinic or practice must use the entire practice's patient volume and not limit it in any way. EPs may attest to patient volume under the individual calculation or the group/clinic proxy in any participation year. Furthermore, if the EP works in both the clinic and outside the clinic (or with and outside a group practice), then the clinic/practice level determination includes only those encounters associated with the clinic/practice.

We have revised our regulations to make clear that when patient volume is calculated on a group-practice/clinic level, the above rules will apply.

Comment: Similar to the last comment, we received comments requesting clarification on how the patient volume requirements will apply in States with seamless eligibility determinations and payments for their program. For example, some States have streamlined their programs so that the potential beneficiary is applying for any public health care program for which they might be eligible (for example, Medicaid, CHIP, State-only) in one application. Often these States have one enrollment card as well. In other words, it is likely that both the beneficiary and the health care provider might have no indication as to whether the beneficiary is receiving assistance under Title XIX, Title XXI, or State-only funds. This becomes a problem when attempting to determine if the provider meets the patient volume requirements.

Response: If there is a combined program like the one in the example, this does not mean that all the encounters are being paid for with Title XIX funds (or the individual's premium or cost-sharing is funded through Title XIX), which is how we explained we would determine Medicaid patient encounters. We do not believe it would be reasonable to allow an encounter that is paid for with Title XXI or State-only funds to be considered a "Medicaid encounter." Thus, States with combined programs (for example, Medicaid/CHIP expansion programs), may indeed have difficulty determining who is eligible

for participation in this incentive program.

Considering these States have made enormous strides to reduce the confusion and burden associated with eligibility and payment for these programs, and also to reduce the stigma sometimes associated with Medicaid, we want to support the work they have done.

After consideration of the public comments received, we believe that the best course of action is to work with these States on a case-by-case basis through providing guidance as they develop the SMHP. We believe that each State will have different data and information available to them. The States should make sure that the health IT coordinators are working closely with the Medicaid (and CHIP, as it pertains to this program) policy staff on all aspects of the program. The goal will be to find a solution that leverages the State's existing and/or future data sources, as well as looking for flexible alternatives, while still honoring Congress' intent for the patient volume requirements, as established in the statute.

Comment: Some commenters pointed out that not all Medicaid providers use an EHR or submit electronic claims, making it tedious to capture a numerator and denominator for patient volume until the providers have adopted an EHR. Additionally, some commenters expressed concern about how providers would determine the denominator for patient volume and how States would audit the resulting percentage.

Response: While the commenters may be correct about the assertion that not all providers use an EHR or submit electronic claims, we do not believe it will prevent EPs and eligible hospitals from participating. These providers are businesses and there is an expectation that they are tracking their receivables from all entities (including Medicaid) associated with specific patients. In other words, we do not see a connection between electronic claims and current EHR use and calculation of the patient volume. Furthermore, when EHRs are used with practice management systems, we believe that in most cases, this data should be derived from the electronic systems.

When States consider their audit strategies, they should leverage existing data sources to the extent possible, but also consider future data sources. Part of the Medicaid Information Technology Architecture (MITA) principles associated with the SMHP development includes consideration of the "as is" world, as well as the "to be" world. While States may not have the systems in place today for a complete picture, we expect a longer-term strategy leveraging better data systems.

After consideration of the public comments received, we are not making any change on the basis of this comment. We provided additional flexibility in the patient volume requirements, which may help providers more easily calculate their patient volume and provide for flexibility when States begin to audit providers.

Comment: Commenters requested clarification on how to determine eligibility for the five types of Medicaid EPs. Commenters also noted that there was a potential difference between Medicare and Medicaid for the definition of "physician." Finally, other commenters were confused if, as a specialty practitioner, they qualified as one of the EP types.

Response: We agree with the commenters that there is a distinction between the Medicare and Medicaid definitions of physician. The Medicare statute at section 1848(o)(5)(C) defines an eligible professional as including all the professionals listed in section 1861(r) of the Act (which, generally stated, includes podiatrists, chiropractors and optometrists), the Medicaid statute does not incorporate all of 1861(r). Rather, the Medicaid statute defines what are physician services for purposes of qualifying as medical assistance under section 1905(a)(5)(A) of the Act, and states that physician services constitutes services furnished by a physician as defined in section 1861(r)(1) (which includes only doctors of medicine or osteopathy legally authorized to practice medicine and surgery by their State). In addition, section 1905(e) permits States the option to consider optometrist services as physician services. In this case, the State plan must specifically provide that the term "physicians' services" includes services of the type which an optometrist is legally authorized to perform.

Thus, in keeping with the statute, a physician would be limited to doctors of medicine or osteopathy legally authorized to practice in their State, and, in cases where States have specifically adopted the option of 1905(e) in their State plans, optometrists.

In addition, States would need to refer to their own scope of practice rules to determine whether an individual qualifies as providing dental, nurse practitioner, physician assistant, or certified nurse midwife services. Also, States and EPs would need to refer to CMS regulations. These regulations, at 42 CFR 440.60 require that practitioners be licensed and that they are within the scope of practice defined under State law (see also 1905(a)(6)). 42 CFR 440.100(b), defines a dentist as an individual licensed to practice dentistry or dental surgery in his or her State. 42 CFR 440.165 defines a nurse midwife as a registered professional nurse who meets the following requirements: (1) Is currently licensed to practice in the State as a registered professional nurse; (2) is legally authorized under State law or regulations to practice as a nurse-midwife, (3) has completed a program of study and clinical experience for nurse-midwives as specified in the State, unless the State does not specify such a program. (4) In the case where the State has not specified a particular program of study and clinical experience, the regulation provides alternative means for demonstrating this training. *See* also section 1905(a)(17), defining certified nurse midwife with reference to section 1861(g). 42 CFR 440.166 contains a definition of what qualifies as nurse practitioner services and requires a nurse practitioner to be a registered professional nurse who meets the State's advanced educational and clinical practice requirements, if any, beyond the 2 to 4 years of basic nursing education required of all registered nurse. States will have a Medicaid State Plan (and often State regulations) that designates how each provider is eligible to participate in the Medicaid program by practice type. All of these practitioners must meet all other eligibility requirements (including Medicaid patient volume) in order to participate.

Regarding the confusion by some specialty providers (for example, advanced practice nurses, pediatricians, physician sub-specialties, etc.), so long as an EP qualifies as a practitioner within the State's scope of practice rules for each of the five EP types, they are eligible for this program. In other words, since pediatricians are physicians, they must meet the physician scope of practice rules and then they may be eligible for an incentive when they meet all other requirements. Advanced practice nurses who meet their State's criteria for qualifying as a nurse practitioner would qualify as nurse practitioners. We believe most States would recognize APNs as NPs within their scope of practice rules. Eligible provider types must be specified in a State's SMHP.

After consideration of the public comments received, we are revising the definition of these EPs under section

495.304 to clarify additional scope of practice requirements.

Comment: Commenters requested clarification on how full- or part-time status impacts an EP's eligibility for incentives.

Response: Full or part-time status does not affect patient volume calculations or whether an EP's practice is predominantly in an FQHC or RHC. There is no mention of requisite number of hours in the statute or this final rule as a pre-condition for eligibility.

After consideration of the public comments received, we are not making any revisions to this section of the final rule.

e. Entities Promoting the Adoption of Certified EHR Technology

We 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 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. Under 1903(t)(6)(A)(ii) of the Act and as proposed in § 495.332, 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 proposed 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 definition for promoting the adoption of certified EHR technology is in § 495.302.

Comment: A commenter recommended that CMS require that entities designated by States that promote the adoption of EHR technology must use qualified EHR technology and be able to capture, query and/or exchange data from beyond a practice or closed system in order to foster interoperability, and to promote competition among EHR vendors with vendor-neutral and provider-neutral solutions. The commenter recommended that entities that promote the adoption of certified EHR technology be certified to an electronic hub that permits the exchange of electronic structured data on a provider-neutral basis.

Commenters also requested that the Regional Extension Centers funded by ONC be permissible as entities designated by the State to be eligible to receive EPs assigned incentive payments.

Response: States will have the discretion to identify entities that promote the adoption of certified EHR technology in accordance with our definition in regulation. We do not agree that the definition of "promotion of the adoption of EHR technology" requires the designated entity itself to utilize certified EHR technology. A variety of entities might offer services that meet the language included in this final rule defining promoting EHR adoption. We wish to point out that there is also a discussion of reassignment of payments in Section II.B.1.d. of this rule.

After consideration of the comments, we are adopting the language as written with the additional clarification that we encourage States to consider how they will verify on an ongoing basis that the entities that they designate are in fact promoting EHR adoption, per the requirements. Their responsibility to audit this element might be a factor in identifying which entities they wish to designate, in terms of tangible EHR promotion activities.

We agree that our definition of "promoting EHR adoption" does not preclude the ONC-funded Regional Extension Centers from being designated by States for this role.

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.

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 set the average allowable cost at $54,000. We established this average allowable cost at the high end of the range since the data we reviewed is based on certification criteria that may not be appropriate moving forward. Specifically, since the ONC is establishing new certification criteria for EHR technology, we believe the average cost of certified EHR technology incorporating the new criteria 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 requirements in the ONC interim final rule for the adoption of an initial set of standards, implementation specifications, and certification criteria for EHRs and the health measures data discussed in this final 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 originally 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 set the average allowable cost at $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. 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.

Comment: Several commenters are concerned that States are required to develop a method to determine the payment amount for each provider. Commenters believed that incentive payments should be based on the maximum amount and that individual calculations are cumbersome and a difficult process for both States and eligible professionals.

Response: We would like to clarify the requirements in the statute and the process by which incentive payments will be established. 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 is also 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. CMS conducted a literature review of recent studies on EHR technology to determine the average allowable cost of implementing

and using such technology. CMS reviewed the results from four recent, comprehensive studies and determined that these costs are $54,000 per professional. We recognize that this cost is variable and since the ONC is establishing certification criteria for EHR technology, we believe this cost is reasonable since we expect that current EHR technology will need to be upgraded in order to meet the new certification criteria.

Next, in accordance with the statute, in order to determine the net average allowable costs for each provider, average allowable costs for each provider must be adjusted in order to subtract any payment that is made to Medicaid eligible professionals and is directly attributable to payment for certified EHR technology or support services of such technology. The only exception to this requirement, as discussed above, is that payments from State, or local governments do not reduce the average allowable costs. The resulting figure is the net average allowable costs. The statute further indicates that Medicaid eligible professionals can receive up to 85 percent of a maximum of the net average allowable cost. In year one the maximum net average allowable cost is $25,000 and in subsequent years is $10,000. Additionally, the statute indicates that Medicaid eligible professionals are responsible for the remaining 15 percent of the net average allowable cost (1903(t)(6)(B)). We believe the commenters are concerned with the 85 percent of net average allowable cost maximum incentive payment amount and the responsibility of the Medicaid professional for the remaining 15 percent of the net average allowable cost.

Since the statute is clear that to get to the net average allowable cost, payments made to the EP that are directly attributable to the payment for certified EHR technology or support services for such technology for each provider have to be subtracted from the average allowable cost, this must be an individual provider calculation. We do not believe we have discretion to change this netting process directed by the Congress. We have provided an example calculation so that in using the average allowable cost established by the Secretary of $54,000 professionals could receive as much as $29,000 in payments from outside sources and still receive 85 percent of the maximum capped net average allowable cost of $25,000. We have also required that States must have a process in place and a methodology for verifying that payment incentives are not paid at amounts higher than 85 percent of the net average allowable cost and a process in place and a methodology for verifying that professionals pay 15 percent of the net average allowable cost of the certified EHR technology.

States may wish to establish a process whereby individuals attest to having completed their forms correctly and risk the circumstance of audit in the event the State has reason to believe individuals did not complete the forms appropriately. States could develop a process for providers to attest to having received no other sources of funding from other than State and local governments as payment that is directly attributable to the cost of the technology. States could select a random sample of providers to audit after the incentive payment has been paid. Additionally, States could determine that certain types of providers should be selected for a more extensive review since it may be true that this particular provider group was most likely to have received payment for certified EHR technology from sources other than State, or local governments. This process could eliminate some of the burden.

Comment: Commenters also asked that we provide some examples of the costs that must be subtracted to get to the net average allowable cost and therefore the incentive payment amount. Commenters do not want to be penalized because they did not have a fair chance at understanding the rule before participating in the program. Commenters further argued that reducing incentive payments due to other non-State/local resources could immobilize innovation and temper research activities.

Response: When States begin to think through the payments that are not considered acceptable and that must be subtracted from the average allowable cost to get to the net average allowable costs and consequently, the incentive payment, we believe that States should consider the situation in which professionals may have been provided with the certified EHR technology through, for example, an employer/employee relationship. We do not believe in this case that there could be any payments directly attributable to the professional for the certified EHR technology; therefore, there are no payments that must be subtracted. This situation would apply in the case of clinics like FQHCs/RHCs or IHS facilities. Additionally, States should consider that any in-kind contributions such as EHR technology or free software provided by vendors are not cash payments and therefore are also not costs that must be subtracted. Further, in the case of grants like the HRSA Capital Improvement Program grants that are used to finance many projects within an organization; for example, research projects, infrastructure, construction or repair and renovation of health centers, health care services, etc., we do not believe these grants are directly attributable as payments for the certified technology but rather are payments for several projects of the organization. Again, we do not believe that these costs are directly attributable to payment costs for the certified technology and therefore must be subtracted. These are just some examples but the clarifying point is that any costs that are subtracted from the average allowable cost to get to the net average allowable cost have to be cash payment that is "directly attributable to the professional for the certified EHR technology." Aside from specific costs related to computer hardware, software, staff training, and/or upgrades of the technology, we believe there are limited situations that exist in which cash payment has been made that is directly attributable to the professional solely for the purpose of certified EHR technology.

In any case, we are requiring that States submit to CMS for review and approval a description of their process and methodology for verifying payment incentives in State Medicaid HIT plans. CMS has the flexibility to approve State Medicaid HIT plans that require provider attestation initially with subsequent auditing of either a random sample, or a sample of payment incentive recipients most likely to have received funding from other sources.

We also would like to provide clarifying information concerning the responsibility of the professional for 15 percent of the net average allowable cost. Section 1903(t)(6)(B) of the Act dictates that EPs are responsible for payment of the remaining 15 percent of the net average allowable cost and States are responsible for ensuring that the Secretary pays no more than 85 percent of the net average allowable cost as incentive payments. In ensuring EPs' responsibility for the remaining 15 percent, we believe States may consider funding that the EP receives from other sources as essentially meeting the EPs responsibility. For example, as stated earlier, States should consider the previous examples of employer/employee relationship, certain grants, and in-kind contributions. Specifically, if a professional is an employee at an FQHC/RHC or IHS facility, since the employer has provided the technology to the employee it is assumed that the employer has contributed the 15 percent

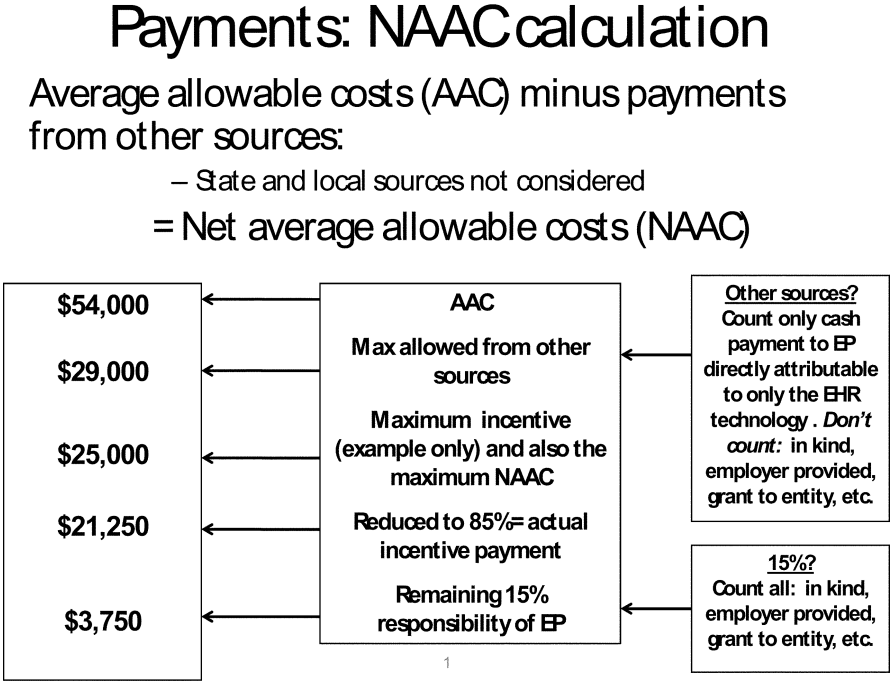
to the net average allowable cost on behalf of the employee. Additionally, in the case of in-kind contributions, the professional's 15 percent responsibility to the net average allowable cost is of no consequence since the entity has assumed that responsibility for the professional. It should be noted that in the case of a vendor supplying the 15 percent on behalf of the EP because the technology, training, support services, etc. was either in-kind contributions or free, conflict of interest safeguards apply and the parties should be mindful of the requirement to comply with applicable fraud, waste, and abuse laws, rules, and regulations.

In those cases in which the professional himself must satisfy the responsibility for the 15 percent net average allowable costs, we believe in determining the calculation, States should consider costs related to the providers' efforts to address workflow redesign and training to facilitate meaningful use of EHRs as contributing to the providers' 15 percent share.

Considering the costs of training, preparing for, and installing or upgrading EHR technology, we believe the vast majority of EPs will spend, or receive funding from other sources in the amount of 15 percent of the maximum net average allowable cost (or $3,750 in the first year and $1,500 in subsequent years). We also believe that for providers' first payment for having adopted, implemented or upgraded certified EHR technology, States should take into consideration providers' verifiable contributions up through the date of attestation. For example, if a provider adopted EHR technology for $100 in January 2010 and then paid for the upgrade to the newly certified version for an additional $100 in December of 2010, the sum of both investments; that is, $200, should be applicable to their 15 percent of the net average allowable cost.

In summary, in response to these comments, we are clarifying in the final rule that State Medicaid HIT plans must explain the process and methodology States will put in place to ensure that Medicaid eligible professionals comply with this responsibility (see section 495.332). Additionally, we have clarified the rules at section 495.310 that providers are responsible for 15 percent of the net average allowable costs of the certified EHR technology.

The following chart is useful in depicting the effect of this calculation.



Comment: Several commenters have raised questions about the cost of the certified EHR technology for hospitals. Specifically, commenters believed that $54,000 is identified as the initial costs for providers with 20 percent per year thereafter for ongoing costs; and $5 million for initial costs for hospitals with 20 percent per year thereafter for ongoing costs. The commenters believed that the $54,000 assumption for providers may be accurate; however, the $5 million assumption for hospitals could be off by a factor of 4 or 5. Other commenters believed that even the $54,000 assumption seriously underestimates the total cost of ownership for EHR systems and their ongoing expenses and argued that this assumption does not account for the training and labor costs associated with implementation of an EHR system, nor does it account for the lost revenues resulting from the decreases in productivity during the initial implementation phase. One commenter questioned whether the $54,000 average allowable cost for certified EHR technology takes into account leasing of an ASP (applicable service provider web based) model as an allowable cost.

Response: As explained above, we conducted a literature review of recent studies on EHR technology and determined that these costs are $54,000 per professional. We are not establishing an average allowable cost for hospitals. The reference to the costs of EHRs for hospitals was only to make the point that the costs of EHRs vary greatly because of the size and type of provider practices, differences in available features of systems, and the additional costs associated with licensing, support, training and maintenance. Additionally, there is no reason to establish the average allowable costs of EHR technology for hospitals since the hospital incentive payments are based on a formula that is defined in the statute and that does not rely on the

average allowable cost. In terms of the $54,000 average allowable cost figure, we indicated that we believe this is a reasonable figure but recognize that there are many variables to determining the average allowable cost of certified EHR technology because of practice size, the differences in available features of systems, and the additional costs associated with licensing, support, training and maintenance. The $54,000 average allowable cost figure does take into account web based models since the Secretary is tasked to study the average costs associated with the purchase, initial implementation, and upgrade of certified EHR technology, including support services, and integral related training.

We are making no additional revisions to this section of the final rule as a result of this comment.

Comment: One commenter requested that CMS make clear that any funding an FQHC receives because the Medicaid eligible professional voluntarily chooses to reassign his/her incentive payment or any funds the center may have received through HRSA Capital Improvement Funds cannot be the basis for a State reducing its per visit payment to FQHCs required under Section 1902(bb).

Response: We agree with the commenter with respect to the incentive payments authorized under section 1903(t); however, we are not addressing the HRSA Capital Improvement funds, as this funding is outside the scope of this rulemaking. Since FQHCs are not eligible providers, incentive payments will not be made to FQHCs. It is true, however, that an eligible professional could choose to reassign his/her incentive payment to the FQHC. Any reassignment of payments must be consistent with applicable laws, rules, and regulations, including, without limitation, those related to fraud, waste, and abuse. Incentive payments are payments designed to promote the adoption and meaningful use of certified EHR technology and are not payments for medical assistance provided in the FQHC. We do not have the authority under this program to provide that these funds be the basis for the State to reduce its per visit payment to the FQHC.

After consideration of this comment, we are making no further additions to this section of the final rule.

(4) Payments for Medicaid Eligible Professionals

One important difference we proposed 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 final 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.

As previously discussed in this final rule, based on the 85 percent threshold applied to the net average allowable costs, we proposed 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 to up 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 16: 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

All State Medicaid EHR incentive program calculations, payments, and limits under this section are subject to our review.

Comment: Commenters suggested that CMS apply the health professional shortage area (HPSA) bonus offered under Medicare to Medicaid providers.

Response: There is no statutory authority for HPSA bonuses in the Medicaid incentive program. However, it is worth noting that in comparing the maximum participation period for EPs in Medicare and Medicaid, EPs can earn higher total incentive payments under Medicaid, even when compared to the Medicare payments with the HPSA bonus.

We are not making any changes to this rule as a result of this comment.

Comment: Commenters requested clarification on how the Medicare payment adjustments apply to Medicaid providers. Commenters suggested that if these apply to Medicaid providers, it could be a reason not to participate. One commenter asked about a provider who began in the Medicare incentive program and then switched to Medicaid, but then stopped meaningfully using the certified EHR.

Response: The Medicaid program does not have the payment adjustments that apply, beginning in 2015, in the Medicare program. However, all Medicare providers will have a payment reduction in 2015 if they are not demonstrating meaningful use, regardless of whether they participate in the Medicare or Medicaid EHR incentive program. Whether an EP, hospital or CAH is a meaningful user of certified EHR technology will continue to be determined on a year-by-year basis. A provider who stops meaningfully using certified EHR cannot receive an incentive payment. This is discussed in greater detail in II.A.

We are not making any changes to this rule as a result of this comment.

(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 17 demonstrates the payment scenarios available to a Medicaid EP who begins in their first year by adopting, implementing, or upgrading certified EHR technology, and receives all six years of payments consecutively. 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 17: 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 proposed 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 18.

TABLE 18: Maximum Incentive Payments for Medicaid EPs Who Are Meaningful Users in the First Payment Year

	Medicaid EPs who begin meaningful use of certified EHR technology in--					
Calendar Year	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

We also requested comment on an alternative approach that would 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. We refer readers to our proposed rule (75 FR 1937) for a discussion of this approach.

Medicaid EPs are not required to participate on a consecutive annual basis, however, the last year an EP may begin receiving payments is 2016, and the last year the EP can receive payments is 2021. See our discussion on consecutive versus non-consecutive payments in section II.A. of this final rule. We wish to point out to readers that this is one area where the Medicare and Medicaid incentive payment programs differ. That is, Medicare EPs do not have the same flexibility afforded to Medicaid EPs, who are permitted to participate in a non-consecutive annual basis, or to skip years, in other words, without the omitted years necessarily reducing the total number of years for which they may receive payment. 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.

Comment: Some commenters rejected the alternative scenario (including 5 years of payment instead of 6), as it would effectively result in a penalty for early adopters, and reward those who delayed adoption.

Response: We agree that early adopters should not be penalized. Further, we agree that Medicaid EPs that have adopted EHR technology before the first year should have an opportunity for the same maximum incentive payments as EPs that are meaningful users in the first year. Accordingly, the alternative scenario we presented in Table 30 of the proposed rule will not be used for incentive payments.

As we are adopting our proposed policy as final, we are not making any changes to the regulations as a result of this comment.

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. Section 1905(t)(5)(D) requires that no payments can be made to hospitals after 2016 unless the provider have been paid a payment in the previous year; thus, while Medicaid EPs are afforded flexibility to receive six years of payments on a non-consecutive, annual basis, hospitals receiving a Medicaid

incentive payment must receive payments on a consecutive, annual basis after the year 2016. Prior to 2016, Medicaid incentive payments to hospitals can be made on a non-consecutive, annual basis. 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.

States are responsible for using auditable data sources to calculate Medicaid 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 hospital 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 year (for subsequent 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 require that States 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 first payment year.

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 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.

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 interpreted these managed care individuals to be individuals enrolled in an 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 sub-acute wing or skilled nursing wing, so long as States and contracting entities are in compliance with the actuarial soundness rules in § 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 proposed 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 § 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.

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 19 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 19 is to illustrate the general timeline for Medicaid hospital incentives.

TABLE 19: 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	

Comment: Many commenters recommended that CMS instruct States to provide hospitals the maximum incentive payments possible in their first two payment years. Commenters provided many examples of how CMS should instruct States to make payments. For instance, commenters suggested that CMS require States to pay 50 percent of hospitals' aggregate incentive payment in the first year and another 40 percent in the second year—as a limited source of capital for adoption, implementation, and upgrades. Many commenters stated that it is critical that EHR incentive payments be made in a timely manner and not delayed or affected by State budgetary problems or changes.

Response: After consideration of the public comments received, we are finalizing these provisions as originally proposed, with one clarification to ensure the statutory requirement that eligible hospitals, after 2016, may not receive an incentive payment, unless a payment was received in the prior year. The statute is imposing maximums on what the State is authorized to pay eligible hospitals. At section 1903(t)(5)(A) the statute requires that a State can make no more than 50 percent of the hospital's aggregate incentive payment in any one year. Likewise, over a 2-year period, the State cannot pay more than 90 percent of the aggregate incentive. Finally, under 1903(t)(5)(D) no more than six years of payment may be made, and payment may not be paid

for any year beginning after 2016, unless the hospital was provided an incentive payment for the preceding year. However, these are limits on State payments, not required minimums. We believe that States should work with their provider communities to determine the best timeframes for implementing their EHR programs and making payments to providers.

Comment: Some commenters indicated that incentive payments should not be included in any calculation of total Medicaid payments for the purpose of determining Medicaid shortfalls, disproportionate share payments, upper payment limits, or any general Medicaid program service.

Response: According to the statute, Medicaid HIT incentive payments are made to encourage the adoption and use of certified EHR technology defined by the statute, as well as support services including maintenance and training that is for, or is necessary for the adoption and operation of, such technology. Payments to providers under this rule are not being made for the provision of services or the cost of the provision of services to Medicaid beneficiaries or the uninsured. Therefore, we are clarifying that EHR incentive payments made to providers in accordance with the statute and final regulation are not subject to the same limits as payments for items and services provided to Medicaid beneficiaries and the uninsured including Medicaid upper payment limits and disproportionate share hospital limits. This comment is also addressed in the Medicare section at II.B.4.b.

Comment: One commenter noted a technical error in the proposed rule at 495.310 (g) (2) Medicaid Share. The commenter questioned whether (2)(iii) meant to qualify (2)(ii) or (2)(i), noting that the latter would result in dual eligibles being removed from Medicaid days (the numerator) and would not conform to the Act which would require that they be removed from the denominator.

Response: We agree that the regulation includes a technical error, and we read the statute as requiring that dually eligible individuals be excluded from the denominator. Section 1903(t)(5)(C) states that the Medicaid share should be calculated using a numerator that does not include individuals "described in section 1886(n)(2)(D)(i)." Individuals described in that section are individuals for whom payment may be made under Medicare Part A as well as individuals enrolled with a Medicare Advantage Organization under Part C. Thus, dually eligible individuals are excluded from the numerator in determining the Medicaid share.

We are therefore revising section 495.310(g)(2)(iii) to ensure that it refers to clause (i), rather than clause (ii), of § 495.310(g)(2).

Comment: One commenter highlighted a technical error in the proposed rule at § 495.310(g)(1)(i)(B) when he requested clarification for that section which reads: "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." He interpreted the language to mean that if the payment year begins in 2011, the Federal fiscal year would be 2010; and the discharge related amount would be for 2009.

Response: Section 495.310(g)(1)(i)(B) is improperly worded in the proposed rule and should read, "The discharge related amount for a 12-month period selected by the State, but ending in the Federal fiscal year before the hospital's fiscal year that serves as the first payment year." For 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, the State would employ the relevant data from the hospital's cost reporting period ending June 30, 2010 in order to determine the EHR incentive payment amount for the hospital.

We are revising this language in the final rule at section 495.310(g)(1)(i)(B) to be clear.

Comment: Some commenters indicated that CMS should specify an alternative source of charity care data that States may use so that Medicare and Medicaid incentive payments can be determined appropriately. Others commented that while CMS has proposed the Medicare cost report, Medicaid cost report data, MMIS data, hospital financial statements, and accounting records to determine Medicaid EHR incentives, there is no absence of State-level usable data to implement this definition.

Response: We agree that there are a number of data sources available at the State and hospital levels that would allow States to accurately capture charity care data for the purposes of calculating hospital EHR amounts. However, we have no vehicle for identifying which of these tools exist in individual States or across the country. Medicare cost reports, Medicaid cost report data, MMIS data, hospital financial statements, and accounting records are all items that we feel confident are accessible to all States and providers. Additionally, we believe that States and their provider communities are better versed at determining the tools that will be most beneficial for their individual programs. As such, we included the standard items listed as auditable data sources, but did not prohibit the use of other appropriate auditable data sources. States must describe their auditable data sources in their SMHP and submit to CMS for review and approval.

After consideration of this comment, we are making no further additions to this section of the final rule.

Comment: One commenter asked whether the criteria for determining Medicaid eligible days and Medicaid managed care days in the Medicaid share portion of the hospital incentive payment calculation is the same criteria for determining Medicare DSH payments.

Response: The criteria for determining Medicaid eligible days and Medicaid managed care days for Medicare DSH and Medicaid managed care days for EHR incentive payments are not the same. Medicare DSH includes unpaid days, while the EHR incentive payment calculation requires the inclusion of only paid inpatient-bed days.

After consideration of this comment, we are making no further additions to this section of the final rule.

Comment: One commenter asked for clarification of the term "estimated" Medicaid inpatient bed days.

Response: We are unclear about the commenter's question. Specifically, the statute permits the use of "estimated" days in the Medicaid share portion of the EHR hospital incentive payment calculation. Therefore, we refer the reader to the hospital calculation at section 1903(t)(5) and section 495.310 of this rule.

After consideration of this comment, we are making no further additions to this section of the final rule.

Comment: One commenter requested that for purposes of accurately calculating and auditing the Medicaid Share, CMS should eliminate data provisions at 2080.18 of the State Medicaid Manual.

Response: We disagree. The provisions at 2080.18 of the State Medicaid Manual do not adversely impact the calculation or auditing of the Medicaid Share.

We have not made any changes to the regulation related to this comment.

Comment: On commenter requested that we include as an auditable data sources, data acquired through authorized trading partners, such as clearing houses, eligibility systems maintained by CMS, state Medicaid programs, and/or their agents.

Response: We agree that there are a number of data sources available that would allow States to accurately data for the purposes of calculating the Medicaid Share. However, we have no vehicle for identifying which of these tools exist in individual States or across the country. Medicare cost reports, Medicaid cost report data, MMIS data, hospital financial statements, and accounting records are all items that we feel confident are accessible to all States and providers. Additionally, we believe that States and their provider communities are better versed at determining the tools that will be most beneficial for their individual programs. As such, we included the standard items listed as auditable data sources, but did not prohibit the use of other appropriate auditable data sources.

After consideration of this comment, we are making no further additions to this section of the final rule.

Comment: One commenter asked whether the Medicaid payment is based on an annually-calculated Medicaid Share, or is the Medicaid Share established in the base year only and to be applied to the duration of payments.

Response: For purposes of calculating the Medicaid hospital incentive, the Medicaid Share is established in the base year.

After consideration of this comment, we are making no further additions to this section of the final rule.

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. In our proposed rule we discussed the fact that some States might be prepared to implement their programs and make EHR incentive payments to Medicaid providers in 2010 for adopting, implementing, or upgrading certified EHR technology. We proposed to allow States to initiate implementation of these payments to Medicaid EPs and hospitals after the effective date of the final rule if they could successfully demonstrate to CMS that they are ready to make timely and accurate payments through the SMHP. States would include an additional attestation for providers assuring that they are not accepting payment in any other State.

We also proposed that to be approved for early implementation, a State would be required to have an electronic system for provider registration capable of collecting the relevant information (this information is identified in section II.A.5.c of this final rule, where we describe the data collection requirements).

Participating States would be responsible for transmitting the required data to CMS so that CMS could ensure that no duplicate payments were made to providers. We proposed to use the single provider election repository described in section II.A.5.c. of this final rule to assure no duplicative payments were made between States.

We did not propose that States would be able to make early payments to meaningful users. Rather, our proposal was intended to offer Medicaid providers an early opportunity for capital so that they would be more likely to have the certified EHR technology required to demonstrate meaningful use in successive periods. We stated that since hospitals may qualify under both programs, we hoped that they would use the early capital to qualify as meaningful users under the Medicare program in the first year.

Comment: We received comments suggesting that our proposal on early State implementation creates unreasonable pressure on States, particularly given the status and timeline of the ONC rule on certification criteria.

Response: We agree with commenters. We proposed this option in order for States with very mature programs to proceed with early incentive payments for adoption, implementation, and upgrading certified EHR technology. However, in considering the complexity associated with States establishing an electronic registration system (which would only be temporary), as well as the fact that very few providers (if any) will have certified EHR technology early enough for this option, we believe that this may not be an efficient, cost-effective option for many States.

Consequently, as a result of these comments, we are removing this option. States will not be permitted to make payments until January 2011. Additionally, we wish to reiterate that States must have a SMHP approved by CMS before making any payments to EPs and eligible hospitals.

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 eligible hospitals, State Medicaid agencies (or their contractors) are fully responsible for administering and disbursing the incentive payments to Medicaid eligible providers.

We proposed to 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 would be required to choose only one State from which to receive Medicaid incentive payments in each payment year. (We note that readers should also refer to section section II.A of this final rule for additional information regarding the EHR reporting period and the single provider election repository).

As we noted in the proposed rule, the statute anticipates coordination between the Medicare and Medicaid EHR incentive programs to ensure no duplicate payments are made to EPs (see 1903(t) and 1848(o)(1)(D)(iii). Additionally, section 1848(o)(1)(B) of the Act requires that Medicare incentive payments for eligible professionals 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 further direction 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 January 1, 2011. This also gives CMS, ONC, and States an opportunity to coordinate between Medicare and Medicaid, which will simplify administrative complexity in the EHR incentive program and facilitate provider adoption.

Under this final rule Medicaid EPs, as discussed in section II.D.5 and II.A.5.c, will enroll in the program through the single provider election repository. Once an EP selects the Medicaid EHR incentive program, 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 are required to submit to CMS data on 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 must receive prior approval, concurrent with the requirements described in section II.D.8 of this final 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 discussed in section II.A.1.e. of this final rule. As discussed in that section, for the first payment year based on meaningful use, the reporting period for eligible hospitals and EPs will be a continuous 90-day period that both starts and ends within the payment year. As long as the period spans the 90-day continuous period and ends within the payment year (fiscal year for hospitals, calendar year for EPs), the reporting period can begin at any time during such payment year. States also are expected to process payments on a rolling basis. We will issue further guidance regarding the timing expectations needed for State systems to coordinate with CMS and make timely payments

Comment: Several commenters were concerned that Medicaid EPs and eligible hospitals that qualify for incentive payments in their first year by adopting, implementing or upgrading certified EHR technology are not afforded the same flexibility as Medicare EPs and eligible hospitals in their second payment year. The commenters wrote that they would be required to demonstrate meaningful use for the full year, rather than 90 days in their second payment year, (even though it will be their first year demonstrating meaningful use). The commenters recommended that Medicaid EPs and eligible hospitals be subject to a 90-day reporting period in their second payment year when it is the first year they are demonstrating meaningful use.

Response: We agree with the commenters and as discussed in section II.A., we clarify that there is no EHR reporting period for adopting, implementing, or upgrading certified EHR technology for Medicaid provider's first payment year. In order to offer parity with Medicare providers who must achieve meaningful use in the first year over a 90-day period and over 12 months in subsequent years, the same policy will apply to Medicaid providers. In other words, Medicaid providers in their second participation year (or in their first payment year if they are qualifying based on meaningful use) shall demonstrate meaningful use over a 90-day reporting period and over 12-months for their third and subsequent years.

e. Avoiding Duplicate Payment

In our proposed rule, we discussed the statutory requirement at section 1903(t)(7) of the Act that the Medicare and Medicaid programs coordinate payments to avoid duplication, and that CMS and the States coordinate payments through a data matching process, utilizing NPIs to the extent practicable. We also discussed section 1903(t)(2) of the Act, which states that Medicaid EPs must waive rights to Medicare incentive payments under sections 1848(o) and 1853(l) of the Act; hospitals, however, may qualify for incentives under both programs. We also proposed requirements under the review and approval of SMHPs in part 495 subpart D for States to verify that providers meet these requirements.

In section II.A of this final rule, we discuss the final requirements we are adopting in order to avoid duplicate payments in the Medicare and Medicaid incentive programs. We also respond to comments in that section (*see* section II.A.5.c. of this final rule). As discussed in that section of the final rule, 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, we will collect this data in a single provider election repository. Next, in administering each State Medicaid EHR incentive program, States will 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 requirements that a State must have an approved SMHP that will include a mechanism for cross-checking this information prior to payment.

f. Flexibility for EPs To Alternate Between Medicare and Medicaid EHR Incentive Programs One Time

We refer readers to section II.A.5.b of this final rule, which discusses rules that would allow Medicare and Medicaid EPs to make one EHR incentive program election change prior to the 2015 payment year, and not to permit any switching after the 2014 payment year. 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 (assuming the professional meets all eligibility criteria for the Medicaid incentives program). Similarly, an EP who initially selected the Medicaid EHR incentive program could switch to the Medicare program one time prior to 2015. (In other words, the last payment year an EP could switch would be the 2014 payment year.)

Comments received on these policies are addressed in section II.A.5.b. of this final rule.

g. One State Selection

In the proposed rule, we proposed that EPs and hospitals with multi-State Medicaid practice locations 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. Medicaid EPs and hospitals could annually change the State they select when they re-attest to program requirements.

We considered the possible impact of this proposed approach with respect to patient volume calculations on Medicaid EPs and hospitals in border State areas, stating that because the Medicaid incentive payment for EPs will remain the same—regardless of whether they receive payment from one State or from multiple States—we did not think the administrative complexity associated with dividing and administering payments between or among more than one State could be justified. We recommended, however, that States consider border State providers when developing their policies on patient volume and the attestation methodology. We afforded additional flexibility in the patient volume at proposed § 495.306 to account for unique circumstances and data collection.

Comment: Providers inquired whether it is permissible for an EP who practices in more than one State to aggregate patient encounters in order to achieve the 30 percent Medicaid patient volume criteria.

Response: First, it is not clear that aggregating patient volume across States will be an issue once EPs actually begin tallying up patient volume. Patient volume is calculated as a percentage, and not an absolute number. Thus, it does not appear that, but for aggregating patient volume across multiple States, an EP would not be able to qualify for incentive payments in any State. For example, if an EP has 10 percent patient volume in one State (10 of 100 encounters are Medicaid) and 20 percent patient volume in a second State (20 of 100 encounters are Medicaid), this does not add up to 30 percent patient volume (but, rather, results in a 15 percent patient volume

as a result of dividing 30 by 200). To restate, we do not believe that an EP will need to sum patient encounters across multiple States in order to reach the 30 percent patient volume—as in order to reach this patient volume threshold, the EP would likely meet the 30 percent in at least one State. Indeed, it appears that the only benefit of aggregating patient volume across States would be to permit an EP who has more than a 30 percent patient volume in one State to receive incentive payments from another State in which s/he does not meet the 30 percent threshold.

Nevertheless, we recommend that States consider the circumstances of border State providers when developing their policies and attestation methodologies. To afford States maximum flexibility to develop such policies, we will not be prescriptive about whether a State may allow a Medicaid EP to aggregate his/her patients across practice sites, if the State has a way to verify the patient volume attestation when necessary. States will propose their policies and attestation methodologies to CMS for approval in their State Medicaid HIT plans.

We are making no additional revisions to this section of the rule as a result of this comment.

5. Single Provider Election Repository and State Data Collection

We refer readers to section II.A.5.c of this final rule for a discussion of the single provider election repository and the comments received on this policy. 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

In our proposed rule, we proposed that EPs in multiple group practices or multiple types of practice locations would be required to select one TIN for Medicaid EHR payment disbursement. In other words, such EPs would not be permitted to require a State to divide payments among different practices or practice locations based upon group TINs. We explained that 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 stated that requiring reimbursement to be made to one TIN would reduce opportunities for fraud or abuse, as States would be able to cross-check EP and TIN combinations more easily to verify EP attestations.

We also stated that although the State would not divide payments among the various TINs of an individual EP, Medicaid EPs could, themselves, decide to divide payment. These EPs could independently distribute funds among their respective group practices or practice locations after the initial disbursement from the State to their designated TIN.

Comment: We received comments suggesting that EPs should be allowed to proportion their payments and give multiple TINs.

Response: For these reasons advanced in the proposed rule, we believe that permitting an EP to divide the incentive payment among multiple TINs would introduce an unnecessary level of administrative complexity into this temporary program. It also could increase the opportunities for fraud and abuse as it would be more administratively cumbersome for States to track multiple payments (to ensure correct payments) and to track and verify multiple eligibility-related EP attestations. Once a payment is disbursed from the State, nothing precludes the EP from further disbursing the incentive payment, subject to the applicable fraud, waste, and abuse laws, regulations, and rules.

After consideration of the public comments received, we are finalizing these provisions as proposed.

7. Activities Required To Receive Incentive Payments

a. General Overview

As we discussed in our proposed rule, to qualify to receive a first year Medicaid incentive payment, section 1903(t)(6)(C)(i) of the Act indicates that EPs and eligible hospitals 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 Public Health Service Act) that is certified pursuant to section 3001(c)(5) of such Act as meeting standards adopted under section 3004 of such 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 II.A of this final 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" 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, we proposed that 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. We proposed that 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). We proposed that the State's SMHP would detail these processes.

The CMS Medicaid Transformation Grants 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 proposed to include staff training and efforts to redesign provider workflow under the definition of implementing certified EHR technology. We explained that 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 proposed that there be evidence that a provider demonstrated actual installation prior to the incentive, rather than "efforts" to install. We stated that this evidence would 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. As Medicaid incentive payments are intended to stimulate meaningful use of EHR technology, we stated our belief that the payments need to result in tangible adoption, implementation, or upgrading of certified EHR technology. We stated that States would be responsible for verifying this evidence of EHR adoption.

In establishing criteria for the "implementation" portion of "adopt, implement or upgrade" requirement, we proposed 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 proposed "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. We proposed that States describe in their SMHPs the process that would be in place 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.

Comment: Several commenters recommended that CMS clarify if "upgrade" does or does not apply to an already certified EHR. They recommended that CMS confirm that an upgrade is intended to enable a provider to expand existing functionality of an EHR so that it meets the new certification criteria.

Response: To clarify this question, an example of upgrading that would qualify for the EHR incentive payment would be upgrading from an existing EHR to a newer version that is certified per the EHR certification criteria promulgated by ONC related to meaningful use. Upgrading may also mean expanding the functionality of an EHR in order to render it certifiable per the ONC EHR certification criteria.

We are making no additional revisions to this section of the final rule as a result of this comment.

Comment: Commenters wrote that given that adopt/implement/upgrade (AIU) involves significant practice workflow redesign and that the States' overarching goal is to increase the level of provider participation, the commenters recommended that CMS require only AIU for participation Year 1 and Year 2. They further recommended that CMS allow AIU compliance to be further defined as the provider developing, submitting, and following a customized plan for the necessary workflow changes with timelines (whose development can be assisted by the Regional Extension Centers); the provider would have to meet their timelines for each year in Stage 1 to qualify for the incentive payment; and the AIU plan timelines would have to be structured so submission of HIT and clinical quality measures would begin in Stage 2.

Response: The statute at section 1903(t)(6)(C) permits Medicaid providers to receive the EHR incentives for adopting, implementing or upgrading to certified EHR technology in their first participation year. A provider's first participation year may be any year between 2011 through 2016. In their State Medicaid HIT Plans, States will propose to CMS how they will audit and oversee Medicaid providers' adoption, implementation or upgrading to certified EHR technology. States should propose further details to CMS about how they will verify that providers have met this requirement.

After consideration of the comments received, we do not believe that just the development and submission of an implementation plan for EHR adoption is a significant enough commitment to warrant the AIU incentive payment. There is nothing binding, nor is there any financial contribution towards such a plan.

We are making no additional revisions to this section of the final rule as a result of this comment.

Comment: Many commenters suggested that they believe the goal of this incentive is to help defray some of the costs of adopting, implementing, and upgrading to certified EHR technology. As such, the commenters believe "proof" of AIU should not require completion of AIU but demonstrated commitment to AIU. For example, a proof of purchase, a schedule for training and implementation, and periodic reporting from practices on progress on the schedule could suffice. The commenters requested that States have flexibility to define what is sufficient to trigger payment.

Response: States should provide details to CMS on how they will audit and oversee Medicaid providers' adoption, implementation or upgrading to certified EHR technology in their SMHP. States' SMHP should include further details about how they will verify that providers have met this requirement. However, while States may propose how they will determine what AIU activities are sufficient for the EHR incentive payment; CMS must approve their proposals via the SMHP. The definitions included in this final regulation by CMS for adopt, implement or upgrade do imply completion of at least one of the three tasks. A proof of purchase or signed contract would likely be an acceptable indicator of EHR adoption per the States. Implementation is on-going, therefore working actively with Regional Health IT Extension Centers on implementation, completion of specific benchmarks or other activities towards implementation would be acceptable.

We are making no additional revisions to this section of the final rule as a result of this comment.

Comment: A commenter recommended that State Medicaid agencies provide eligible hospitals with

the maximum incentive payments for their first two payment years as a limited source of capital for AIU.

Response: The Medicaid hospital calculation was part of the HITECH statute and not defined by CMS. Eligible Medicaid hospitals can receive their first year's payment for AIU and not meaningful use, but must meet the meaningful use requirement in their second and subsequent participation years.

We are making no additional revisions to this section of the final rule as a result of this comment.

Comment: A commenter recommended that a Medicaid provider be permitted to qualify for their first year Medicaid EHR incentive even if they have not actually installed certified EHR technology but have spent or are committed to spend an amount equal to at least the lesser of $50,000 or 5 percent of the Medicaid EHR incentive amount.

Response: In consideration of the comments, we are clarifying that the final definition of adopt, implement or upgrade is inclusive of providers' acquisition, such as a purchase, of a certified EHR. Providers will be responsible for providing documentation which substantiates AIU as required by the State Medicaid Agency.

We are revising the definition of adopt, implement, and upgrade as a result of these comments, see section 495.302.

c. Other General Terminology

In our proposed rule, we proposed definitions for "EHR reporting period" and "payment period," stating that these definitions 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 demonstrate meaningful use of certified EHR 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 were specified in proposed § 495.332). In the proposed rule, we specified that States would 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, States would need to refer to providers' reports on meaningful use, including reporting of clinical quality measures (*see* section II.A. of this final rule for requirements for clinical quality measures), in accordance with the appropriate EHR reporting period. States could not appropriately make incentive payments in the absence of such reporting.

We proposed that 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 other requirements. 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. We proposed that permissible means for ensuring patient volume and all of the requirements described in this section would include survey, attestation, or the creation of special codes on claims, subject to our prior approval.

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 our proposed rule, we discussed our expectation that the bar for demonstrating meaningful use of certified EHR technology will rise in years to come. In this final rule, meaningful use and its evolving criteria are discussed in section II.A. In order to receive Medicaid incentive payments, providers will be required to demonstrate (and States will be required to track and validate) meaningful use, as described in section II.A.2. of this final rule. In section II.D.8 of this final rule, we also discuss our policies regarding States' ability to require additional objectives in the demonstration of "meaningful use," or otherwise add to the Federal definition of meaningful use. We also discuss the requirement that States receive prior approval of any such additions.

As we discussed in the proposed rule, we believe that 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 the extent practicable, 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 will be evaluating States' HIT Planning Advanced Planning Documents (PAPDs) and SMHPs with this objective in mind, as described section II.D.8 of this final rule.

As we discussed in the proposed rule, States' system requirements for monitoring meaningful use must include the capacity to determine the appropriate stage of meaningful use and the appropriate incentive payment amount, depending upon the providers' payment year. 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 a provider's year of entry into the Medicaid EHR incentive program to determine the correct eligibility criteria and generate the appropriate Medicaid incentive payments.

Once States are giving providers the Medicaid EHR incentive payments for being meaningful users of EHRs, and in 2012 begin receiving clinical quality measures data from those providers, we proposed that States would 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 the Medicare and Medicaid EHR incentive programs, we proposed that we would use the meaningful use measures hospitals report to us to make quality data on Medicaid eligible hospitals available to States.

Comment: Commenters requested clarification on the reporting period for

adopting, implementing, and upgrading, and whether this period is similar to the 90-day period for demonstrating meaningful use in the first year.

Response: As discussed earlier, we are clarifying that there is a no reporting period for AIU for the providers' first participation year. However, there is a 90-day reporting period for the first participation year in which Medicaid providers qualify by demonstrating meaningful use. The rationale is that we understand that not all AIU activities require 90 days, such as EHR acquisition. States will determine how they plan to implement this requirement.

As a result of this comment and a similar comment above, we are revising section 495.4 to indicate that there is no EHR reporting period for adopting, implementing, or upgrading in Medicaid providers' first participation year, if they qualify based on AIU, and there is a 90-day reporting period for both the first year that a Medicaid provider demonstrates MU (regardless of whether they demonstrated AIU in their first participation year or are qualifying based on MU in their first participation year).

Comment: Several commenters requested that CMS clarify the process that will assure Medicaid access to Medicare meaningful use data, at a minimum for (1) hospitals who receive both Medicaid and Medicare payments and (2) eligible providers that may switch once between the Medicaid and Medicare incentive programs. Commenters requested that CMS provide States with Medicare quality reporting/data in a timely fashion (for example, within 30 days of receipt of such information). Alternatively, commenters suggested that the providers could be required to report separately to both Medicare and Medicaid.

Response: We are finalizing our policy as proposed. We believe that it would represent an undue burden on hospitals eligible for both EHR incentive payments to report their data to both CMS and the States. We will issue further guidance about how States will be able to access the meaningful use data submitted to CMS by hospitals eligible for both Medicare and Medicaid EHR incentive payments in order for the State to meet its audit and oversight requirements. It is not clear to CMS why a State would require access from CMS to an eligible professional's meaningful use data if they were a Medicare EHR Incentive Program participant in the prior year. States can only base a Medicaid provider's EHR incentive payment, as it pertains to meaningful use, on the current participation year's EHR reporting period.

We are making no additional revisions to our regulations as a result of this comment.

Other than the changes explained above, we are finalizing the remainder of our proposed policies as they were proposed.

d. Quality Measures

We refer readers to section II.A.3 of this final rule-for a discussion of the clinical quality measure reporting required for demonstrating meaningful use of certified EHR technology. As discussed previously, we intend to update our definition of meaningful use biennially, 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 final rule).

Comment: Several commenters believe that the current clinical measures do not reflect key clinical services and issues for the Medicaid population, including behavioral health, dental, long-term care, and care coordination (particularly across physical and behavioral health care).

The commenters recommend that CMS work with the Medicaid Medical Directors and ONC and consider the development and inclusion of clinical and non-clinical quality measures that are more representative of the Medicaid population. Alternatively they wrote that CMS and ONC should have a "placeholder" to accommodate data and interoperability for these measures. Commenters wrote that the areas with gaps are behavioral health, dental care, long-term care, special needs populations and care coordination, particularly across physical and behavioral health. The commenters recommended that new clinical quality measures be added as "placeholders" for care provided by non-eligible, but critical Medicaid providers, such as Community Mental Health Centers, Home Health, and Renal Dialysis Centers.

Many commenters noted that with regard to pediatric clinical quality measures, they recommend that first-year measures focus on immunizations, diabetes, asthma, autism, and lead screening. They also recommend measures to introduce in 2012 and beyond to include smoking, obesity, disease- or condition-specific measures, and measures aimed at reducing disparities. They further recommended measures to introduce in 2013 and beyond include the development of clinical quality measures on psychology, child abuse, developmental delays, and efficiency measures.

Response: We agree that these measures (listed directly above) have clinical relevance for providers. However we are aligning with the Medicare Stage 1 meaningful use provisions regarding publication and opportunity for public comment on quality measures before they are finalized. We are not including additional meaningful use objectives and measures that were not discussed in the proposed rule.

Comment: Several commenters believed that the quality measures proposed in the interim rule do not match the quality measures that HRSA currently requires FQHCs to report. The commenters would like to work with CMS and HRSA to move forward and harmonize the quality measures by 2013 but requested that until quality measures are harmonized across the federal government system, FQHCs and the EPs who qualify and assign their Medicaid incentive payments to the FQHC should be allowed to report on the current HRSA measures.

Response: Meaningful use applies to each individual EP. Therefore the HRSA quality measures, which are facility-based, not necessarily NQF-endorsed, or reportable from EHRs are not an acceptable alternative for EPs who practice at an FQHC. Furthermore, as explained in section II.A. of this final rule, we are not including in the final rule quality measures that were not included in the proposed rule. To ensure uniformity across both programs, we have adopted this same policy for Medicaid. We believe it is important to offer Medicaid providers and stakeholders the same opportunity for public comment on quality measures.

We agree with the goal of harmonizing quality measure reporting across Federal programs and will engage with stakeholders and experts to address this priority as part of the development of the Stage 2 definition of meaningful use.

We are finalizing these provisions as proposed and we will continue to work to identify, and develop electronic specifications for additional clinical quality measures that address current gaps, such as long-term care, behavioral health, pediatrics and oral health for Stage 2 of meaningful use. In particular, we recognize the lack of endorsed oral health clinical quality measures, with identified and tested electronic specifications. This poses a challenge for dentists, who are eligible professionals for the Medicaid EHR

incentives, to demonstrate meaningful use, other than with the general, profession-neutral measures.

While an eligible professional can report "zero" for the denominator of any measure for which s/he does not have any relevant patients, we will work to include in Stage 2 of meaningful use, clinical quality measures that would provide useful data to CMS and States on oral health care as reported by EHRs.

In addition, in order to minimize provider burden, and to maximize measure reporting efforts and resources, we seek to align the quality measures for the Stage 2 definition of meaningful use with other quality measures development and reporting related to health care reform and other CMS quality measures programs, as appropriate and feasible. Stage 1 of meaningful use is limited to objectives and measures that are already in existence, not those still under development. Measures will be included that have operational relevance to the care provided to Medicaid and CHIP beneficiaries by eligible professionals and hospitals defined in the HITECH Act.

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. (See 1903(t)(9) of the Act.)

This section of the final 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 defined 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 proposed to separately include definitions in part 495.

We proposed to include in our regulations the requirements that in order to qualify to receive FFP for administering the incentive program, States must develop a SMHP, an HIT Planning APD (PAPD), and an HIT Implementation APD (IAPD). These documents lay out the process used by States to implement and oversee the EHR incentive program, and will help States to construct an HIT roadmap to develop the systems necessary to support eligible 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, while reducing 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 (SMD) letter on September 1, 2009, on this process and the State efforts necessary to receive the 90 percent FFP for planning-related expenditures. As stated in that letter, and as further required through this rulemaking, our review process ensures that States are complying with requirements of the HITECH 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 would not ensure the 90 percent FFP. As explained in the letter, and as further reflected in this rulemaking, we must review and prior approve all elements of the State's SMHP, and APD documents, and work with States to determine the appropriate level and type of FFP.

States are required to submit these advance planning documents in order for us to approve receipt of the 90 percent Federal match. Specifically, prior approval is required for the HIT PAPD (see also § 495.336). The deliverable resulting from the HIT PAPD is the SMHP. The SMHP must be reviewed and approved before it is included in an IAPD (see also § 495.338). The IAPD also must be prior approved. Until approval is granted States cannot draw down funds.

For purposes of the Medicaid EHR incentive program, we believe there are 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 includes initial planning, including an assessment of the State EHR environmental landscape, and development of the SMHP. As explained in our September 1, 2009 letter, the vehicle for informing us of Phase I activities is the HIT PAPD, and indeed, over 40 States have already submitted their PAPDs and have received funding to begin Phase I activities. Phase II then involves further development and full implementation of the SMHP. Consequently, the HIT IAPD is the vehicle for reporting of Phase II activities. As discussed in the SMD letter, and as further reflected in this final rule, States need to receive prior approval of their planning documents. In fact, we have already worked closely with the majority of States in developing their HIT PAPDs, prior to them initiating their EHR planning activities, and we expect this close coordination to continue between the States and CMS.

Also, as proposed, in this final rule we will require States 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, we designed the prior approval conditions, and the prior approval process, to mirror what is presently used in support of acquiring automated data processing equipment and services in conjunction with development and operation of State MMIS (the State's automated mechanized claims processing and information retrieval system approved by CMS).

As proposed, this final rule (at 495.348) will require State Medicaid programs to comply with current procurement standards. Specifically, at 495.348 we have included language that accords with the procurement requirements in 45 CFR part 95 subpart F and incorporates many 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.

Under these standards the State must ensure that when procuring HIT equipment and/or services, there is maximum practical open and free competition, and that any procured materials or services are obtained in a cost-effective manner. The regulations also make clear that the State, as the grantee, is responsible for meeting its contractual responsibilities under any of its procurements, and will not have recourse to the Federal government to settle or satisfy its contractual and administrative issues. Further, States must have written standards of conduct regarding the performance of its employees that are engaged in the award and administration of the HIT equipment/services contracts (including conflict of interest rules contained in 495.348(c)). States must have written procurement procedures that accord with 495.348(e) and a system for administering contracts in accordance with 495.348(f). Procurement contracts must meet the additional requirements contained in 495.348(g) as well as describe the conditions under which the contract may be terminated for default or because of circumstances beyond the control of the contractor (see 495.348(h)). Procurement contracts must include provisions allowing State and Federal access to the materials and staff of the contractor, in accordance with 495.348(i).

As was proposed, our final regulations at 495.346 also will require the State agency to allow the Department access to all records and systems operated by the State in support of the program. Final regulations at 495.352 impose reporting requirements on States to submit to the Department, on a quarterly basis, a progress report documenting specific implementation and oversight activities performed during the quarter. Regulations at 495.354 through 495.360 contain rules for charging equipment, non-discrimination requirements, requirements for cost allocation plans, and requirements for ownership rights in software. Our rules would require termination of FFP in the case of States failing to provide access to information relating to any of the requirements we have included in this subpart. We believe the procurement and other rules discussed above are authorized under section 1902(a)(4) of the Act, as well as under section 1903(t)(9) of the Act requiring a State to conduct adequate oversight of its program, and use its funds to administer the incentive payments. In addition, any reporting and other requirements will assist us in submitting the reports that are required under section 1903(t)(10) of the Act, which requires us to monitor and report on the progress of implementation of the EHR provisions.

As proposed, State Medicaid agencies will be required to attest, as required by section 1903(t)(6)(A)(i) of the Act, that States 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. States must also attest that payments to an entity promoting the adoption of certified EHR technology, as designated by the State, will 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. (See 495.332 of our final rules). States are required to attest that the entire incentive payment has been forwarded to the eligible Medicaid provider, and that no Medicaid eligible professional or hospital is required to return any portion of the incentive payment to the State Medicaid agency. States must establish a process to ensure that any existing fiscal relationships with eligible professionals or hospitals 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 requiring 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 have allowed for claiming of such reasonable costs incurred on or after February 18, 2009, prior to publication of the final rule. Specifically, a State that can show that 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 may potentially receive retroactive FFP back to the date in which these efforts began, with CMS approval, but not before February 18, 2009.

Comment: Several commenters expressed concerns about the timing of planning and implementation and request flexibility in this area. Commenters indicated that there will be a need for ongoing planning while rules and guidelines are being promulgated. Commenters indicated that they envision a phased approach to implementation, and request that CMS permit simultaneous expenditure of both planning and implementation funds.

Response: We proposed specific requirements for States to request FFP from CMS for the Medicaid EHR incentive program modeled on the process States use to request FFP from CMS for Medicaid Management Information Systems technology projects. CMS proposed to utilize information and documentation that will result from the process described in this section to evaluate approaches proposed by States, track and monitor progress of implementation, and perform the statutory program and financial oversight required for this new program.

In establishing the requirements we believe States will have flexibility to request FFP for planning and implementation activities to implement the provisions of the EHR incentive program in a manner that is similar to and consistent with current approaches to receive enhanced FFP for MMIS systems under the Medicaid program. This will enable States to modify or adapt as changes occur during the planning and implementation phases envisioned under this proposed rule. Further, we believe that the information required is consistent with section 1903(t)(9) of the Act that States must demonstrate to the satisfaction of the Secretary that the State is conducting adequate oversight.

We agree with the need for flexibility in planning for the Medicaid incentive program, and the conduct of implementation activities to ensure the program is successful in the long-term. We have added additional clarifying information in the sections regarding the HIT PAPD, HIT IAPD, As-needed HIT PAPD update and as-needed HIT IAPD update, Annual HIT IAPD requirements, and SMHP requirements. These clarifications are consistent with guidance issued in our State Medicaid Director's letter on September 1, 2009, which indicated that CMS anticipates a phased approach to planning and implementation activities.

Finally, for the final rule we are making numerous changes in order to be more specific and provide additional clarity regarding certain terms and

requirements. These revisions are reflected here; however, regulations text is not updated since the concepts of these terms remain the same. Clarifications are as follows:

We have further defined the terms "service oriented architecture (SOA)", or "service component based architecture" to indicate that they are 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 health IT projects authorized under the Act to ensure that different systems and programming languages provide a basis for interoperability among and between applications that may reside on different platforms through a communication protocol to achieve health information exchange required under the Act. CMS anticipates that States will describe proposed HIT projects in the context of SOA principles, and intends to evaluate plans for health information exchange, and interoperable health IT based on these commonly used information technology principles.

We have also further defined the term "State self-assessment (SS–A)," a component of MITA, as a process that a State will use to review its Medicaid information technology strategic goals and objectives, measure its current baseline business processes and capabilities against defined MITA business capabilities, and develop targeted future capabilities to transform the Medicaid enterprise to be consistent with the MITA principles of interoperability and exchange of health information. Although we are including a definition of State self assessment in this final rule, we are deleting the requirement that a State provide the MITA SS–A, as we believe the as-is assessment supercedes the need for a separate MITA SS–A. However, we believe it is important to keep a definition of SS–A, because there is an inter-connection between activities accomplished under the Medicaid EHR Incentive Program and States' MMIS enhancements. For example, data exchanges between various State systems that comprise the Medicaid enterprise of the State might also support the State's administration of the EHR Incentive Program.

We are further defining MITA, because we expect that States will describe proposed health IT projects as well as their "as is" landscapes using MITA concepts and principles. We intend to evaluate States' proposed strategies and plans for development of Medicaid health information exchange and interoperable health IT using these MITA principles, as applicable. These strategies and plans must be included in the State Medicaid Health Information Technology Plan (SMHP), a term discussed below. We have previously published a document entitled "MITA Framework 2.0" on the CMS Web site at *http://www.cms.hhs.gov/MedicaidInfoTechArch.* The MITA Framework 2.0 was developed by CMS in collaboration with State Medicaid agencies and information technology vendors to facilitate the adoption of information technology principles and practices that will lead to increased deployment of state-of-the-art technologies and improved management of the Medicaid program. States presently are utilizing MITA and the SS–A for Medicaid IT projects approved by CMS, and application of these principles for activities required under this proposed rule will not add additional burden to State efforts to adopt HIT as envisioned under the Section 1903(a)(3)(F) of the Act.

The MITA principles and tools foster integrated business processes and IT transformation for all States. It achieves this in part by demonstrating that planned enhancements to Medicaid systems, including MMIS, support State and Medicaid strategic goals and how intra-state systems other than the MMIS have been considered in developing the solutions. We believe that as States and providers implement EHRs, it will be necessary and essential to plan technology upgrades that will facilitate health information exchange with Medicaid providers receiving incentive funding.

We are further clarifying that we are defining the Medicaid Management Information System (MMIS) as it relates to specific requirements for Medicaid claims processing and information retrieval contained in current regulations at 42 CFR part 433, subpart C. We proposed a definition of the term MMIS because it is the common term that CMS, State Medicaid agencies, and industry use to refer to the Mechanized Claims Processing and Information Retrieval Systems specified in section 1903(a)(3) of the Social Security Act. MMIS means the system of software and hardware used to process Medicaid claims from providers of medical care and services for the medical care and services furnished to recipients under the medical assistance program and to retrieve and produce service utilization and management information required by the Medicaid single State agency and Federal Government for program administration and audit purposes. The objectives of the MMIS 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. The MMIS is also compatible with the claims processing and information retrieval systems used in the administration of the Medicare program.

We believe that States will utilize their MMIS extensively in administering the provisions of this proposed rule, including but not limited to payment and tracking of Medicaid incentive payments, access to data and information necessary to establish the vision for Medicaid health IT, and achieving interoperability and health information exchange envisioned in the Act.

In the proposed regulation at § 495.332 we proposed a definition of the term State Medicaid Health Information Technology Plan (SMHP) as an integral part of planning and implementation of the EHR incentive program. The SMHP is a comprehensive document that describes the State's current and future health IT activities in support of the Medicaid EHR incentive program. We further clarify that we require that the SMHP will be developed by the State Medicaid agency, after consulting with other stakeholders across the State. The SMHP will be reviewed and approved by CMS prior to any activities described in the SMHP being funded and implemented. We anticipate State agencies will engage a wide range of stakeholders within and outside of State and Federal government to develop a vision of how the Medicaid EHR incentive program will operate in concert with the larger health system and statewide efforts. The SMHP is required to participate in the Medicaid incentive program because we believe that States must develop a strategic vision and plan that includes clear targets and measurable outcomes to be consistent with the intent of section 1903(a)(3)(F) of the Act to encourage the adoption and meaningful use of certified EHR technology.

The SMHP is intended to serve as the vision for developing the desired future state for the Medicaid IT environment that furthers the goals of health information exchange and meaningful use envisioned under the Act. The SMHP should be coordinated and integrated with the Statewide plan for health IT developed under section 3013 of the Public Health Service Act, which is developed by the designated statewide entity. To ensure that the SMHP is coordinated and integrated

with the Statewide plan, we will develop criteria and processes for the evaluation of the SMHP consistent with ONC's review of the Statewide plans. The SMHP must contain: (a) A current health IT landscape assessment; (b) a vision of the State's HIT future landscape, and (c) the specific actions necessary to implement the incentive payments program, including a health IT roadmap to achieve those actions. This deliverable will be the "plan" to determine how the incentive payments will be administered; however, it is not the implementation of such plan. The SMHP must include all of the elements listed in 495.332; however, we realize that States may not have all of the answers initially. States will not be permitted to make incentive payments to providers unless they have a comprehensive EHR incentive payment program established. However, if States are not completely clear, for example, about their "to be" world at the time of the submission of their SMHP, States can present the components that are finalized and revise the SMHP to further discuss their "to be" world at a later time. Additionally, as stated previously in this final rule, we have revised the rule to include a requirement that the SMHP must describe the process in place and the methodology for verifying that eligible professionals meet their responsibility for 15 percent of the net average allowable cost for certified EHR technology and that the SMHP include information about how States will validate the patient volume consistent with the menu of options listed in § 495.306.

For this final rule, we are also explaining our understanding that the elements of the SMHP, as listed in § 495.332, may be separated into four categories, as follows:

(1) Assessment and Planning. This category of SMHP elements addresses requirements in the Act relating to increasing the use of health IT, including EHR, ensuring interoperability, and meaningful use of certified EHRs. As proposed, States will perform comprehensive assessments of the current health IT landscape environment in the State, including the inventory of existing health IT in the State, including "as is" and "to be" landscape assessments. Also, as proposed, States will develop a 5-year strategic plan, and a description of how the State Medicaid HIT plan will be planned, designed, developed and implemented, including how it will be implemented, and a description of how intrastate systems, including the MMIS, and other claims systems, have been considered in developing a health IT solution. The SMHP will include a description of data-sharing components of proposed health IT solutions, including security provisions, and description of how the State will support integration of clinical and administrative data.

(2) Ensuring improvements in health outcomes, clinical quality, and efficiency. This category of SMHP elements will address requirements in the Act relating to improving healthcare quality and lowering costs. As proposed, States will include components that describe a process for ensuring improvements in health outcomes, clinical quality, or efficiency resulting from the adoption of certified EHR technology by recipients of Medicaid EHR incentive payments and a methodology for verifying such information. As proposed, we are requiring a description of how the State will address, in the long-term, 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. We proposed that in order to obtain approval for their SMHP and implementation funding, a State would have to detail how their EHR Incentive Program addressed the concepts of self-direction including budget development and expenditure tracking for persons with disabilities. After additional consideration, CMS decided that these concepts are not directly applicable to electronic health records or meaningful use, per se, and while important, are more associated with other e-Health tools, such as personal health records. Furthermore, the provider types to whom this is most directly relevant, such as home, institutional and community-based providers and facilities, are not eligible for EHR incentives so including planning for this issue was not perceived as rising to the level of a requirement. It is anticipated that Stage 2 of meaningful use will include greater levels of patient engagement, including via personal health records. However, we think it is premature to require that States fully address this issue in their SMHPs order to initiate their EHR Incentive Programs for Stage 1.

As proposed, we will also require a description of the process in place for ensuring that any certified EHR technology used as the basis for incentive payments 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.

(3) Interoperability and Health Information Exchange. This category of SMHP elements will address requirements in the Act relating to ensuring interoperability and increasing health information exchange. We proposed a series of elements that explain how the State will adopt national data standards for health and data exchange and open standards for technical solutions as they become available. These elements of the SMHP also are included in our final rule.

(4) Administration and Oversight. This category of SMHP elements address the requirements in the Act relating to implementation and financial oversight of the program. For provider eligibility, we proposed that States provide a description of the process they will use for ensuring that each EP and eligible hospital meets provider enrollment eligibility criteria upon enrollment and re-enrollment to the Medicaid EHR payment incentive program, and the process for ensuring patient volume consistent with the criteria in § 495.304 and § 495.306, and for ensuring that each Medicaid EP is not hospital-based and that there is a methodology in place used to verify such information. We are finalizing most of these requirements, as proposed. However, in response to comments suggesting that CMS define the term "encounter" and take a menu approach to patient volume to allow States several options, based on their data sources, CMS has included changes to the SMHP requirements for the patient volume requirement in § 495.302, § 495.306, and § 495.332. These changes are discussed under the patient volume section of this final rule. We note that States that wish to offer an alternative for estimating patient volume would be required to involve key stakeholders in the determination of such alternative. We also proposed, and are finalizing, specific elements in the SMHP relating to monitoring and validation of information, including a method of ensuring all information from provider attestations is captured, stored, and verified, and any information added to the CMS Single Provider Repository is all true and accurate. We also proposed, and are finalizing, that States include a list of the specific actions planned to implement the EHR incentive program, including a description and organizational charts for workgroups within State government and external partners. As proposed, States will need to describe the process they have 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 incentive payment program, and a methodology for verifying such information is available and the process to ensure that no amounts higher than 90 percent of FFP will be claimed for CMS-approved administrative expenses in administering the certified EHR technology incentive payment program, including a methodology for verifying such information. As proposed, States will need to include mechanisms for making timely and accurate payments and a requirement that providers attest that they are not receiving a payment in any other State under the Medicaid EHR incentive program. This category also includes elements relating to financial management and auditing necessary to ensure the proper and efficient management and oversight of the program and FFP.

Finally, we proposed that the States may propose in the SMHP alternatives to measuring patient volume or achieving meaningful use. The rules for proposing alternatives are discussed elsewhere in this final rule.

We are further clarifying the definition of Health Information Technology Planning Advance Planning Document (HIT PAPD) (and any necessary update documents) to mean a plan of action that requests FFP and approval to initiate and accomplish planning activities necessary for a State agency to determine the need for and plan the acquisition of HIT equipment and services, and to acquire information necessary to prepare a HIT Implementation Advanced Planning Document (HIT IAPD), described below, or common procurement instruments, such as requests for proposals, or requests for qualifications and quotations, necessary to implement the SMHP. CMS is including a definition of the HIT PAPD so that States may submit proposed resources and planning activities, which are described in further detail in our State Medicaid Director's letter on September 1, 2009, to receive the 90 percent FFP match for initial planning activities related to the Medicaid EHR incentive payment program. In order to qualify for the 90 percent FFP administrative match, section 1903(t)(9) of the Act requires a State to demonstrate, to the satisfaction of the Secretary, compliance with three specific criteria:

(A) The State uses the funds for purposes of administering the incentive payments, including the tracking of meaningful use of certified EHR technology by Medicaid providers;

(B) The State conducts adequate oversight of the incentive program, including routine tracking of meaningful use attestations and reporting mechanisms; and

(C) The State pursues initiatives to encourage adoption of certified EHR technology to promote health care quality and the exchange of health care information under Medicaid, subject to applicable laws and regulations governing such exchange, while ensuring privacy and security of data provided to its data exchange partners.

We are further clarifying the definition of Health Information Technology Implementation Advance Planning Document (HIT IAPD) (and any necessary update documents) to mean a plan of action that requests approval of FFP to acquire necessary resources to implement and administer the activities and objectives of the State's proposed SMHP, once the SMHP is approved by CMS, including the allocation or acquisition of human resources, services and equipment. To qualify to receive FFP for administering the incentive program, States must develop an HIT PAPD, SMHP, 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 and maintain a health IT roadmap to develop the systems necessary to support providers in their adoption and meaningful use of certified EHR technology.

With respect to FFP under the Medicaid incentive program, we are clarifying that the incentive payments to providers are matched at 100 percent FFP as described above, and therefore there is no non-Federal share for these payments. However, there is a non-Federal share necessary for the administration of the payment incentives. That is, CMS is reimbursing States at 90 percent FFP for reasonable expenses related to the administration of the payment incentives. States must fund the 10 percent non-Federal share of Medicaid health information technology (health IT) administrative payments consistent with existing rules and regulations regarding funding of the non-Federal share. We review non-Federal share funding sources to ensure compliance with existing statute and regulations. Consistent with current practice, we will review non-Federal share funding sources on an individual basis using information provided by the State and gathered by CMS staff. Existing rules permit States to provide the non-Federal share of administrative claims through various sources, including appropriations, intergovernmental transfers, certified public expenditures, bona fide donations, and permissible health care related taxes. CMS' regional financial management staff will review funding sources and will review the Medicaid Budget and Expenditure System to ensure that all claims for reimbursement are appropriate. Additionally, States are required to submit SMHPs outlining their process for making payments and ensuring that all claims for reimbursement are appropriate to CMS for review and approval.

At § 495.324 we proposed to review and prior approve all elements of the State's APD documents and SMHP described in this rule to ensure that all of the intended objectives of the program are addressed. We are finalizing this proposal. States are required to submit these APD documents and the SMHP in order for us to approve FFP. Specifically, prior approval is required for the HIT PAPD (see also § 495.336). The deliverable resulting from the HIT PAPD is the SMHP. The SMHP will be reviewed and approved before it is included in an HIT Implementation APD (HIT IAPD) (see also § 495.338). The HIT IAPD also must be prior approved. After a HIT PAPD is approved for planning activities, and these planning activities are complete, we anticipate that in certain cases, States may decide to submit the SMHP and HIT IAPD together in one submission for CMS review and approval. In all cases, until approval is granted, States cannot draw down Federal funds. We envision that the prior approval process described at § 495.324 will permit States to work closely with CMS in developing the HIT PAPD prior to initiating EHR planning activities and prior to submission of the initial HIT PAPD.

We are defining "as needed" and "annual" updates to the HIT PAPD and HIT IAPD at § 495.340 and § 495.342. In consultation with States and other key stakeholders, CMS has determined that planning and implementing the Medicaid EHR incentive payment program will be a complex process that will result in a need for "as needed" and "annual" updates to the original scope of work. Therefore, we proposed that the APD process would allow States to update their APD documents when they anticipate changes in the amount of FFP, duration of the project, or scope of work or activities under the APD. We are finalizing this proposal, as it allows States flexibility to add additional tasks and milestones as the project evolves, as determined since the date the APD was

initially approved or since the most recently updated and approved APD.

We initially proposed that we envision two phases in the process of planning and implementing the incentive program, as well as the promotion of adoption and meaningful use of EHR. We are further clarifying that based on submission of HIT PAPDs in response to guidance provided in our State Medicaid Director's letter of September 1, 2009, initial planning timelines are ranging from 6 months to 18 months to develop the SMHP. CMS envisions that States will begin to administer the EHR incentive program on January 1, 2011, once the SMHP and IAPD are approved. As proposed, we will issue additional written guidance, similar to our earlier SMD letter, concerning timelines for implementation of the EHR incentive program as States develop the SMHP.

We require the HIT IAPD as the vehicle for informing us of Phase II activities. We anticipate that States will also have ongoing planning needs as implementation activities, once approved under the IAPD, are under way. We further envision that the IAPD "annual" or "as needed" updates may also include requests for approval of FFP for other Phase II that are necessary to continue planning and development for the ongoing implementation phases of the program. In section 495.388, we proposed to require that States submit information in the IAPD regarding an estimate of prospective cost allocation (OMB Circular A–87, Cost Principles for State, Local, and Indian Tribal Governments) to the various State and Federal funding sources and the proposed procedures for distributing costs including a detailed payment list file to include NPI, name, and type of provider for which the State will provide incentive payments. For the final rule, we are continuing to require the estimate of prospective cost distribution and the procedures for distributing costs; however, we are eliminating the requirement that States have to submit NPI, name and provider type as part of the estimates for cost distribution since we realize that in continuing to require this information States will not be able to submit approvable IAPDs to CMS because States will not have this information at the time of submittal; hence, States will not be successful in implementing this program.

We wish to further clarify that in proposing termination of funding if the State fails to meet the requirements and undertakings of the approved HIT PAPD, SMHP, and HIT IAPD, or fails to provide access to the required information, this requirement is necessary to ensure the proper and efficient use of FFP and is consistent with present authority under the Act and existing regulations that are promulgated by CMS, including at 45 CFR Part 95, Subpart F.

Comment: One commenter questioned whether the EHR incentive payments will be required to be processed through the Medicaid Management Information System (MMIS).

Response: Payments under the Medicaid EHR incentive program are authorized under Title XIX of the Social Security Act as part of the Medicaid program. We require that States have an automated claims processing and information and retrieval system, known as MMIS to manage health care provider payments for health care services, and provide information for program management, administration, and auditing. As such, we believe that most States will choose to process, monitor, and report Medicaid incentive payments to eligible professionals and hospitals participating in the Medicaid EHR incentive program using the MMIS. States may propose alternative methods to process, monitor, and report Medicaid incentive payments in their SMHP. Any proposed method to process, monitor, and report Medicaid incentive payments, including utilization of the State's MMIS, must be approved by CMS. Through guidance issued in a State Medicaid Directors Letter and via case by case analysis of APDs, CMS will collaborate with States to approve system development and enhancement expenditures under the most appropriate funding source, HITECH or MMIS.

Comment: One commenter provided comments on § 495.348(d), Procurement standards; Competition, and § 495.360(a). The commenter agrees that procurement transactions are conducted to provide, to the maximum extent practicable, open and free competition and recommends that procurement transactions require that bidders bid specifically for the EHR portion of any project (to ensure that the discrete costs are clearly identified), (2) no certified EHR technology may be excluded from bidding, and (3) all projects must be both EHR-neutral and provider-neutral. They further comment that CMS could consider having either a cap or percentage limits on the amount of administrative costs or consulting fees to ensure that the bulk of the award is used for the hard costs of the project: equipment, connectivity, and training.

Response: The requirement in § 495.348(d) is limited to States and other grantees of Federal funds authorized under Title XIX of the Social Security Act and does not apply to procurement standards for vendors bidding on EHR technology for eligible providers. However, CMS will encourage States to include adoption of interoperable solutions that align with the MITA principles that address IT architectural and platform neutrality.

We are making no additional revisions to this section of the rule as a result of this comment.

Comment: One commenter recommended that CMS reconsider the general rule set forth in § 495.360 that "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." The commenter states that it is typical for the vendor to own the underlying software, and State or local governments are provided a license to use the software, and this is contrary to the proposed general rule.

Response: We disagree with the recommendation to exclude a clause in all State procurement instruments that provides that the State or local government will have all ownership rights in software developed or modified using Federal funding. This is a long-standing principal for use of FFP associated with the development of information technology solutions that may be licensed for use by other State or Federal government agencies to benefit the Medicaid program, at no additional cost for the license. CMS clarifies that costs of the license agreements for proprietary software may be reimbursable under the provisions of 1903(a)(3)(F)(ii) of the Act that provides for 90 percent FFP for costs associated with certain administrative activities performed by a State. However, costs associated with developing or modifying software may not be funded with Federal funds unless the State has ownership rights to that software. This provision does not apply to eligible providers or hospitals purchasing software for which Federal funding has been provided by States through the Medicaid EHR incentive program. Proposed costs may be submitted for review and consideration for approval by CMS as part of the HIT PAPD and HIT IAPD requirements described in this proposed rule under § 495.336 and § 495.338.

We are making no additional revisions to this section of the rule as a result of this comment.

Comment: One commenter indicated that the process for State Medicaid plans seems to be lengthy, with no timeframes specified for initial submission from the State to the Department, nor is there a timeline for the approval process from CMS back to the State. There is also no timeline for the implementation of the health IT programs after a State receives approval. The commenter also notes that with the burden for administration on the States, there may not be adequate time to get all of the activities completed to have infrastructure and processes in place to accept data or attestations from the Eligible Providers and Eligible Hospitals.

Response: We provided specific guidance on timelines and process prior to the initial planning period regarding State planning activities and administrative expenses for provider incentive payments in our State Medicaid Director's letter on September 1, 2009. We also indicated in our letter that CMS will work with States to determine when each State is ready to begin making payments. We have provided additional rationale about the process for submitting documents and required content in the final rule. In the near future, CMS will issue more guidance on specific implementation activities and timelines, prior to States submission of their SMHP and IAPD.

We are making no additional revisions to this section of the rule as a result of this comment.

Comment: One commenter requested that CMS require that States pass through the matching funds to providers.

Response: The regulation at section 495.366 requires that States 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. This language is consistent with the statutory language at 1903(t)(6). We will require that this process be established in the SMHP.

We are making no additional revisions to this section of the rule as a result of this comment.

Comment: One commenter requested that CMS clarify that use of certified public expenditures (CPE) or intergovernmental transfers in the context of the Medicaid EHR incentive payments would be inappropriate, since these payments do not have a non-federal share. If CMS does permit use of CPEs in the Medicaid EHR incentive program context, CMS must require that States pass through the matching funds to providers.

Response: We believe the commenter is not clear. As explained above incentive payments to providers are matched at 100 percent; thus, there is no non-Federal share for these payments. However, there is a non-Federal share necessary for the administration of the payment incentives. CMS is reimbursing States at 90 percent for reasonable expenses related to the administration of the payment incentives and States must fund the 10 percent non-Federal share of Medicaid health information technology administrative payments consistent with existing rules and regulations regarding funding of the non-Federal share. Please see our above discussion of this issue for further detail.

We are making no additional revisions to this section of the rule as a result of this comment.

Comment: One commenter questioned why Medicaid is allowed to determine its own requirements and the impact this may have on other stakeholders.

Response: We are clarifying that we have provided specific guidance for State planning activities that must be addressed in order to qualify to receive FFP for administering the incentive program. We provided guidance in a State Medicaid Director's letter published on September 1, 2009, on this process. CMS intends to require submission of documentation that will enable the agency to evaluate whether the activities for which FFP was, or may be approved for, are being completed according to Federal requirements, including any terms and conditions of FFP approval. States must develop a HIT PAPD, a SMHP, and a HIT IAPD. These documents would describe the processes and resources States will use to implement and oversee the EHR incentive program, and would help States to construct an health IT 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) also 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. Our review process ensures 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 CMS is responsible for overseeing States in their administration of the Medicaid program, as well as ensuring the overall financial integrity of the program, States cannot simply propose activities in order to secure the 90 percent FFP. We propose to review and prior approve all elements of the State's SMHP, and APD documents described in this rule to ensure that all of the intended objectives of the program are addressed. One of the key components of the SMHP is stakeholder collaboration and coordination to ensure that an integrated strategy is developed addressing stakeholder needs.

We are making no additional revisions to this section of the rule as a result of this comment.

Comment: One commenter recommended that all the source materials needed to create the quality measure registry, is submitted to the MITA Information Architecture Review Board (IARB) for approval as a MITA standard and all the source materials be added to the MITA artifact repository. Doing this will prevent duplicative efforts and associated expense both by CMS and the participating States.

Response: We agree with the commenter. We support the concept that States should apply MITA principles to any IT development work performed for the EHR incentive program, where applicable. If a State chooses to integrate a clinical data warehouse into its MMIS system, all recommended steps, and required approvals, for MMIS development, including application of MITA guidelines, should apply. The goal of MITA is not to focus on creating new standards so much as utilizing data standards developed by other national organizations, such as those responsible for implementation of HITECH and also defining information requirements for new business processes. If a State is going to develop its own clinical data repository to store Medicaid providers' submitted clinical quality measures data (one of the MU objectives), then use of the MITA Governance boards would be a recommended approach. States whose SMHPs successfully apply MITA to their EHR incentive program systems are encouraged to store approved artifacts in the Clemson University MITA repository so that other States may benefit: *http://mita.clemson.edu.*

We are making no additional revisions to this section of the rule as a result of this comment.

Comment: One commenter, as a large pediatric provider with five physicians and four nurses in a relatively rural area, is concerned that States have not yet sent, or had approved by CMS, the State's Medicaid requirements.

Response: States are in the process of developing their SMHPs. States could not be approved to start offering incentives prior to a final rule becoming effective.

We are making no additional revisions to this section of the rule as a result of this comment.

Comment: Some commenters asked for clarification on how managed care entities would be involved in this program besides potentially being used to disburse incentive payments, as mentioned in the proposed rule. Examples included things like monitoring providers in the health plans to ensure compliance. The commenters suggested that any work done by the managed care entity should be reflected in the capitation rate.

Response: Service agreements between States and their managed care contractors are not governed by this regulation, but must be in compliance with 42 CFR part 438. We agree there are many opportunities to leverage the efficiencies of the managed care entities' activities and role with the larger goals and State responsibilities for administering the payments. We suggest that activities like distributing informational materials about the incentive program and health IT to health plan providers and enrollees would fall under most current contracts and would be considered part of the cost of doing business, which may be reflected in the administrative portion of the capitation rate.

If more significant activities are expected, such as monitoring and reporting information on the providers, health plans may exceed the normal costs of doing business and what would be adequately reflected in the administrative portion of the capitation rate. An alternative option would be for the State and managed care organization to have contractual requirements and deliverables separate from the capitation rate, including the administrative component. In the latter scenario, it would be acceptable to develop a contract amendment specifying the terms.

We are making no additional revisions to this section of the rule as a result of this comment.

Comment: A commenter asked whether or not a State would need to file a State Plan Amendment that incorporates the SMHP into their State Plan, or if the SMHP can stand alone. The commenter further asked that if the SMHP can stand alone, then would the state need to file a State Plan Amendment that references the SMHP in their plan.

Response: CMS clarifies that the State does not need to file a State Plan Amendment or reference the SMHP in their State Plan. As part of the Advance Planning Document process, the SMHP is a deliverable that is submitted to CMS for review and approval prior to expending funds for the incentive program implementation activities.

We are making no additional revisions to this section of the rule as a result of this comment.

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 proposed requirements for States' financial oversight and monitoring of expenditures. Additionally, we proposed 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). 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. 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, which may include an 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. Additionally, we would monitor provider demonstration of meaningful use.

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 also are requiring States to establish § 495.370, Provider Appeals. This section specifies 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 § 447.253(e).

Comment: One individual commented on potential fraud and abuse opportunities if large amounts of medical data can be mined, as a result of electronic health records.

Response: First, it is important to note that as part of demonstrating meaningful use providers will be submitting only aggregated, not individually identifiable data, to States. Second, we wish to clarify that providers will be required to comply with the Health Insurance Portability and Accountability Act of 1996 (HIPAA) to the extent that they are covered entities. States must provide CMS with details about how their implementation of the EHR incentive program will address Federal and State privacy laws and how all data will be secured in the SMHP.

Additionally, the act of preventing fraud should be paramount in implementing this program. In accordance with Section 1903(t)(9) of the Social Security Act, States must demonstrate to the satisfaction of the Secretary that they are conducting adequate oversight of this program and that they are complying with Federal requirements to: (a) Ensure the qualifications of providers who request Medicaid EHR incentive payments, (b) detect improper payments and (c) refer suspected cases of fraud and abuse to the Medicaid fraud control unit. In conducting required oversight responsibilities, States can receive 90 percent matching funds for allowable expenditures. States are required to assure CMS through the State's Medicaid HIT plan that they have processes in place to prevent against fraud and abuse. CMS will review and approve each State's Medicaid HIT plan.

We are making no additional revisions to this section of the rule as a result of this comment.

Comment: One commenter noted that use of electronic health records may provide claims adjudication auditors with documentation to verify that items or services provided are reasonable and necessary, supporting an upfront clean claims process and the opportunity to conduct pre- and post-pay audits without the need to request documentation in retrospect. Another commenter wanted an assurance that CMS will perform audits of a random sample of attestation surveys and that any providers that are found to be making false claims would be penalized and listed in a public report posted on CMS' Web site.

Response: We thank the commenter for the comments, but point out that meaningful use currently would not include using EHRs to provide electronic documentation in support of claims adjudication. We do, however, want to address the issue of pre- and post-audits. While one commenter is concerned with the process for adjudicating claims, the other commenter is concerned that there are other areas of this program that will necessitate pre- and post-pay audits. For Medicaid, States are required to provide information to CMS in the State Medicaid HIT plan outlining the processes and methodologies they will use to ensure that payments are being made to the right person, at the right time, for the right reason. Specifically, in year one in order to receive an incentive payment, providers will be attesting to, among other things, whether they are using a certified EHR, demonstrating meaningful use, demonstrating adopting, implementing or upgrading certified EHR technology, etc. States will be required to "look behind" provider attestations. We believe that this will require audits both pre- and post-pay. CMS believes a combination of approaches is in order which should result in accurate payments. CMS wishes to point out that States must provide assurances to CMS that they are conducting adequate oversight in order to receive the 90 percent FFP for administration of the incentive payments. Additionally, it should be noted that this program is consistent with other programs under Title XIX. States must properly administer the program or risk FFP. All costs claimed under the program are subject to review or audit. Furthermore, CMS' approval of the State Medicaid HIT plan does not relieve the State of its responsibility to comply with changes in Federal laws and regulations and to ensure that claims for Federal funding are consistent with all applicable requirements. We should point out that for Medicaid there is no statutory requirement to post individual provider's name and/or incentive payment program information to the CMS Web site.

We are making no additional revisions to this section of the rule as a result of this comment.

Comment: One commenter is concerned about the circumstances under which Medicaid is required to recoup incentive payments from providers. Specifically, the commenter requests clarification on the scenario in which a provider receives a payment for demonstrating adoption, implementation, or upgrading EHR technology in year one, demonstrating meaningful use in years two and three, but receives no payment in year four because the provider could not demonstrate meaningful use. The commenter is concerned that Medicaid will be responsible for recouping payments made in years one, two, and three.

Response: First, it should be noted that it is possible for a provider to be able to demonstrate meaningful use in one year, but not others. Thus, the failure of the provider to demonstrate meaningful use in year four would not necessarily mean that the provider failed to demonstrate meaningful use in prior years, although it could possibly alert the State to more closely review a specific provider's prior year attestations or demonstrations of meaningful use. For hospitals demonstrating meaningful use in both the Medicare and Medicaid incentive payment programs, CMS will issue further guidance about how States will be able to access the meaningful use data submitted to CMS in order for the State to meet its audit and oversight requirements. States will be required to outline in the SMHP the process for "looking behind" provider attestations and the demonstration of meaningful use including any record retention requirements.

In accordance with section 1903(t)(9) of the Social Security Act and § 495.332(c) and (e) of the regulations as well as § 495.368, States are required to include in their State's Medicaid HIT plan processes for detecting improper payments and for combating fraud and abuse. This would mean that States will be responsible for conducting audits of providers and ensuring that any requests for reimbursement for FFP meet all requirements of this subpart. When States conduct audits and determine that improper payments have been made, States are responsible for recovering and returning to CMS FFP for any incentive payments that are discovered to be improper.

We are making no additional revisions to this section of the rule as a result of this comment.

Comment: Another commenter is concerned with a similar issue. That is, the commenter requested that CMS identify and develop "safe harbor"

processes and methods for administering the incentive program that would assure States that if these processes/methods are used, States would not be at risk if the processes/methods are less successful than anticipated. An example would include a process for auditing the adoption, implementation, and upgrading process. If an audit approach was agreed to but ended up being less than effective when applied, the State should not be responsible for re-auditing providers for previous years, nor would it be denied participation in the incentive program and lose the FFP. Another commenter is similarly concerned that this is a new program and they requested that CMS explicitly recognize the States' ability to revise and redirect the program without penalty from CMS.

Response: Our focus is on ensuring that EHR incentive payments are made to the eligible provider, and are for the correct amount in the appropriate payment year (or payment cycle). CMS will ensure 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.

States can receive FFP if they are conducting adequate oversight and States must provide their plans for financial oversight and the processes and methodologies they will use to verify provider information to CMS for review and approval as part of its State's Medicaid HIT plan. We believe States may want to consider multiple ways in which to audit their providers; for example, to ensure that a provider is not excluded from the program, the State should review on a prepay basis the Office of the Inspector General's List of Excluded Individuals and Entities to determine if providers are excluded. Additionally, States may wish to consider attestation in year one for demonstrating adopting, implementing, or upgrading or meaningfully using certified EHR technology. States will have to "look behind" these attestations and we assume this will be done on a post-pay basis. One size does not fit all and we believe several audit options should be used by States to ensure "adequate oversight." However, if it is determined that the State's audit methodologies are proving to be less than effective we will require that the State update its State Medicaid HIT plan and present more effective audit strategies that will work to accomplish conducting adequate oversight of the program. States must ensure due diligence in conducting adequate oversight and all requirements of this subpart must be met or FFP could be at risk.

We are making no additional revisions to this section of the rule as a result of this comment.

Comment: One commenter requested information regarding the appeals process.

Response: For Medicaid, CMS has specified the appeals process for a Medicaid provider receiving electronic health record incentive payments in § 495.370. Specifically, the State must have a process in place consistent with the requirements established at § 447.253(e) to allow for providers 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. CMS is requiring that the State Medicaid HIT plan describe the process in place for provider appeals. We believe the States, not the Federal government, are in the best position to determine the administrative process that would best meet their needs and we believe States are in a position to design an effective appeal procedure; thus, we are providing for a great deal of State flexibility. Within the parameters of the regulation, States are free to establish reasonable criteria for appeals, to limit the issues on appeal that may be appropriate, or to adopt other procedures to prevent frivolous appeals. However, State appeal processes should be consistent with the requirement in § 447.253(e) for prompt administrative review. (States define what would constitute a prompt review, and we have not specified a time period for conducting or concluding a provider appeal.) This requirement is in keeping with providing States flexibility while retaining for providers an opportunity to avail themselves of an exception process when they believe an exception is warranted. Additionally, § 447.253(e) provides that the Medicaid agency must allow providers an opportunity to submit additional evidence. Our regulations at § 495.370 also require that the appeals processes established by the States comply with the State's own administrative procedure laws and that the State provide any additional appeal rights that would otherwise be available under the procedures established by the State.

We are making no additional revisions to this section of the rule as a result of this comment.

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 final rule. This analysis finalizes our projections which were proposed in the January 13, 2010 **Federal Register** (75 FR 1844 through 2011). 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 32 in section IV of this final rule.

A. ICRs Regarding Demonstration of Meaningful Use Criteria (§ 495.8)

Section 495.8(a)(1) of the proposed rule contained requirements for EPs, in CY 2011, to attest, through a secure mechanism, to meeting meaningful use criteria. As described in the proposed rule (75 FR 1949), we divided meaningful use objectives/measures into Sets A and B. We estimated that the total burden for an EP to attest to § 495.8(a)(1)(i) and (ii) for Set A meaningful use objectives/measures and ambulatory quality measures would be one hour. For all 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), the burden therefore equaled 442,600 hours. We estimated that the associated cost burden was $79.33 for an EP to attest to § 495.8(a)(1)(i) and (ii) for Set A meaningful use objectives/measures and ambulatory quality measures, and the total associated annual cost burden for all EPs to attest was $35,111,458. We invited comments on the estimated percentages and the numbers of (registered) EPs that will attest to the above including Set A meaningful use

objectives/measures in CY 2011, but did not receive any on this issue.

In the proposed rule, we also estimated that it would take 8 hours for an EP to attest to meeting the Set B meaningful use objectives/measures. We estimated that the total annual burden for all 442,600 non-hospital-based EPs to attest to Set B meaningful use objectives and measures was 3,540,800 hours. We estimated the associated cost burden for an EP to attest was $634.64 and the total cost burden for all non-hospital-based EPs to attest was $280,891,664. We solicited comments on the estimated percentages and the numbers of (registered) EPs that will attest to Set B objectives and measures in CY 2011, but did not receive any on this issue.

Although, as we proposed, we continue to have an attestation requirement in § 495.8(a)(1), we are revising the burden estimates for two reasons. First, as described elsewhere in this final rule, the definition of hospital-based EP has changed, resulting in about 73,000 outpatient hospital EPs becoming potentially eligible to participate in the EHR incentive program. Therefore, we are increasing the number of EPs in our burden estimates. We estimate that in CY 2011, there will be 521,600 non-hospital-based Medicare and Medicaid EPs (382,000 Medicare EPs, 95,500 dual Medicare/Medicaid EPs, and 44,100 Medicaid-eligible-only EPs) participating in the EHR incentive program. Second, in response to public comments, we have made significant changes in § 495.6 meaningful use objectives and measures for EPs, eligible hospitals and CAHs, which has changed the burden estimates.

In section II.A.2.d. of this final rule, Stage 1 Criteria for Meaningful Use in this final rule, we have re-categorized meaningful use objectives/measures as core criteria and menu criteria. Unless an exception applies, § 495.6(a) requires that an EP must meet all 15 Stage 1 meaningful use core criteria under § 495.6(d) and 5 out of 10 meaningful use menu criteria under § 495.6(e). The burden associated with the requirements in § 495.8 and § 495.6 is the time and effort required to attest to the required elements.

To comply with § 495.8(a)(1), we estimate that it would take an EP 8 hours 52 minutes to prepare and attest that during the EHR reporting period, the EP used certified technology, specify the technology, and satisfied all 15 mandatory Stage 1 meaningful use core criteria. We estimate that it would take an EP an additional 0.5 hours to select and attest to the clinical quality measures, in the format and manner specified by CMS. We estimate the total burden associated with this requirement for an EP is 9 hours 22 minute (8 hours 52 minutes + 0.5 hours) and the total burden for all the EPs to attest to these requirements is 4,855,827 hours (521,600 EPs × 9 hours 22 minutes). We estimate the associated cost burden for an EP to attest to these requirements is $743.08 (9 hours 22 minutes × $79.33 (mean hourly rate for physicians based on the May 2008 Bureau of Labor Statistics)), and the total cost burden for all EPs to attest to these requirements is $387,592,672 (4,855,827 hours × $79.33).

We recognize that some Stage 1 meaningful use menu set measures are easier to accomplish than others. We cannot predict which of the measures in the menu set an EP will select. Therefore, our burden estimates are based on two scenarios to illustrate how different scenarios would impact the burden incurred. Our "least burdensome" or "low" scenario of meaningful use demonstration assumes that an EP defers the five most burdensome objectives/measures while our "most burdensome" or "high" scenario of meaningful use demonstration assumes that an EP defers the five least burdensome meaningful use menu set measures. We recognize that in reality, nothing is absolute, and we have no basis for estimating the "all low" or "all high" scenario and have therefore created estimates for both. To compensate for the uncertainties of selection of meaningful use criteria by an EP, we use the averages of the "high" and "low" scenario estimates in Table 33. Section 495.6(a) requires that an EP must meet five out of 10 Stage 1 meaningful use menu set measures (unless exceptions apply). The burden involved is the time and effort to select and attest to the meaningful use menu set measures. In the "low" scenario, we estimate that an EP may defer the five most burdensome meaningful use measures. We estimate it will take an EP 42 minutes to comply with the remaining five Stage 1 meaningful use menu set measures. We estimate the total burden for all 521,600 EPs to comply with the meaningful use menu set criteria is 365,120 hours (521,600 EPs × 42 minutes). In the high scenario, we estimate that an EP may defer the five least burdensome meaningful use criteria. We estimate that it will take an EP 2 hours 40 minutes to comply with the remaining five Stage 1 meaning use menu measures. We estimate that the total burden for all 521,600 EPs to comply with the meaningful use menu set criteria is 1,390,586 hours (521,600 EPs × 2 hours 40 minutes). Based on the two scenarios, the average burden for an EP to comply with meaningful use menu set criteria is 1 hour 41 minutes ((42 minutes + 2 hours 40 minutes)/2). Based on the two scenarios, the average burden for all EPs to comply with meaningful use menu set criteria is 877,853 hours ((365,120 hours + 1,390,586 hours)/2). We estimate the cost burden for an EP to comply with the "low" scenario Stage 1 meaningful use menu criteria is $55.53 (42 minutes × $79.33 (mean hourly rate for physicians based on the May 2008 Bureau of Labor Statistics)), and the total cost burden for all 521,600 EPs to comply is $28,964,970 (521,600 EPs × $55.53). We estimate that the cost burden for an EP to comply with the "high" scenario Stage 1 meaningful use menu criteria is $211.49 (2 hours 40 minutes × $79.33), and the total cost burden for all EPs is $110,315.156 (521,600 EPs × $211.49). The average cost burden estimate for an EP to comply with the meaningful use menu set criteria is $133.51 (($55.53 + $211.49)/2). The average cost burden estimate for all 521,600 EPs to comply with meaningful use menu set criteria is $69,640,063 (($28,964,970 + $110,315.156)/2).

In the proposed rule, we expected that there would be steady growth in the number of participating EPs. We estimated that in 2012, there would be 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) qualified to receive EHR incentive payment. We estimated that the burden for meeting § 495.8(a)(2), which required attestation for most meaningful use measures, and electronic reporting of clinical quality measures in CY 2012, would be 0.5 hours for an EP to attest to the Set A objectives and measures and 8 hours to gather information and attest to the Meaningful Use Set B objectives/measures. For burden estimate purposes, we estimated that all 447,400 non-hospital-based Medicare, and Medicaid EPs might attest. We estimated that the total annual attestation burden for all EPs was 223,700 hours for the Set A objectives/measures and 3,579,200 hours for Set B objectives/measures. We estimated that the associated cost burden was $39.67 for the Set A meaningful use objectives/measures and $634.64 for the Set B meaningful use objectives/measures. The total cost burden for all EPs was $17,746,121 for Set A and $283,937,936

for Set B. We invited comments on the estimated percentages and the numbers of registered EPs that would attest to EHR technology used and Meaningful Use Set A and Set B objectives/measures in CY 2012, but we did not receive any comments on this issue.

We expect steady growth in EPs in CY 2012. In the final rule, based on legislation altering the definition of "hospital-based," we are increasing our estimates of participating EPs, and estimate that in CY 2012, there will be about 527,254 non-hospital-based Medicare and Medicaid EPs (385,954 Medicare EPs, 96,500 dual Medicare/Medicaid EPs and 44,800 Medicaid-eligible-only EPs) who are qualified to receive EHR incentive payments. The Stage 1 meaningful use criteria (core and menu sets) are the same for CY 2011 and CY 2012. We estimate that it would take 8 hours 52 minutes for an EP to attest that during the EHR reporting period, the EP used certified technology, specify the technology, and satisfied all 15 mandatory Stage 1 meaningful use core criteria. We estimate the total burden associated with this requirement for all EPs is -4,675,161 hours (527,254 EPs × 8 hours 52 minutes). The associated cost burden for an EP to comply with this requirement is $703.42 (8 hours 52 minute × $79.33) and the associated cost burden for all EPs is $370,880.589 (44,675,161 hours × $79.33 (mean hourly rate of physicians based on the May 2008 Bureau of Labor Statistics)).

The Stage 1 meaningful use objectives and measures are the same for CY 2011 and CY 2012. Therefore, in CY 2012, the burden associated with attesting to Stage 1 meaningful use core and menu criteria for an EP is the same as CY 2011. Again, we cannot predict which of the measures in the menu set will be selected by an EP. Therefore, as explained above, we use a "low" and "high" scenario to estimate burden. For the "low" scenario, we estimate it will take an EP 42 minutes to attest to five Stage 1 meaningful use menu-set measures. The total burden for all 527,254 EPs, therefore, would be estimated at 369,078 hours (527,254 EPs × 42 minutes). Under the "high" scenario, we estimate it will take 2 hours 40 minutes for an EP to attest to five Stage 1 meaningful use menu-set criteria. The total burden for all 527,254 EPs, therefore, is estimated to be 1,405,659 hours (527,254 EPs × 2 hours 40 minutes). Based on the two scenarios, the average burden hours for an EP to attest to meaningful use menu set measures is 1 hour 41 minutes ((42 minutes + 2 hours 40 minutes)/2), and the total average burden for all EPs is 887,369 hours ((369,078 hours + 1,405,659 hours)/2). Under the "low scenario," we estimate that the cost burden for an EP is $55.53 (42 minutes × $79.33 (mean hourly rate for physicians based on the May 2008 Bureau of Labor Statistics)), and the total cost burden for all 527,254 EPs to comply with is $29,278,942 (527,254 EPs × $55.53). For the "high scenario," we estimate that the cost burden is $211.49 (2 hours 40 minutes × $79.33), and the total cost burden for all EPs is $111,510,942 (527,254 EPs × $211.49). The average cost burden is $133.51 (($55.53 + $211.49)/2). The average cost burden for all 527,254 EPs is $70,394,942 (($29,278,942 + 111,510,942)/2).

Section 495.8(a)(2)(iii) requires that for CY 2012, EPs must report electronically to CMS, or, in the case of Medicaid EPs, the States, clinical quality information in the form and manner specified by CMS. We have limited the required measures only to those that can be automatically calculated by a certified EHR, and to those for which we have electronic specifications currently available and we are able to post as final by the date of display of this final rule. The burden associated with this requirement is the time and efforts to report the required clinical quality measures. We estimate the burden for an EP to comply with this requirement is 0.5 hours and the total burden for all EPs to comply with this requirement is 263,627 hours (527,254 EPs × 0.5 hours). We believed that an EP may assign a medical secretary to submit the specific clinical quality measures to CMS or the States. We estimate the cost burden for an EP to comply with this requirement is $7.40 (0.5 hours × $14.81 (mean hourly rate of medical secretaries based on the May 2008 Bureau of Labor Statistics)) and the cost burden for all EPs to comply with this requirement is $3,904,316 (263,627 hours × $14.81).

To estimate capital costs for EPs, we assume a certified EHR system will cost roughly $54,000. If 521,600 EPs adopt these EHRs, total capital costs prior to incentives would be roughly $23.9 billion. We also estimate that in 2011, $0.2 billion of Medicare incentive payments and $0.2 billion of Medicaid incentive payments would be provided to EPs under a low scenario, and $0.6 billion Medicare incentive payments and $0.9 billion of Medicaid incentive payments would be provided to EPs under a high scenario to help offset those costs. Therefore, we estimate that total net capital costs for EPs in 2011 would be $23.5 billion ($23.9 billion − $0.2 billion − $0.2 billion) under a low scenario and $22.4 billion ($23.9 billion − $0.6 billion − $0.9 billion). 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 $22.1 billion ($23.5 billion − $1.0 billion of Medicare incentives − $0.4 billion of Medicaid incentives) under the low scenario and 419.0 billion ($22.4 billion − $2.3 billion − $1.1 billion) under the high scenario.

As with EPs, for eligible hospitals and CAHs, we proposed, at section 495.8(b) of the proposed rule, that hospitals demonstrate they are meaningful EHR users through an attestation mechanism. As with EPs, we divided meaningful use criteria into Sets A and B. We estimated that it would take an eligible hospital or CAH 0.5 hours to attest to the requirements in § 495.8(b)(1)(i) and (ii) including the Set A meaningful use objectives/measures, .0.5 hours to select and attest to the hospital quality measures, and 7 hours to comply with gathering the information, attesting and reporting Set B objectives/measures. Therefore, the estimated the total burden for all 5,011 Medicare and Medicaid eligible hospitals and CAHs (3,620 acute care hospitals, 1,302 critical access hospitals, 78 Medicaid children's hospitals, and 11 Medicaid cancer hospitals) equaled 5,011 hours. For Set B objectives and measures, we estimated the total burden at 35,077 hours.

We believed that an eligible hospital or CAH might assign an attorney to attest on their behalf. We estimated the cost burden for an eligible hospital or CAH to attest to the Set A and hospital quality requirements was $59.98 and the total estimated annual cost burden for all eligible hospitals and CAHs to attest was $300,560. For Set B objectives/measures, we estimated a per-hospital cost burden of $419.86, and a total cost burden of $2,103,918, not including capital costs. We solicited public comments on the estimated percentages and the numbers of (registered) eligible hospitals and CAHs that would attest in FY 2011, but we did not receive any comments on this issue. We also invited comments on the type of personnel or staff that would mostly likely attest on behalf of eligible hospitals and CAHs, but we did not receive any comments on this issue.

For the final rule, as proposed, § 495.8(b) will require demonstration of meaningful use through an attestation mechanism. However, as with EPs, we have revised the burden estimates due to the changes in meaningful use

objectives and measures, in response to comments. Unless an exception applies, § 495.6(b) requires that an eligible hospital or CAH must meet all 14 Stage 1 meaningful use core criteria under § 495.6(f) and five out of 10 meaningful use menu criteria under § 495.6(g). The burden associated with the requirements in § 495.8 and § 495.6 is the time and effort required to attest to the required elements.

To comply with § 495.8(b)(1), we estimate that it would take an eligible hospital or CAH 8 hours 42 minutes to prepare and attest that during the EHR reporting period, the hospital or CAH used certified technology, specify the technology, and satisfied all 14 mandatory Stage 1 meaningful use core criteria. We estimate that it will take an eligible hospital or CAH an extra 0.5 hours to select and attest to the hospital quality measure, in the format and manner specified by CMS. We estimate the total burden associated with this requirement for an eligible hospital or CAH is 9 hours 12 minutes (8 hours 42 minutes + 0.5 hours) and the total burden all eligible hospitals and CAHs to attest to these requirements is 46,101 hours (9 hours 12 minutes × 5,011 hospitals). We believe an eligible hospital or CAH may use an attorney to attest on their behalf. We estimate the associated cost burden for an eligible hospital or CAH to attest to these requirements is $551.82 (9 hours 12 minutes × $59.98 (mean hourly rate for attorneys based on the May 2008 Bureau of Labor Statistics)) and the total cost burden for all eligible hospitals and CAHs to attest to these requirements is $2,765,150 ($551.82 × 5,011 hospitals and CAHs)).

We recognize that some Stage 1 meaningful use menu criteria are easier to accomplish than others. Therefore, as with the EPs, our burden estimates are based on a "low" and "high" scenario. Unless an exception applies, § 495.6(b) requires that an eligible hospital or CAH must meet five out of 10 Stage 1 meaningful use menu criteria. The burden involved is the time and effort to select and attest to the meaningful use menu-set measures. Under the "low" scenario, we estimate it will take an eligible hospital or CAH 42 minutes to attest to five Stage 1 meaningful use menu-set measures, resulting in a total burden for all 5,011 eligible hospitals and CAHs of 3,508 hours (5,011 hospitals × 42 minutes). Under the high scenario, we estimate it will take an eligible hospital or CAH 3 hours 30 minutes to attest to five Stage 1 meaningful use menu-set measures, resulting in a total burden for all 5,011 eligible hospitals and CAHs of 17,539 hours (5,011 hospitals × 3 hours 30 minutes). Based on the two scenarios, the average burden is 2 hours 6 minutes (42 minutes + 3 hours 30 minutes)/2), and the average burden for all eligible hospitals and CAHs is 10,523 hours (3,508 hours + 17,539 hours)/2).

We believe an eligible hospital or CAH may use an attorney to attest on their behalf. For menu-set meaningful use criteria, low scenario, we estimate the associated cost burden for an eligible hospital or CAH is $41.99 (42 minutes × $59.98 (mean hourly rate for attorneys based on the May 2008 Bureau of Labor Statistics)) and the total cost burden for all eligible hospitals and CAHs is $210,392 ($41.99 × 5,011 hospitals and CAHs). For menu-set meaningful use criteria, high scenario, we estimate the associated cost burden for an eligible hospital or CAH is $209.93 (3 hours 30 minutes × $59.98) and the total cost burden for all eligible hospitals and CAHs is $1,051,959 ($209.93 × 5,011 hospitals and CAHs). Based on the two scenarios, the average cost burden for an eligible hospital or CAH to attest to meaningful use menu set criteria is $125.96 (($41.99 + $209.93)/2). The average burden for all eligible hospitals and CAHs to attest to meaningful use menu set criteria is $631,176 (($210,392 + $1,051,959)/2).

As with EPs, our proposed regulations (at § 495.8(b)(2)) required that for FY 2012 and subsequent years, eligible hospitals and CAHs demonstrate meeting most meaningful use criteria through attestation, and electronically report hospital quality measures. As with EPs, we divided meaningful use objectives and measures into Sets A and B. For Set A, we estimated that it would take an eligible hospital or CAH 0.5 hours to attest to the requirements in § 495.8(b)(2). For Set B, we estimated it would take an eligible hospital or CAH 7 hours to gather information and attest. Assuming that 5,011 hospitals might attest, we estimated that the total annual attestation burden for all eligible hospitals and CAHs was 2,506 hours (Set A) and 35,077 hours (Set B). We estimated the total annual cost burden for all eligible hospitals and CAHs to attest was $150,310 (Set A) and $2,103,918 (Set B). We invited public comments on the estimated percentages and the numbers of registered EPs that would attest to EHR technology used in CY 2012, but we did not receive any comments on this issue.

In the final rule, we also require that for FY 2012, eligible hospitals and CAHs demonstrate meeting meaningful use criteria through attestation, except for clinical quality measures, which must be electronically reported to CMS or the States. We do not expect growth in the number of eligible hospitals or CAHs. The meaningful use criteria (core and menu sets) are the same for FY 2011 and FY 2012. To comply with § 495.8(b)(1), we estimate that it would take an eligible hospital or CAH 8 hours 41 minutes to prepare and attest that during the EHR reporting period, the eligible hospital or CAH used certified technology, specify the technology, and satisfied all 14 mandatory Stage 1 meaningful use core criteria. We estimate the total burden associated with this requirement for all eligible hospitals and CAHs to attest to these requirements is 43,596 hours (8 hours 42 minutes × 5,011 hospitals). We believe an eligible hospital or CAH may use an attorney to attest on their behalf. We estimate the associated cost burden for an eligible hospital or CAH to attest to these requirements is $521.83 (8 hours 42 minutes × $59.98 (mean hourly rate for attorneys based on the May 2008 Bureau of Labor Statistics)) and the total cost burden for all eligible hospitals and CAHs to attest to these requirements is $2,614,870 ($521.83 × 5,011 hospitals and CAHs).

We recognize that some Stage 1 meaningful use menu criteria are easier to accomplish than others. We cannot predict which of the measures in the menu criteria will be selected by an eligible hospital or CAH. Therefore, as with EPs, our burden estimates are based on a "low" and "high" scenario. Unless an exception applies, § 495.6(b) requires that an eligible hospital or CAH must meet five out of 10 Stage 1 meaningful use menu criteria. The burden involved is the time and effort to select and attest to the meaningful use menu criteria. Under the "low" scenario, we estimate it will take an eligible hospital or CAH 42 minutes to attest to five Stage 1 meaningful use menu-set measures, resulting in a total burden of 3,508 hours (5,011 hospitals × 42 minutes). Under the high scenario, we estimate it will take an eligible hospital or CAH 3 hours 30 minutes to attest to five Stage 1 meaningful use menu-set measures, resulting in a total burden of 17,539 hours (5,011 hospitals × 3 hours 30 minutes). Based on the two scenarios, the average burden for an eligible hospital or CAH to attest to meaningful use menu set criteria is 2 hours 6 minutes ((42 minutes + 3 hours 30 minutes)/2), and the average burden hours for all eligible hospitals and CAHs is 10,523 hours ((3,508 hours + 17,539 hours)/2).

We believe an eligible hospital or CAH may use an attorney to attest on their behalf. For menu-set meaningful use criteria, low scenario, we estimate

the associated cost burden for an eligible hospital or CAH is $41.99 (42 minutes × $59.98) and the total cost burden for all eligible hospitals and CAHs is $210,392 ($41.99 × 5,011 hospitals and CAHs). For menu-set meaningful use criteria, high scenario, we estimate the associated cost burden for an eligible hospital or CAH is $209.93 (3 hours 30 minutes × $59.98) and the total cost burden for all eligible hospitals and CAHs is $1,051,959 ($209.93 × 5,011 hospitals and CAHs). Based on the two scenarios, the average cost burden for an eligible hospital or CAH to attest to meaningful use menu set criteria is $125.96 (($41.99 + $209.93)/2). The average burden for all eligible hospitals and CAHs to attest to meaningful use menu set criteria is $631,175 (($210,392 + $1,051,959)/2).

Section 495.8(b)(2)(iii) requires that for FY 2012, eligible hospitals or CAHs must report electronically to CMS, or, in the case of Medicaid hospitals, the States, clinical quality information in the format and manner specified by CMS. Given that we limit the required measures only to those that can be automatically calculated by a certified EHR and to those for which we have electronic specifications currently available that we are able to post as final by date of display of this final rule. The burden associated with this requirement is the time and effort to report the required hospital quality measures. We estimate the burden for an eligible hospital or CAH to comply with this requirement is 0.5 hours and the total burden for all eligible hospitals or CAHs to comply with this requirement is 2,506 hours (5,011 hospitals and CAHs × 0.5 hours). We believe that an eligible hospital or CAH may assign a medical secretary to submit the specific hospital clinical quality measures to CMS or the States. We estimated the cost burden for an eligible hospital or CAH to comply with this requirement is $7.40 (0.5 hours × $14.81 (mean hourly rate of medical secretary based on May 2008 Bureau of Labor Statistics)) and the cost burden for all eligible hospitals or CAHs to comply with this requirement is $37,107 (2,506 hours × $14.81).

To estimate capital costs for eligible hospitals and CAHs, consistent with the sources cited in section V.G.4 of this final rule, 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, $0.2 billion of Medicare incentive payments and $0.4 billion of Medicaid incentive payments would be provided to eligible hospitals and CAHs under the low scenario, and $0.5 billion of Medicare incentive payments and $0.8 billion of Medicaid incentive payments would be provided to eligible hospitals and CAHs under the high scenario to help offset those costs. Therefore, we estimate that total net capital costs for hospitals in 2011 would be $24.5 billion ($25.1 billion − $0.2 billion − $0.4 billion) under the low scenario and $23.8 billion ($25.1 billion − $0.5 billion − $0.8 billion) under the high scenario. 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 $23.5 billion ($24.5 billion − $0.9 billion of Medicare incentives − $0.1 billion of Medicaid incentives) under the low scenario, and $21.4 billion ($23.8 billion − $2.1 billion of Medicare incentives − $0.3 billion of Medicaid incentives) under the high scenario.

Comment: Some commenters believed that CMS grossly underestimated the cost and hour burden for EPs, eligible hospitals and CAHs to comply with meaningful use Set A and Set B measures. Some commenters stated that we should take into consideration all the time required to prepare all attestation of meaningful use measures, including the manual counting of numerators and denominators in our burden estimates.

Response: Prior to and after the publication of the proposed rule, we have worked with ONC to ensure that our meaningful use objectives/measures are well aligned with certified EHR technology. In the final rule, we only require meaningful use measures that can be achieved by the functionality and capability of certified EHR technology. Furthermore, based on comments, we have explained in section II.A.2.d. of this final rule that we are including a substantial amount of flexibility in the final rule to lower the burden for EPs, eligible hospitals and CAHs in meeting the attestation and demonstration of meaningful use criteria. Some examples of such flexibility are the categorization of Stage 1 meaningful use core and menu (optional) criteria, reducing the number of meaningful use objectives/measures for 2011 and 2012, limiting the denominators, in certain cases, only to patients whose records are maintained using certified EHR technology, and lowering thresholds for many of the meaningful use measures. We believe these changes reduce burden without compromising the intent of the Congress, and the ability of EHR technology to begin to improve health care quality, efficiency, and outcomes. We have considered the comments and we have made some revisions on our previous burden estimates. While this requirement is subject to PRA, we have no way of accurately quantifying the burden. We will continue to monitor the burden associated with the implementation of EHR technology as our experience continues to grow and as EHR technology continues to evolve.

Comment: CMS received numerous comments regarding the burden (economic and other) of reporting on the large number of measures and the overall quality reporting burden this will add to EPs and other healthcare providers. Others suggested reporting on significantly smaller set of measures.

Response: As we have explained in section II.A.3.(d) of this final rule, we have reduced the reporting burden by decreasing the number of required clinical quality measures and limiting measures to those that can be automatically calculated by a certified EHR. We believe that the proposed burden estimate, which was estimated to be an additional 0.5 hours in 2011 and 2012, is reasonable and we are finalizing it.

Table 20 below lists the objectives and associated measures in which we estimate the burden to fulfill "core set," "menu set", and clinical quality measures requirements. Estimates of total capital costs at the bottom of Table 20 are derived from the estimates used in the "Industry Costs" section in Section V.G.4. of this final rule.

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TABLE 20: Burden and Capital Costs associated with Meaningful Use Objectives and Associated Measures

Stage 1 Objectives (EPs)	Stage 1 Objectives (Hospitals)	Stage 1 Measures	Burden Estimate per Respondent (EPs)	Burden Estimate per Respondent (Hospitals)	Capital Costs
CORE SET					
Use CPOE for medication orders directly entered by any licensed healthcare professional who can enter orders into the medical record per state, local and professional guidelines	Use CPOE for medication orders directly entered by any licensed healthcare professional who can enter orders into the medical record per state, local and professional guidelines	More than 30 percent of all unique patients with at least one medication in their medication list seen by the EP or admitted to the eligible hospital or CAH's inpatient or emergency department (POS 21or 23)have at least one medication order entered using CPOE	10 minutes	10 minutes	TBD - cost of a CPOE module; additionally, the cost of extra functionality to generate numerator and denominator information automatically
Implement drug-drug and drug-allergy checks	Implement drug-drug and drug-allergy checks	The EP/eligible hospital/CAH has enabled this functionality for the entire EHR reporting period	1 minute	1 minute	TBD - cost of associated with medication error e-prescribing functions
Generate and transmit permissible prescriptions electronically (eRx)		More than 40 percent of all permissible prescriptions written by the EP are transmitted electronically using certified her technology	10 minutes		TBD - cost of an e-prescribing system; additionally, the cost of extra functionality to generate numerator and denominator information automatically

Record Demographics • Preferred language • Gender • Race • Ethnicity • Date of birth	Record Demographics • Preferred language • Gender • Race • Ethnicity • Date of birth • Date and preliminary cause of death in the event of mortality in the eligible hospital or CAH	More than 50 percent of all unique patients seen by the EP or admitted to the eligible hospital's or CAH's inpatient or emergency department (POS 21 or 23) have demographics recorded as structured data	10 minutes	10 minutes	TBD – cost of functionality that can incorporate this information is coded
Maintain an up-to-date problem list of current and active diagnoses	Maintain an up-to-date problem list of current and active diagnoses	More than 80 percent of all unique patients seen by the EP or admitted to the eligible hospital's or CAH's inpatient or emergency department (POS 21 or 23) have at least one entry or an indication that no problems are known for the patient recorded as structured data.	10 minutes	10 minutes	TBD - cost of functionality that can incorporate diagnoses in coded format
Maintain active medication list	Maintain active medication list	More than 80 percentof all unique patients seen by the EP or admitted to the eligible hospital's or CAH's inpatient or emergency department (POS 21 or 23) have at least one entry (or an indication that the patient is not currently prescribed any medication) recorded as structured data	10 minutes	10 minutes	TBD - cost of functionality that can incorporate medication information in coded format

Maintain active medication allergy list	Maintain active medication allergy list	More than 80 percent of all unique patients seen by the EP or admitted to the eligible hospital's or CAH's inpatient or emergency department (POS 21 or 23) have at least one entry (or an indication that the patient has no known medication allergies) recorded as structured data	10 minutes	10 minutes	TBD - cost of functionality that can incorporate medication allergy information in coded format
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 more than 50 percent of all unique patients age 2 and over seen by the EP or admitted to eligible hospital's or CAH's inpatient or emergency department (POS 21 or 23), height, weight and blood pressure are recorded as structure data	10 minutes	10 minutes	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	More than 50 percentof all unique patients 13 years old or older seen by the EP or admitted to the eligible hospital's or CAH's inpatient or emergency department (POS 21 or 23) have "smoking status" recorded	10 minutes	10 minutes	TBD - cost of functionality that can incorporate this information in coded format
Implement one clinical decision support rule relevant to specialty or high clinical priority with the ability to track compliance to that rule	Implement one clinical decision support rule relevant to specialty or high clinical priority with the ability to track compliance to that rule	Implement one clinical decision support rule	1 minute	1 minute	TBD - cost associated with clinical decision support functionality

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 the final rule For 2012, electronically submit the measures as discussed in section II(A)(3) of the final rule	10 minutes	10 minutes	TBD - cost of the functionality to capture and report on quality measures
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	More than 50 percentof all patients of the EP or the inpatient or emergency departments of the eligible hospital or CAH (POS 21 or 23) who request an electronic copy of their health information are provided it within 3 business days	10 minutes	10 minutes	
	Provide patients with an electronic copy of their discharge instructions at time of discharge, upon request	More than 50 percent of all patients who are discharged from an eligible hospital or CAH's inpatient or emergency department (POS 21 or 23) and who request an electronic copy of their discharge instructions are provided it		10 minutes	TBD - cost an EHR system capable of storing this information and transmitting it to patients

Provide clinical summaries for patients for each office visit		Clinical summaries provided to patients for more than 50 percent of all office visits within 3 business days	10 minutes		TBD - cost an EHR systems capable of storing this information and transmitting to patients
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	1 hour	1 hour	TBD - cost an EHR system capable of storing this information and transmitting to providers and patient authorized entities
*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 and correct identified security deficiencies as part of its risk management process	6 hours	6 hours	N/A as conducting or reviewing a security risk analysis does not necessarily hinge on the purchase
CORE SET BURDEN			**9 hours 2 minutes**	**8 hours 42 minutes**	
MENU SET					

Implement drug-formulary checks	Implement drug-formulary checks	The EP/eligible hospital/CAH has enabled this functionality and has access to at least one internal or external drug formulary for the entire EHR reporting period	1 minute	1 minute	TBD - cost of associated with medication error e-prescribing functions
	Record advance directives for patient 65 years old or older	More than 50 percentof all unique patients 65 years old or older admitted to the eligible hospital's or CAH's inpatient department (POS 21) have an indication of an advance directive status recorded		1 minute	
Incorporate clinical lab-test results into EHR as structured data	Incorporate clinical lab-test results into EHR as structured data	More than 40 percentof all clinical lab tests results ordered by the EP or by an authorized provider of the eligible hospital or CAH for patients admitted to its inpatient or emergency department (POS 21 or 23) during the EHR reporting period whose results are either in a positive/negative or numerical format are incorporated in certified EHR technology as structured data	10 minutes	10 minutes	TBD - 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, research or outreach	Generate lists of patients by specific conditions to use for quality improvement, reduction of disparities, research or outreach	Generate at least one report listing patients of the EP, eligible hospital, or CAH with a specific condition.	10 minutes	10 minutes	TBD – cost of having an EHR registry function
Send reminders to patients per patient preference for preventive/ follow up care		More than 20 percentof all unique patients 65 years or older or 5 years old or younger were sent an appropriate reminder during the EHR reporting period	1 minute		TBD - cost of functionality to send reminders to patients

Provide patients with timely electronic access to their health information (including lab results, problem list, medication lists, allergies) within four business days of the information being available to the EP		More than 10 percentof all unique patients seen by the EP are provided timely (available to the patient within four business days of being updated in the certified EHR technology) electronic access to their health information subject to the EP's discretion to withhold certain information	10 minutes		TBD - cost an EHR system capable of storing this information and making it continuously available to patients
Use certified EHR technology to identify patient-specific education resources and provide those resources to the patient if appropriate	Use certified EHR technology to identify patient-specific education resources and provide those resources to the patient if appropriate	More than 10 percentof all unique patients seen by the EP or admitted to the eligible hospital's or CAH's inpatient or emergency department (POS 21 or 23) are provided patient-specific education resources	10 Minutes	10 Minutes	
The EP, eligible hospital or CAH who receives a patient from another setting of care or provider of care or believes an encounter is relevant should perform medication reconciliation	The EP, eligible hospital or CAH who receives a patient from another setting of care or provider of care or believes an encounter is relevant should perform medication reconciliation	The EP, eligible hospital or CAH performs medication reconciliation for more than 50 percent of transitions of care in which the patient is transitioned into the care of the EP or admitted to the eligible hospital's or CAH's inpatient or emergency department (POS 21 or 23)	10 minutes	10 minutes	TBD - cost an e-prescribing system capable of medication reconciliation

The EP, eligible hospital or CAH who transitions their patient to another setting of care or refers their patient to another provider of care should provide summary care record for each transition of care and referral	The EP, eligible hospital or CAH who transitions their patient to another setting of care or refers their patient to another provider of care should provide summary care record for each transition of care and referral	The EP, eligible hospital or CAH who transitions or refers their patient to another setting of care or provider of care should provides summary of care record for more than 50 percent of transitions of care and referrals	10 minutes	10 minutes	TBD - cost an EHR system capable of storing this information and transmitting it to patients
Capability to submit electronic data to immunization registries or Immunization Information Systems and actual submission according to applicable law and practice	Capability to submit electronic data to immunization registries or Immunization Information Systems and actual submission according to applicable law and practice	Performed at least one test of certified EHR technology's capacity to submit electronic data to immunization registries and follow up submission if the test is successful (unless none of the immunization registries to which the EP, eligible hospital or CAH submits such information have the capacity to receive the information electronically)	1 hour	1 hour	TBD - cost associated with functionality that can capture immunization information and submit that information to immunization registries

	Capability to provide electronic submission of reportable (as required by state or local law) lab results to public health agencies and actual submission according to applicable law and practice	Performed at least one test of certified EHR technology's capacity to provide electronic submission of reportable lab results to public health agencies and follow-up submission if the test is successful (unless none of the public health agencies to which eligible hospital or CAH submits such information have the capacity to receive the information electronically)		1 hour	TBD - cost associated with functionality that can capture lab results information and submit that information to public health agencies
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 and follow-up submission if the test is successful (unless none of the public health agencies to which an EP. eligible hospital or CAH submits such information have the capacity to receive the information electronically)	1 hour	1 hour	TBD - cost associated with functionality that can capture syndromic surveillance data and submit that information to public health agencies
MENU SET LEAST BURDENSOME CRITERIA			42 minutes	42 minutes	Hospital: $5 million to install; $1 million annual maintenance/ training costs

MENU SET MOST BURENSOME CRITERIA	2 hours 40 minutes	3 hours 30 minutes	
Time to Attest to & Report CQM	30 minutes	30 minutes	
TOTAL – CORE SET (including CQM) + LEAST BURDENSOME MENU SET CRITERIA	10 hours 14 minutes	9 hours 54 minutes	
TOTAL – CORE SET(including CQM) + MOST BURENSOME MENU SET CRITERIA	12 hours 12 minutes	12 hours 42 minutes	

*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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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.

For the proposed rule, § 495.10(a) through (c), we estimated that all 442,600 non-hospital-based Medicare, and Medicaid EPs would register in 2011 to receive an EHR incentive payment, and that it would take no more than 0.5 hours to complete the registration, resulting in a total estimated annual registration burden for all EPs of 221,300 hours (442,600 EPs × 0.5 hours). As we could not predict whether an EP or a medical secretary (on the EP's behalf) would register, we did one high-end and one low-end burden estimate. The cost burden for an EP who chose to register in the EHR incentive payment program himself or herself was $39.67 (0.5 hours × $79.33 (mean hourly rate for physicians based on the May 2008 Bureau of Labor Statistics)), with a total estimated annual cost burden for all EPs of $17,555,729 (221,300 hours × $79.33). Similarly, the cost burden for an EP who chose to use a medical secretary to register on their behalf was $7.41 (0.5 hours × $14.81), with a total estimated annual cost burden for all EPs of $3,277,453 (221,300 hours × $14.81). We used the average of the two estimates in the tally in Table 34 of the proposed rule. We invited comments on whether we should use the higher cost burden estimate ($17,555,729) or the lower cost burden estimate ($3,277,453), but we did not receive any comments on this issue. We invited public comments on the estimated percentages or the numbers of EPs that will register in CY 2011 and subsequent years, but we did not receive any comments on this issue.

We are finalizing both the lower cost estimate using the medical secretary as the personnel registering for the EP and the high cost estimate of the EP registering him or herself. Due to the revised estimates of non-hospital-based EPs eligible for the EHR incentive program, we are revising our burden estimates to reflect this change. In the final rule, we estimate that 521,600 non-hospital-based Medicare, and Medicaid EPs may register in CY 2011 to receive an EHR incentive payment. We believe that an EP may use a medical secretary to register on his/her behalf (low burden) or the EP may register him or herself (high burden). We estimate that it would take no more than 0.5 hours to complete the registration. The low cost burden for a medical secretary to register an EP is $7.41 (0.5 hours × $14.81 (mean hourly rate of medical secretaries based on the May 2008 Bureau of Labor statistics)). The total estimated annual registration burden hours for the low cost estimate is 260,800 (521,600 EPs × 0.5 hours) in the first payment year. The total estimated low cost burden for all EPs to register in CY 2011 is $3,862,448 (260,800 hours × $14.81). The high cost burden for an EP to register him or herself is $39.67 (0.5 hours × $79.33 (mean hourly rate for physicians based on the May 2008 Bureau of Labor Statistics)). In the first payment year, the total estimated annual registration burden hours for the high cost estimate is 260,800 (521,600 EPs × 0.5 hours). The total estimated high cost burden for all EPs to register in CY 2011 is $20,689,264 (260,800 hours × $79.33). We only use the average of the two estimates in the tally in Table 34.

Section 495.10(d) proposed that if there were subsequent changes in the initial registration information, the EP was responsible for providing us with updated changes in the manner specified by us. Based on our experience with provider enrollment, we estimated that about 11 percent of the Medicare and Medicaid EPs might need to update their registration information during a 1-year period. We estimated that 49,214 EPs (11 percent) might only have one occasion that required updating of information in a given year. For each occasion, we estimated that it would take no more than 0.5 hours to notify us of the changes. With that, we estimated that the annual total burden hours for 49,214 EPs to update changes were 24,607. However, we could not predict if the EP would update the registration information himself or herself or assign a medical secretary to do it. Therefore, we did two burden estimates for an EP and his/her medical secretary. The cost burden for an EP who chose to update the registration information himself or herself was $39.67. The total estimated annual cost burden for all 49,214 EPs to update registration information themselves was $1,952,073. Similarly, the cost burden for the EP who chose to use a medical secretary to update registration information on his/her behalf was $7.41. The total estimated annual cost burden for 49,214 EPs who chose to use medical secretaries to update registration information on their behalf was $364,429. We used the average of the two estimates in the tally in Table 34. We invited comments on whether we should use the higher cost burden estimate ($1,952,073) or the lower cost burden estimate ($364,429) but we did not receive any comments on this issue. We also invited 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 but we did not receive any comments on this issue.

We are finalizing both the lower cost estimate using the medical secretary as the personnel to update registration information for the EP and the high cost estimate of the EP updating their registration information. Due to the revised estimates of non-hospital-based EPs eligible for the EHR incentive program pursuant to legislative inclusion of EPs who practice in outpatient hospital setting, we are revising our burden estimate for this requirement to reflect this change. In the final rule, we estimate that about 11 percent of the Medicare and Medicaid EPs may need to update their registration information during a 1-year period. We estimate that 57,998 EPs (527,254 (revised estimated number of EPs for CY 2012) × 11 percent) may only have one occasion that requires them to update their information in a given year. For each occasion, we estimate that it will take no more than 0.5 hours to notify us of the changes. With that, we estimate that the annual total burden hours for 57,998 EPs to update registration changes are 28,999. The lower cost burden estimate for a medical secretary to update an EP's registration is $7.41 ($14.81 (mean hourly rate for medical secretary based on the May 2008 Bureau of Labor Statistics) × 0.5 hours). The total lower cost burden for all EPs to update registration information is $429,475 (28,999 hours × $14.81). The high cost burden for an EP to update their own registration information is $39.67 (0.5 hours × $79.33 (mean hourly rate for physicians based on May 2008 Bureau of Labor Statistics)). The total estimated annual high cost burden to update registration information is $2,300,491 (28,999 hours × $79.33). We only use the average of the two estimates in the tally in Table 34.

In § 495.10(a) and (b), 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 hours 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 hours). 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 hours × $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 hours × $14.81) (mean hourly rate for medical secretaries based on the May 2008 Bureau of Labor Statistics)). We invited 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 but we did not receive any comments on this issue. We are finalizing the burden estimates as proposed.

In § 495.10(d), we proposed that if there were subsequent changes in the initial registration information, the eligible hospital or CAH was responsible for providing us with updated information in the manner specified by us. Based on our experience with provider enrollment, we estimated that about 8 percent of the Medicare and Medicaid eligible hospitals and CAHs (5,011 hospitals and CAHs × 8 percent = 401 hospitals) might need to update their registration information during a 1-year period. We estimated that eligible hospitals in this 8 percent pool might only have 1 occasion that required updating of registration information in a given year. For each occasion, we estimated that it would take no more than 0.5 hours to notify us of the changes. With that, we estimated that the total annual burden hours for eligible hospitals and CAHs to update CMS of registration changes were 201 (401 hospitals and CAHs × 0.5 hours). We believe that eligible hospitals or CAHs might assign a medical secretary to update the registration information. We estimated 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 hours × $14.81) (mean hourly rate for medical secretaries based on the May 2008 Bureau of Labor Statistics)). We invited 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 but we did not receive any comments on this issue. We are finalizing the estimated burden for hospitals and CAHs that will be making subsequent registration changes for FY 2012 as proposed.

In § 495.10(e)(1), we proposed 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 estimated that in 2011, there would be about 80,900 dual Medicare/Medicaid EPs who might 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 believed that all of the 80,900 dual Medicare/Medicaid EPs might make the Medicaid program selection. We estimated that it would take no more than 0.5 hours to submit the initial Medicare or Medicaid selection notification to us. We could not predict if the EP would submit the notification to CMS himself or herself or assign a secretary to do it. Therefore, we did 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 were 40,450 in the first payment year. The cost burden for these EPs who notify CMS of Medicare or Medicaid program selection himself or herself was $39.67. The total estimated annual cost burden for all dual Medicare/Medicaid EPs to notify CMS of program selection themselves was $3,208,899. Similarly, the cost burden for an EP who chose to use a medical secretary to notify CMS of program selection was $7.41. The total estimated annual cost burden for all dual Medicare/Medicaid EPs who use medical secretaries to notify CMS of program selection was $599,065. We used the average of the two estimates in the tally in Table 34. We invited comments on whether we should use the higher cost burden estimate ($3,208,899) or the lower cost burden estimate ($599,065), but we did not receive any comments on this issue. We also invited public comments on the estimated percentages and the number of dual Medicare/Medicaid EPs that would submit initial Medicare or Medicaid program selection in 2011, 2012, 2013, or 2014 but we did not receive any comments.

In the final rule, we are finalizing both the low burden cost estimate using a medical secretary for dual-Medicare/Medicaid EPs to notify CMS of program selection and the high burden cost estimate of an EP who may do this him or herself. We have revised the total number of dual-Medicare/Medicaid EPs and the associated burden estimates pursuant to the legislative inclusion of EPs, who practice in outpatient hospital, in the incentive program. We estimate that in CY 2011, there will be 95,500 dual Medicare/Medicaid EPs who may use a medical secretary to notify CMS of the initial Medicare and Medicaid program selection. We estimate that it would take no more than 0.5 hours to submit the initial Medicare or Medicaid selection notification to us. The estimated burden for all the dual-Medicare/Medicaid EPs to comply with this requirement is 47,750 hours (95,500 EPs × 0.5 hours). The associated low cost burden for a dual-Medicare/Medicaid EP is $7.41 (0.5 hours × $14.81 (mean hourly rate for medical secretaries based on May 2008 Bureau of Labor Statistics) and the total low cost burden for all the dual-Medicare/Medicaid EPs is $707,178 (47,750 hours × $14.81). The associated high cost burden for a dual-Medicare/Medicaid EP is $39.67 (0.5 hours × $79.33 (mean hourly rate for physicians based on the May 2008 Bureau of Labor Statistics)) and the total high cost burden estimate for all dual-Medicare/Medicaid EPs is $3,788,008 (47,750 hours × $79.33). We only use the average of the two estimates in the tally in Table 34.

In § 495.10(e)(2) we proposed that EPs might switch from Medicare to Medicaid EHR incentive program or vice versa one time, and only for payment year 2014 or earlier. The burden associated with this requirement was the time required for the EP to make the Medicare/Medicaid program selection. Since we had no knowledge of how many EPs will make the subsequent changes in program selection, we assumed that all 81,700 (estimated number of dual-Medicare/Medicaid EPs for CY 2012) dual Medicare/Medicaid EPs might make subsequent program selection changes

for burden estimate purposes. We estimated that it would take no more than 0.5 hours to submit the Medicare/Medicaid selection change to us. We could not predict if the EP would submit the change to CMS himself or herself or assign a secretary to do it. Therefore, we did one high end burden estimate for an EP and one low end estimate for a medical secretary. We used the average of the two estimates in the tally in Table 34. The total estimated burden hours for all dual-Medicare/Medicaid EPs to notify CMS of program changes were 40,850 in a given year. The higher cost burden for the EP who chose to notify CMS of Medicare/Medicaid program change him or herself was $39.67. The total estimated annual cost burden for all dual Medicare/Medicaid EPs to notify CMS of program changes themselves was $3,240,630. Similarly, the lower cost burden for an EP who chose to use a medical secretary to notify CMS of program changes was $7.41. The total estimated annual cost burden for all dual-Medicare/Medicaid EPs who use medical secretaries to notify CMS of program changes was $604,989. We invited comments on whether we should use the higher cost burden estimate ($3,240,630) or the lower cost burden estimate ($604,989) but we did not received any comments on this issue. We also invited comments on the estimated percentages and the number of dual-Medicare/Medicaid EPs that would submit initial Medicare or Medicaid program changes in 2012, 2013, or 2014 but we did not receive any comments on this issue.

We are finalizing both the lower cost burden for EPs for may assign medical secretaries as the personnel to submit Medicare/Medicaid program selection changes to CMS and the high cost burden for EPs who may do this him or herself. We revised our burden estimates and the number of dual-Medicare/Medicaid EPs, pursuant to legislative inclusion of EPs who practice at outpatient hospital setting in the incentive program. For CY 2012, we estimate that there will be 96,500 dual-Medicare/Medicaid EPs. The notification will take 0.5 hours and the total burden for all dual-Medicare/Medicaid EPs will be 48,250 hours (96,500 EPs × 0.5 hours). The lower cost burden for each EP is $7.41 (0.5 hours × $14.81 (mean hourly rate for medical secretaries based on the May 2008 Bureau of Labor Statistics) and the total lower cost burden for all the dual-Medicare/Medicaid EPs will be $714,583 (48,250 hours × $14.81). The high cost burden for each EP is $39.67 (0.5 hours × $79.33 (mean hourly rate for physicians based on the May 2008 Bureau of Labor Statistics)) and the total high cost burden for all dual-Medicare/Medicaid EPs is $3,827,673 (48,250 hours × $79.33). We only use the average of the two estimates in the tally in Table 34.

C. ICRs Regarding Identification of Qualifying MA Organizations, MA–EPs and MA-Affiliated Eligible Hospitals (§ 495.202)

Section 495.202(a)(1) states that beginning with bids due in June 2011 (for plan year 2012), 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. There is no burden associated with this requirement for qualifying MA organizations offering MA HMO plans, since they are deemed to meet the definition of HMO in 42 U.S.C. 300gg–91(b)(3) of the PHS Act in accordance with § 495.202(a)(2). However, per § 495.202(a)(3), for MA organizations offering types of MA plans other than HMOs, the burden is the amount of time it will take them to attest to the fact that they meet the definition of HMO in 42 U.S.C. 300gg–91(b)(3). We believe the burden associated with this requirement for MA organizations not offering HMO type plans would be approximately 1 hour per MA organization. We do not believe that there are any MA organizations that are not offering MA HMO type plans that will request reimbursement for qualifying MA EPs or MA-affiliated eligible hospitals under the MA EHR incentive payment program. Although the timeframe goes beyond the effective date of the proposed information collection period (3 years from the effective date of the final rule), we do not believe there are any MA organizations with potentially qualifying MA EPs or potentially qualifying MA-affiliated eligible hospitals that will need to report to us beginning in 2014 (for plan year 2015) per § 495.202(a)(4). Therefore, we believe there will be no burden associated with identification of qualifying MA organizations per § 495.202(a)(1) through (4).

Section 495.202(b)(1) and (2) require a qualifying MA organization, as part of its initial bid starting with its bid for plan year 2012, to make preliminary identification of potentially qualifying MA EPs and potentially qualifying MA-affiliated eligible hospitals for which the organization is seeking incentive payments for the current plan year (2011). The burden associated with this requirement would be the time required for a MA organization to identify their MA-affiliated hospitals to CMS. In the proposed rule, we explained that when MAOs identify amounts of compensation per § 422.204(b)(2) and (5) they will also be identifying MA EPs per this requirement, and therefore there is will be no additional burden related to this requirement with respect to MA EPs. There are approximately 29 MA-affiliated eligible hospitals and approximately 12 MA organizations, or an average of 2.42 eligible hospitals for each MA organization. In the proposed rule, we estimated that the total burden hours for all MA organizations to identify their affiliated hospitals to CMS would be 3 hours. We believe a MA organization may use a billing clerk to identify the eligible hospital to us. The total cost burden for all MA organizations to identify their eligible hospitals to us would be $46.32.

Sections 495.202(b)(1) and (2), state that a MA organization, as part of its initial bid starting with plan year 2012, 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 for the current plan year. A qualifying MA organization must provide the following information on their MA-affiliated EPs and eligible hospitals: (A) name of the EP or eligible hospital; (B) address of the EP's practice or eligible hospital's location; and (C) NPI. We believe that it is within the customary business practices of an MA organization to keep the information in (A), (B), and (C) on file. The burden associated with this requirement would be the time required to provide this information to CMS along with an attestation that the MA EPs or MA-affiliated eligible hospitals meet the eligibility criteria. In the proposed rule, we estimated that it would take 0.5 hours for a MA organization to comply with this attestation requirement. We estimated that the total burden for all MA organizations to attest would be 6 hours. We believe that MA organizations may use an attorney to attest on their behalf. In the proposed rule, we estimated that the cost burden for a MA organization to attest is $29.99 and the total estimated cost burden for all MA organizations to attest would be $359.88.

Section 495.202(b)(4) states that all qualifying MA organizations, as part of their initial bids in June 2015 for plan year 2016, 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)

Section 495.204(b)(2) requires a qualifying MA organization to report to CMS within 60 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 would be 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. In the proposed rule, we estimated that there were 12 MA organizations and 28,000 MA EPs. 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 would be 480. We believe MA organizations may involve a billing clerk to report the required data to CMS. We estimated that the cost burden for a MA organization to report was $617.6 (40 hours × $15.44 (mean hourly rate of billing clerk based on the May 2008 Bureau of Labor Statistics)) and we estimated the total annual cost burden for all MA organizations to comply with this requirement would be $7,411.

Section 495.204(b)(4) states 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; (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; and (iii) methodological proposals must be submitted to CMS by June of the payment year and must be auditable by an independent third party. CMS will review and approve or disapprove such proposals in a timely manner. In the proposed rule, we estimated that it might take a MA organization one and a half hour to develop the methodology. We estimated that there are about two MA organizations that may have the need to develop the methodology. We estimated the total burden hours for the two MA organizations to develop the methodology would be 3 hours. We believed that a MA organization may use an accountant to develop the methodology. We estimated the cost burden for a MA organization was $47.48 (1.5 hours × $31.65 (mean hourly rate for accountants based on the May 2008 Bureau of Labor Statistics)), and the total cost burden for the two MA organizations to develop the methodology would be $94.95 (47.48 × 2 MA organizations).

Section 495.204(b)(5) states that for qualifying MA EPs who are not salaried, qualifying MA organizations may 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 were not salaried and that was an average of 233 non-salaried EPs in each MA organization. Further, we estimate that it might take 0.25 hour to electronically obtain and compile each attestation into a document for transmission to CMS. We estimate the total burden hours for a MA organization would be 58.3, and the total estimated burden hours for all MA organizations would be 699.6 (58.3 hours × 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 would be $900.15 (58.3 hours × $15.44 (mean salary of a 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 would be $10,801.82 ($900.15 × 12 MA organizations).

Section 495.204(b)(6) states that for qualifying MA EPs who are not salaried, qualified MA organizations may also have qualifying MA EPs send MA organization compensation information directly to CMS. We estimated the burden associated with this requirement is the time it would take the MA EP to send the information directly to CMS. However, we believe that the non-salaried MA EPS are employed by a third-party physician group which will be responsible for sending the required information to CMS. Again, we estimate that about 10 percent of the MA EPs are not salaried and that there is an average of 233 non-salaried EPs in each of the third-party physician groups. Further, we estimate that it might take 0.25 hour to electronically obtain and compile the information into a document for transmission to CMS. We estimate the total burden hours for a third-party physician group will be 58.3, and the total estimated burden hours for all third-party physician groups will be 699.6 (58.3 hours × 12 third-party physician group). We believe a third-party physician group may involve a billing clerk to compile and submit the compensation information. We estimate the cost burden for a third-party physician group to comply with this requirement will be $900.15 (58.3 hours × $15.44 (mean salary of a billing clerk based on the May 2008 Bureau of Labor Statistics)). We estimate the total annual cost burden for all third-party physician groups to comply with this requirement will be $10,801.82 ($900.15 × 12 third-party physician groups). Note that this is the same burden we estimate with respect to § 422.204(b)(5). Further, an MAO will either submit non-salary information directly to CMS, or it will have someone else do it on behalf of the MA EPs with respect to that MAO. We believe the burden related to § 422.204(b)(6) is counted in the burden we already projected with respect to § 422.204(b)(5). We do not believe any MAO will submit under both § 422.204(b)(5) and (6).

E. ICRs Regarding Meaningful User Attestation (§ 495.210)

Section 495.210(b) requires qualifying MA organizations to attest within 60 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. We estimate the burden associated with this requirement would be the time necessary to attest to the required information. We estimated that there were approximately 12 MA organizations and approximately 28,000 MA EPs, or an average of approximately 2,333 MA EPs affiliated with each qualifying MA organization. We believe that it would 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 and that meaningful use will be demonstrated through the continued reporting of HEDIS data. We estimate the total estimated annual burden hours for all MA organizations to comply with this requirement will be 480. We believe MA organizations might involve an attorney to attest on their behalf. We estimate the cost burden for a MA organization to attest will be $2,399 (40 hours × $59.98 (mean hourly rate of attorney 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 will be $28,790.

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 60 days after the close of a calendar year whether each qualifying MA-affiliated eligible hospital is a meaningful EHR user. While the EHR incentive payments for Medicare FFS and MA-affiliated hospitals are treated the same as all Medicare-certified MA affiliated hospitals they will demonstrate clinical quality measures through the continued reporting of HEDIS data. This means that § 495.210(c) generally applies to a MA-affiliated hospital that is not Medicare certified, and such a type of hospitals does 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) and through our existing PRA package related to HEDIS reporting by MA organizations—OMB control number 0938–NEW.

F. ICRs Regarding Establishing Patient Volume (§ 495.306)

This section of the final rule contains patient volume requirements, and requires EPs and certain hospitals to attest to meeting such requirement using representative periods in order to qualify for a Medicaid EHR incentive. The minimum patient volume requirements are as follows: 30 percent Medicaid patient volume for most EPs, 20 percent Medicaid patient volume for pediatricians, 30 percent needy individual patient volume for EPs practicing predominantly in an FQHC or RHC, and 10 percent Medicaid patient volume for acute-care hospitals. The burden associated with the requirements in this section is the time and effort necessary to submit the information to CMS. In the proposed rule, in each instance, we estimated it would take no longer than 0.5 hours to submit the necessary information to CMS. We estimated that 119,000 entities would submit the required information to meet 30 percent (or 20 percent pediatrician) requirements for most EPs. We estimated the total annual burden to be 59,500 hours, with total labor cost amounting to $4,720,135 (assuming that physicians (rather than staff assistants) establish patient volume ($79.33 mean hourly rate for physicians based on May 2008 Bureau of Labor Statistics).

For hospitals to attest to patient volume, we estimated that 3,631 entities would submit required information, and estimated a total burden of 1,815.50 hours (3,631 entities × .5 hours). The total labor cost associated with this requirement is $25,617. This cost burden was based on a secretary reporting patient volume on behalf of the acute care hospital at $14.11 (mean hourly rate for secretaries based on May 2008 Bureau of Labor Statistics).

We received no comments on this section; however, since we have revised our definition of hospital-based EP, the burden is revised to account for the additional number of Medicaid EPs that could now be eligible to receive Medicaid incentive payments. We currently estimate that there are an additional Medicare/Medicaid 75,700 EPs that could be eligible for an incentive payment because of the new definition of hospital-based EP. We believe there are 553,200 Medicare EPs of which 86 percent are non-hospital based or 477,500. We believe 20 percent or 95,500 will meet patient volume requirements, and therefore, potentially qualify for Medicaid EHR incentive payments. Additionally, there are 44,100 Medicaid-only EPs (nurse practitioners, certified nurse-midwives, dentists, and physician assistants) that we believe will meet patient volume. Specifically, we believe that 139,600 EPs (95,500 + 44,100) could be reporting patient volume information. Thus, the updated annual burden associated with the requirements in § 495.306 at 0.5 hours for EPs is 69,800.

The total labor cost associated with the requirement is (69,800 × 79.33) $5,537,234. The total labor cost associated with each requirement is $5,537,234.

For hospitals reporting patient volume, we have updated the burden to account for the additional CAHs that meet the definition of acute care hospital. Specifically, there are 3,620 acute care hospitals, 11 cancer hospitals, and 1,302 CAHs that must report 10 percent Medicaid patient volume, or 4,933 entities. The updated annual burden associated with the requirement, at 0.5 hours is 2,466.5 (4,933 × .05). The total labor cost is $34,803.30.

G. ICRs Regarding Process for Payments (§ 495.312)

Section 495.312(b) states that in order to receive a Medicaid EHR incentive payment, a provider must report all necessary data (including data required by subpart A of the regulations, such as meaningful use data) within the EHR reporting period. We believe the information collections associated with this requirement are discussed in the relevant sections discussing each particular requirement that would necessitate data reporting (for example, the burden for demonstrating meaningful use is discussed in the information collection section on meaningful use). Therefore, we have not calculated a separate information collection burden for this requirement.

H. ICRs Regarding Activities Required To Receive an Incentive Payment (§ 495.314)

Section 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 § 495.4.

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 believe we already accounted for this burden in the earlier discussion of the burden associated with § 495.8.

Section 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 estimated that this burden will be the same burden associated with § 495.10 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.

Section 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 § 495.4. 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 § 495.6 and 495.8.

We did not receive any comments on the information collection burdens we estimated for the proposed rule.

I. ICRs Regarding State Monitoring and Reporting Regarding Activities Required To Receive an Incentive Payment (§ 495.316)

Section 495.316(a) requires 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.

For the proposed rule, we estimated that it would take 5 hours per State to accomplish this. 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).

Comment: Some commenters asked CMS to clarify if States are responsible for collecting the MU measure data or if providers will report data directly to CMS. If the collection and reporting of MU data are States' responsibility, this would create tremendous burden on States. The commenters also asked CMS to clarify if States are responsible for validating attestations by eligible providers.

Response: For EPs and some hospitals, States are responsible for collecting the MU measure data; for hospitals that are eligible for both the Medicare and Medicaid incentives, hospitals that meet the Medicare MU objectives are deemed to have met MU for Medicaid; thus, since hospitals are required to report MU data to CMS for the Medicare EHR incentives program, these hospitals do not, in addition, have to report MU data to States. States are required to submit a State Medicaid HIT plan to CMS for review and approval outlining their methodology for collecting MU measure data and other required information outlined in this final rule. States are also responsible for validating attestations by providers. We do not believe collecting data or validating attestations is a tremendous burden on States as noted by our estimates. States can receive 90 percent FFP for administering the incentive payments to providers and for conducting adequate monitoring and oversight. In addition, it should be noted that States voluntarily participate in the Medicaid EHR incentive program.

J. ICRs Regarding State Responsibilities for Receiving FFP (§ 495.318)

Section 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)

Section 495.324(a) requires 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, § 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).

Section 495.324(c) requires 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 subpart D of Part 495 in the regulations, 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. 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)

Section 495.330(a) states that the Department can terminate 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. Section 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 estimated 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. For States to collect and submit the information required, we estimated it would 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 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 providers to demonstrate that they have adopted, implemented, or upgraded certified EHR technology or that they are meaningful users of such technology. We believe much of the burden associated with these requirements has already been accounted for in our discussion of the burden for § 495.316.

N. ICRs Regarding Access to Systems and Records (§ 495.346)

Section 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.

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)

Section 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. Although most States may already have these written standards of conduct, we have estimated the burden associated with this requirement as the time and effort necessary for a grantee to develop and maintain written standards of conduct. We estimate it will take each of the 56 grantees 0.5 hours 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)).

Section 495.348(e) requires 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. Although most States probably have these procedures already, we estimate that it will take each of the 56 grantees 0.5 hours 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)).

Section 495.348(f) imposes 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)

Section 495.350 requires 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 hours to verify the information and 0.5 hours to submit the attestation to the Department, for a total of 1 hour. The estimated annual burden for States associated with the aforementioned submission requirements is 56 hours (56 States-Territories × 1 hour 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 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)

Section 495.352 requires 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. 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 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)

Section 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 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)

Section 495.366(a)(2) requires a State to have a process in place to report actual expenditures for the Medicaid EHR 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. 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 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)).

Section 495.366(a)(3) requires 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.

Section 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.

Section § 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 § 495.8.

Section 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. Section 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. Section 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.

Section 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)

Section 495.370(a) requires states to have a process in place consistent with the requirements established in § 447.253(e) 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.

We continue to believe that 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.

U. General Comments Regarding the Information Collection Requirements

Comment: Some commenters recommended that EPs and eligible hospitals should start tracking time and resources estimates on their overall cost for complying with all the required data collection to achieve meaningful use during the reporting period. They believed the information is beneficial for CMS in developing and assessing future meaningful use objectives and measures.

Response: We welcome provider input on the required resources to comply with the meaningful use requirements. We believe the information would help us to fine-tune burden estimates for future rulemaking for subsequent stages of meaningful use demonstration.

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TABLE 21: 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 (in $)	Total Cost of Reporting (in $)	Total Capital/Maintenance Costs (in $)	Total Costs (in $)
§495.8 (a)(1)- EHR Technology Used, core Set Objectives/Measures & Quality Measures (EPs) (2011)	0938-New	521,600	521,600	9.367	4,885,827	79.33	387,592,672	0	387,592,672
§495.8 (a)(1)- menu Set Objectives/Measures high (EPs) (2011)	0938-New	521,600	521,600	2.666	1,390,586	79.33	110,315,156	21,700,000,000	21,810,315,156
§495.8 (a)(1)- menu Set Objectives/Measures low (EPs) (2011)	0938-New	521,600	521,600	0.700	365,120	79.33	28,964,970	21,700,000,000	21,728,964,970
§495.8 (a)(1)- menu Set Objectives/Measures average (EPs) (2011)	0938-New	521,600	521,600	1.683	877,853	79.33	69,640,063	21,700,000,000	21,769,640,063
§495.8(a)(2) - EHR Technology Used & core Set Objectives/Measures (EPs) (2012)	0938-New	527,254	527,254	8.867	4,675,161	79.33	370,880,539	0	370,880,539
§495.8 (a)(2)- menu Set Objectives/ Measures high (EPs) (2012)	0938-New	527,254	527,254	2.666	1,405,659	79.33	111,510,941	4,500,000,000	4,611,510,941
§495.8 (a)(2)- menu Set Objectives/ Measures low (EPs) (2012)	0938-New	527,254	527,254	0.700	369,078	79.33	29,278,942	4,500,000,000	4,529,278,942
§495.8 (a)(2)- menu Set Objectives/ Measures average (EPs) (2012)	0938-New	527,254	527,254	1.683	887,368	79.33	70,394,942	4,500,000,000	4,570,394,942
§495.8 (a)(2)- Ambulatory Quality Measures (EPs) (2012)	0938-New	527,254	527,254	0.500	263,627	14.81	3,904,316	0	3,904,316
§495.8 (b)(1)-- EHR Technology Used, core Set Objectives/Measures & Quality Measures (hospitals/CAHs) (2011)	0938-New	5,011	5,011	9.200	46,101	59.98	2,765,150	0	2,765,150

Reg Section	OMB Control No.	Respondents	Responses	Burden per Response (in hours)	Total Annual Burden (in hours)	Hourly Labor Cost of Reporting (in $)	Total Cost of Reporting (in $)	Total Capital/Maintenance Costs (in $)	Total Costs (in $)
§495.8(b)(1) - menu Set Objectives/ Measures low (hospitals/CAHs) (2011)	0938-New	5,011	5,011	0.700	3,508	59.98	210,392	20,600,000,000	20,600,210,392
§495.8(b)(1) - menu Set Objectives/ Measures high (hospitals/CAHs) (2011)	0938-New	5,011	5,011	3.500	17,539	59.98	1,051,959	20,600,000,000	20,601,051,959
§495.8(b)(1) - menu Set Objectives/ Measures average (hospitals/CAHs) (2011)	0938-New	5,011	5,011	2.100	10,523	59.98	631,176	20,600,000,000	20,600,631,176
§495.8 (b)(2)-- EHR Technology Used & core Set Objectives/Measures (hospitals/CAHs) (2012)	0938-New	5,011	5,011	8.700	43,596	59.98	2,614,870	0	2,614,870
§495.8 (b)(2)- menu Set Objectives/ Measures low (hospitals/CAHs) (2012)	0938-New	5,011	5,011	0.700	3,508	59.98	210,392	5,000,000,000	5,000,210,392
§495.8 (b)(2)- menu Set Objectives/ Measures high (hospitals/CAHs) (2012)	0938-New	5,011	5,011	3.500	17,539	59.98	1,051,959	5,000,000,000	5,001,051,959
§495.8 (b)(2)- menu Set Objectives/ Measures average (hospitals/CAHs) (2012)	0938-New	5,011	5,011	2.100	10,523	59.98	631,176	5,000,000,000	5,000,631,176
§495.8 (b)(2)- Hospital Quality Measures (hospitals/CAHs) (2012)	0938-New	5,011	5,011	0.500	2,506	14.81	37,106	0	37,106
§495.10(a)-(c) -- (EPs) (2011) low	0938-New	521,600	521,600	0.500	260,800	14.81	3,862,448	0	3,862,448
§495.10(a)-(c) -- (EPs) (2011) high	0938-New	521,600	521,600	0.500	260,800	79.33	20,689,264	0	20,689,264
§495.10(a)-(c) -- (EPs) (2011) average		521,600	521,600	0.500	260,800	47	12,275,856	0	12,275,856
§495.10(d) - (EPs) (2012) low	0938-New	57,998	57,998	0.500	28,999	14.81	429,475	0	429,475
§495.10(d) - (EPs) (2012) high	0938-New	57,998	57,998	0.500	28,999	79.33	2,300,491	0	2,300,491
§495.10(d) - (EPs) (2012) average		57,998	57,998	0.500	28,999	47	1,364,983	0	1,364,983

Reg Section	OMB Control No.	Respondents	Responses	Burden per Response (in hours)	Total Annual Burden (in hours)	Hourly Labor Cost of Reporting (in $)	Total Cost of Reporting (in $)	Total Capital/Maintenance Costs (in $)	Total Costs (in $)
§495.10(e)(1) - (EPs) (2011) low	0938-New	95,500	95,500	0.500	47,750	14.81	707,178	0	707,178
§495.10(e)(1) - (EPs) (2011) high	0938-New	95,500	95,500	0.500	47,750	79.33	3,788,008	0	3,788,008
§495.10(e)(1) - (EPs) (2011) average		95,500	95,500	0.500	47,750	47	2,247,593	0	2,247,593
§495.10(e)(2) - (EPs) (2012) low	0938-New	96,500	96,500	0.500	48,250	14.81	714,583	0	714,583
§495.10(e)(2) - (EPs) (2012) high	0938-New	96,500	96,500	0.500	48,250	79.33	3,827,673	0	3,827,673
§495.10(e)(2) - (EPs) (2012) average		96,500	96,500	0.500	48,250	47	2,271,128	0	2,271,128
§495.10(a) (b) (hospital) (2011)	0938-New	5,011	5,011	0.500	2,506	14.81	37,106	0	37,106
§495.10(d) - (hospital) (2012)	0938-New	401	401	0.500	201	14.81	2,969	0	2,969
§495.202(b)(2) (2012) EPs-preliminary ID	0938-New	12	12	0.500	6	59.98	360	0	360
§495.202(b)(2) (2012) MA-affiliated hospitals-preliminary ID	0938-New	12	12	0.250	3	15.44	46	0	46
§495.202(b)(2) (2012) EPs-final ID	0938-New	12	12	0.500	6	59.98	360	0	360
§495.202(b)(2) (2012) MA-affiliated hospitals-final ID	0938-New	12	12	0.250	3	15.44	46	0	46
§495.204(b)(2) (2012) Revenue reporting	0938-New	12	12	40.000	480	15.44	7,411	0	7,411
§495.204(b)(4) (2012) EPs-method	0938-New	2	2	1.500	3	31.65	95	0	95
§495.204(b)(5) or (b)(6)(2012) EPs-salary	0938-New	12	12	58.300	700	15.44	10,802	0	10,802
§495.210(b) (2012) EPs-attestation	0938-New	12	12	40.000	480	59.98	28,790	0	28,790
§495.306(a)(1)(i)	0938-New	139,600	139,600	0.500	69,800	79.33	5,537,234	0	5,537,234
§495.306(a)(1)(ii)(A)	0938-New	139,600	139,600	0.500	69,800	79.33	5,537,234	0	5,537,234
§495.306(a)(1)(ii)(B)	0938-New	139,600	139,600	0.500	69,800	79.33	5,537,234	0	5,537,234

Reg Section	OMB Control No.	Respondents	Responses	Burden per Response (in hours)	Total Annual Burden (in hours)	Hourly Labor Cost of Reporting (in $)	Total Cost of Reporting (in $)	Total Capital/Maintenance Costs (in $)	Total Costs (in $)
§495.306(a)(2)	0938-New	4,933	4,933	0.500	2,467	14.11	34,802	0	34,802
§495.316	0938-New	56	56	5.000	280	100	28,000	0	28,000
§495.330(a) - high	0938-New	56	56	5.000	280	35.37	9,904	0	9,904
§495.330(a) - low	0938-New	56	56	5.000	280	14.11	3,951	0	3,951
§495.330(a) - average		56	56	5.000	280	24.74	6,927	0	6,927
§495.348(c)	0938-New	28	56	0.500	28	35.37	990	0	990
§495.348(e)	0938-New	28	56	0.500	28	35.37	990	0	990
§495.348(f)	0938-New	28	56	5.000	280	35.37	9,904	0	9,904
§495.350--high	0938-New	56	56	1.000	56	35.37	1,981	0	1,981
§495.350--low	0938-New	56	56	1.000	56	14.11	790	0	790
§495.350--average		56	56	1.000	56	24.74	1,385	0	1,385
§495.352--high	0938-New	56	56	5.000	280	35.37	9,904	0	9,904
§495.352--low	0938-New	56	56	5.000	280	14.11	3,951	0	3,951
§495.352--average		56	56	5.000	280	24.74	6,927	0	6,927
§495.366--high	0938-New	56	56	5.000	280	35.37	9,904	0	9,904
§495.366--low	0938-New	56	56	5.000	280	14.11	3,951	0	3,951
§495.366--average		56	56	5.000	280	24.74	6,927	0	6,927
Total 2011*					6,344,458		481,944,348		42,781,944,348
Total 2012*					6,175,290		466,366,443		9,966,366,443

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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We will accept comments on the aforementioned information collection requirements for 60 days from the date of display for this final rule. At the conclusion of the 60-day comment period, we will publish an additional notice announcing the submission of the information collection request associated with this final rule for OMB approval. At that time, the public will have an additional 30 days to submit public comments to OMB for consideration.

To obtain copies of the supporting statement associated with the information collection requirements contained herein, access CMS' Web site at *http://www.cms.hhs.gov/PaperworkReductionActof1995*, or E-mail your request, including your address, phone number, OMB number, and CMS document identifier, to Paperwork@cms.hhs.gov, or call the Reports Clearance Office on (410) 786–1326.

In commenting on the information collection requirements, please reference the information collection request identifier (CMS–10336). To be assured consideration, comments and recommendations must be submitted in one of the following ways by September 13, 2010:

1. *Electronically.* You may submit your comments electronically to *http://www.regulations.gov.* Follow the instructions for "Comment or Submission" or "More Search Options" to find the information collection document(s) accepting comments.

2. *By regular mail.* You may mail written comments to the following address: CMS, Office of Strategic Operations and Regulatory Affairs, Division of Regulations Development, *Attention:* Document Identifier/OMB Control Number, Room C4–26–05, 7500 Security Boulevard, Baltimore, Maryland 21244–1850.

IV. Regulatory Impact Analysis

A. Overall Impact

We have examined the final impacts of this rule as required by Executive Order 12866, the Regulatory Flexibility Act, 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 final rule is anticipated to have an annual effect on the economy of $100 million or more, making it an economically significant rule under the Executive Order and a major rule under the Congressional Review Act. Accordingly, we have prepared a RIA that to the best of our ability presents the costs and benefits of the final rule.

This final 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 HHS' final rule on EHR certification programs. Each rule assessed the direct economic effects of its provisions. This final rule on Medicare and Medicaid EHR Incentive Programs addresses the impacts related to the actions taken by EPs or eligible hospitals, or CAHs to demonstrate meaningful use 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 final analysis, but also the final provisions of the other rules. Readers should understand that these forecasts are also subject to substantial uncertainty since demonstration of meaningful use will depend not only on the standards and requirements for FYs 2011 and 2012 for eligible hospitals and CYs 2011 and 2012 for EPs, but on future rulemakings issued by the HHS.

The HITECH Act provides Medicare and Medicaid incentive payments 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 payment reductions under the sustainable growth rate (SGR) formula for determining Medicare payments. Under the current law, physician payments were reduced by 23 percent beginning December 1, 2010, and are scheduled for further reductions in CY 2011. Such reductions could cause major changes in physician behavior, enrollee care, and other Medicare provider payments, but the specific nature of these changes is exceptionally uncertain. Under a current law scenario, the EHR incentives or payment adjustments 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 Medicare physician payment reductions are not included in our estimate and likewise we do not assume any additional behavioral changes from EHR incentive payments for Medicare 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 show two scenarios, which illustrate how different scenarios would 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." 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, eligible hospitals and CAHs may choose not to adopt and meaningfully use 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" scenario estimate for the demonstration of meaningful use each year, which assumes less robust adoption and meaningful use. Our "low" scenario of meaningful use demonstration assumes that roughly a decade from now, nearly 95.6 percent of hospitals and 36 percent of EPs will be "meaningful users."

Both the high and low scenario estimates are based on current law, which includes a scheduled physician payment cut of 23 percent on December 1, 2010. Such a reduction could cause major changes in physician behavior, enrollee care, and other Medicare provider payments, but the specific nature of these changes is exceptionally uncertain. In our estimates, we did not assume changes in physician behavior as a result of these payment cuts, as this 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, and the Office of the Actuary in HHS.

Since this RIA was published in the proposed rule, legislation has been enacted that increases the number of EPs that may be eligible to receive an incentive payment by changing the determination of hospital-based. A complete discussion of the issue, including comments and responses are available in section 2 of this rule stated. The determination of whether an EP is hospital-based will be based upon whether substantially all of the EP's services are furnished in places of service classified under place of service codes 21 (Inpatient Hospital) or 23 (Emergency Room, Hospital). Previously under the old definition, CMS estimated that 27 percent of EPs would meet the definition of hospital-based, however, now, under this final definition of hospital-based EPs, about 14 percent of Medicare EPs would be considered hospital-based and thus not eligible to receive any incentive payments.

There are many estimates of current EHR adoption and usage rates. There is one EHR function—e-prescribing—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 ONC's 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 (CPOE) 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 advanced 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 likely 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, despite, as those providers have commented, not being included in this final rule.

Overall, we expect spending under the EHR incentive program for transfer payments to Medicare and Medicaid providers over 10 years to be $9.7 billion under the low scenario, and $27.4 billion under the high scenario (these estimates include net payment adjustments for Medicare providers who do not achieve meaningful use in 2015 and beyond in the amount of $3.9 billion under the high scenario and $8.1 billion under the low scenario). We have also estimated "per entity" costs for EPs, eligible hospitals, and CAHs. 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. We remain persuaded after consideration of the public comments that implementation costs will be significant for each participating entity because providers who would like to qualify as meaningful users of EHRs will need to purchase certified EHR technology. We further acknowledge that certified EHRs may differ in many important respects from the types of EHRs noted in these comments and the functionalities they contain may differ. However, we still 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. Thus it remains that although both cost and benefit estimates are highly uncertain, the RIA that we have prepared to the best of our ability presents the costs and benefits of the final rulemaking.

B. Regulatory Flexibility Analysis

The Regulatory Flexibility Act requires agencies to prepare an Initial Regulatory Flexibility Analysis to describe and analyze the impact of the final rule on small entities unless the Secretary can certify that the regulation will not have a significant impact on a substantial number of small entities. In the healthcare sector, Small Business Administration size standards define a small entity as one with between $7 million and $34 million in annual revenues. For the purposes of the Regulatory Flexibility Act, 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 Regulatory Flexibility Act's definitions, it is the normal practice of HHS simply to assume that all affected providers are "small" under the Regulatory Flexibility Act. In this case, most 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 believe that the adoption and meaningful use of EHRs will have an impact on virtually every EP and eligible hospital, as well as CAHs and some EPs and hospitals affiliated with MA organizations. While the program is voluntary, in the first 5 years it carries substantial positive incentives that will make it attractive to virtually all eligible entities. Furthermore, entities that do not demonstrate meaningful use of EHR technology 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, CAHs 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 may 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 that EPs, CAHs and eligible hospitals 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, implement this new technology, and train their staff on its use. The costs for implementation and complying with the criteria of meaningful use could lead to higher operational expenses. However, we believe that the combination of payment incentives and long-term overall gains in efficiency will compensate for the initial expenditures.

1. Number of Small Entities

In total, we estimate that there are approximately 624,000 healthcare organizations (EPs, eligible hospitals, or CAHs that will be affected by the incentive program. These include hospitals and physician practices as well as doctors of medicine or osteopathy, dental surgery or dental medicine, podiatric medicine, optometry or a chiropractor. Additionally, eligible nonphysicians (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 and implement a certified EHR and $10,000 annually for ongoing maintenance according to the CBO. In that paper, Evidence on the Costs and Benefits of Health Information Technology, May 2008, in attempting to estimate the total cost of implementing health IT systems in office-based medical practices, recognized the complicating factors of EHR types, available features and differences in characteristics of the practices that are adopting them. The CBO estimated a cost range of $25,000 to $45,000 per physician. For all eligible hospitals, the range is from $1 million to $100 million. Though reports vary widely, we anticipate that the average would be $5 million to achieve meaningful use. We estimate $1 million for maintenance, upgrades, and training each year. See the Costs of EHR adoption in section a under Background and Assumptions portion of this analysis for a discussion regarding the costs of adoption and variation by size and details on our estimates for the number of entities that are eligible for the incentive within each eligibility type category.

Comment: One commenter suggested that the Regulatory Flexibility Act analysis did not include an assessment of the cost to implement the rule at state and local health departments. State and local health departments do operate clinics and provide care to the public. Some state and local health departments would be considered small businesses under the Regulatory Flexibility Act and an assessment of the implementation costs for these entities would allow us to work together to identify possible funding sources and cost savings strategies.

Response: Under Medicaid, clinics such as rural health clinics or FQHCs are not eligible providers that can receive incentive payments. However, EPs within these clinics can receive incentive payments if they meet all other eligibility requirements. The Federal costs and payments associated with EHR implementation for EPs are captured on in Tables 32 and 33.

2. Alternatives Considered

This final rule implements new provisions of the Act for providing incentives for EPs, eligible hospitals, and CAHs that adopt and demonstrate meaningful use of certified EHR technology. HHS has no discretion to change the incentive payments or Medicare 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 through the definition of 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 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 HITECH Act. We note that with regard to reporting of clinical quality measures for purposes of demonstrating meaningful use, we initially 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 final rule, is to require reporting of quality measures in phases. In 2011, there will be a requirement to report clinical quality measures through attestation with a numerator, denominator, and exclusions. Electronic clinical quality measure reporting will begin in FY 2012 for hospitals and CY 2012 for EPs. We expect that additional clinical 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 time period for demonstrating adequate patient volume, and the requirements and methods for demonstrating meaningful use are

discussed in section II.D. of this final 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 Regulatory Flexibility Act to minimize burden on small entities are met by this rule as final.

Comment: Commenters cited the variation in the costs of EHR adoption across EP settings. For example, smaller practices believe their costs of EHR adoption to be higher per physician than larger counterparts. They believe they cannot realize the staff reductions and related cost savings from EHR adoption due to greater cross-functionality for their staff.

Response: We acknowledge the different experiences EPs have with EHR adoption and implementation. Two additional studies relating to the costs of adoption among small practices (Miller et al. (2005) "The Value Of Electronic Health Records In Solo Or Small Group Practices" Health Affairs 24(5): 1127–1137, and Zaroukian and Sierra (2006) "Benefiting from Ambulatory EHR Implementation: Solidarity, Six Sigma, and Willingness to Strive" The Journal of Healthcare Information Management 20(1): 53–60) estimate the cost per physician to be $44,000 per year with roughly $8,500 to $13,000 in ongoing maintenance. However, even among these studies there was still variation in experience. The per provider design of meaningful use incentive payments and orientation of other government health IT grant programs is to facilitate adoption and positive return on investment across health care settings. Thus we continue to hold that our cost estimates are reasonable estimations of provider experience while acknowledging that variations in experiences will be inevitable.

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 604 of the Regulatory Flexibility Act. For purposes of section 1102(b) of the Act, we define a small rural hospital as a hospital that is located outside of a metropolitan statistical area and has fewer than 100 beds. This final rule 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 Medicare payments. As stated above, we have determined that this final rule would create a significant impact on a substantial number of small entities, and have prepared a Regulatory Flexibility Analysis as required by the Regulatory Flexibility Act 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.

Comment: Several commenters have disagreed with our assessment, noting that the unique circumstances of small rural hospitals will not lead to efficiency and lower costs as it might with urban hospitals, but would lead to increased costs related to loss of productivity among the staff for implementing and learning an EHR system, and in later years, Medicare payment adjustments because of the lack of broadband access in these areas among other reasons.

Response: Although we agree that small rural hospitals will have challenges inherent in their location, size and staffing complexity, we also acknowledge that smaller, more rural hospitals could experience added burden in achieving meaningful use. Supplemental funding to Regional Extension Centers to assist CAHs will work to lessen disparity between urban and rural hospitals. We also believe that the presence of incentive payments, market demands and rewards for data exchange, and future cost savings resulting from meaningful use will increase hospital adoption and meaningful use of EHRs.

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 2010, that threshold is approximately $135 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. This program is voluntary for States and States offer the incentives at their option. The State role in the incentive program is essentially to administer the Medicaid incentive program. While this entails certain procedural responsibilities, these do not involve substantial State expense. In general, each State Medicaid Agency that participates in the incentive program will be required to invest in systems and technology to comply—States will have to identify and educate providers, evaluate their attestations and pay the incentive. However, the Federal government will fund 90 percent of the State's related administrative costs, providing controls on the total State outlay.

The investments needed to meet the meaningful use standards and obtain incentive funding are voluntary, and hence not "mandates"within the meaning of the statute. However, the potential reductions in Medicare reimbursement 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 $135 million; however, because EPs may choose for various reasons not to participate in the program, we do not have firm data for the percentage of participation within the private sector.

This RIA, taken together with the remainder of the preamble, constitutes the analysis required by UMRA.

E. Federalism

Executive Order 13132 establishes certain requirements that an agency must meet when it promulgates a final rule that imposes substantial direct requirement costs on State and local governments, preempts State law, or otherwise has Federalism implications. This final rule 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 for expenses associated with administering the program. As previously stated, we believe that State administrative costs are minimal. We note that this final rule does add a new

business requirement for States, because of the 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. States will interface with the NLR since registration of providers will be stored in the NLR. For tracking and making payments, we believe that most States will use their current MMIS system to make payments. States must inform us of their plans for payments, systems, etc, via the SMHP, PAPD and IAPD; additionally, States will indicate the costs associated with these activities in their PAPD and IAPD. CMS is providing 90 percent FFP to States for building the interface and/or for updates to the MMIS related to EHR incentive payment administration. We believe the Federal share of the 90 percent match will protect the States from burdensome financial outlays and, as noted above, States offer the Medicaid EHR incentive program at their option.

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 final rule would implement the provisions of the American Recovery and Reinvestment Act of 2009 (ARRA) (Pub. L. 111–5) that provide incentive payments to EPs, eligible hospitals, and CAHs participating in Medicare and Medicaid programs that adopt and meaningfully use certified EHR technology. The final rule specifies the initial criteria that an EP, eligible hospital, or CAH 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. As noted earlier in this RIA, changes both in legislation and policy based on comments from the public have been taken into account for the preparation of this final impact analysis.

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 demonstrate meaningful use of certified EHR technology. However, we have discretion around how best to meet the HITECH Act requirements for meaningful use for FY 2011 and beyond, which we have exercised in this final rule. Additionally, we have used our discretion to appropriately time the registration, attestation and payment requirements to allow EPs and eligible organizations as much time as possible in coordination with the anticipated certification of EHR technology to obtain and meaningfully use certified EHRs. 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 HITECH Act, however, those costs cannot be estimated and are not captured in this analysis.

3. Background and Assumptions

The principal costs of this final rule are the additional expenditures that will be undertaken by eligible entities in order to obtain the Medicare and Medicaid incentive payments to adopt, implement or upgrade and/or demonstrate meaningful use of certified EHR technology, and to avoid the Medicare payment adjustments that will ensue if they fail to do so. The estimates for the provisions affecting Medicare and Medicaid EPs, eligible hospitals, and CAHs are somewhat uncertain for several reasons: (1) The program is voluntary although payment adjustments will be imposed on Medicare providers who are unable to demonstrate meaningful use starting in 2015; (2) the criteria for the demonstration of meaningful use of certified EHR technology has been finalized for stage one but will change over time; (3) the HHS certification process although defined, has yet to be implemented;, and, (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. The net costs and savings shown for this program represent two possible scenarios and actual impacts could differ substantially.

As written in the preamble, this final 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, CAHs 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 final 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, including CAHs under Medicare, Medicaid, and MA and used them throughout the analysis.

- About 553,200 Medicare FFS EPs in 2011 (some of which will also be Medicaid EPs).
- About 14 percent of the total EPs are hospital-based Medicare EPs, and are not eligible for the program. This leaves approximately 477,500 nonhospital-based Medicare EPs in 2011.
- Twenty percent of the nonhospital-based Medicare EPs (approximately 95,500 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. We assume that any EP in this situation will choose to receive the Medicaid incentive payment, because it is larger.
- About 44,100 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
  - ++ 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 third quarter 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 continue to 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. Although reports vary widely, we anticipate that the average would be $5 million to achieve meaningful use, 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 EHRs currently in use and may differ in the functionalities they contain. We estimate $1 million for maintenance, upgrades, and training each year. 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.

For an eligible Medicaid EP, the first year incentive can be based on 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 studied 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 (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. 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 95,500 in 2011). Since the Medicaid incentive payments are higher than those for Medicare and EPs can only receive payments from one program, we assume the dually eligible EPs will receive their payments through the Medicaid program. It is also important to note that just as there is overall variation in state Medicaid programs, we anticipate there will be variation in the design and timing of state Medicaid EHR incentive programs. New data on the pace of state planning for meaningful use was used to adjust Medicaid adoption scenarios. Thus, how and when providers apply for meaningful use through Medicaid will likely differ by state. Medicaid also offers incentive payments for 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

The American Hospital Association (AHA) conducts annual surveys that among other measures, track hospital spending. We have updated these data to reflect the latest figures from the 2008 AHA Survey. Costs at these levels of adoption were significantly higher in 2008 than 2007. This may better reflect the costs of implementing additional functionalities. We have also updated the number of discharges using the most recent cost report data available. The range in yearly information technology spending among hospitals is large—from $36,000 to over $32 million based on 2007 and 2008 AHA data. EHR system costs specifically were reported by experts to run as high as $20 million to $100 million; HHS discussions with experts led to cost ranges for adoption that varied by hospital size and level of EHR system sophistication. Research to date has shown that adoption of comprehensive EHR systems is limited. In the aforementioned AHA study, 1.5 percent of these organizations had comprehensive systems, which were defined as hospital-wide clinical documentation of cases, test results, prescription and test ordering, plus support for decision-making that included treatment guidelines. Some 10.9 percent have a basic system that does not include physician and nursing notes, and can only be used in one area of the hospital. Applying a similar standard to the 2008 AHA data results in roughly 3–4 percent of hospitals having comprehensive systems and 12 to 13 percent having basic systems. According to hospital CEOs, the main barrier to adoption is the cost of the

systems, and the lack of capital. Hospitals have been concerned that they will not be able to recoup their investment, and they are already operating on the smallest of margins. Because uptake of advanced systems is low, it is difficult to get a solid average estimate for implementation and maintenance costs that can be applied across the industry. In addition, we recognize that there are additional industry costs associated with adoption and implementation of EHR technology that are not captured in our estimates that eligible entities will incur. Because the impact of those activities, such as reduced staff productivity related to learning how to use the EHR technology, the need to add additional staff to work with HIT issues, administrative costs related to reporting, and the like are unknown at this time and difficult to quantify.

5. Medicare Incentive Program Costs

a. Medicare Eligible Professionals (EPs)

In the proposed rule, CMS said that an EP would be a hospital-based EP and therefore ineligible to receive a Medicare or Medicaid EHR incentive payment if more than 90 percent of their services are provided in the following place of service (POS) codes for HIPAA standard transactions: 21—Inpatient Hospital, 22—Outpatient Hospital, 23—Emergency Room.

However, as previously noted here and discussed elsewhere in this final rule, Congress amended the law to include only POS codes 21 (inpatient) and 23 (emergency room), excluding 22 (outpatient hospital), thereby permitting some hospital-based EPs to qualify for the incentive payment. Accordingly we have updated our tables to reflect the increased number of EPs that may now qualify for the incentive payments, and those revisions to the numbers flow throughout these updated tables.

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 14 percent of those EPs are hospital-based, based on the definition final in § 495.4, and therefore, do not qualify for incentive payments. This percentage of EPs were 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 is uncertain, so we established high and low scenarios 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 a 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 21.3 percent beginning June 1, 2010, and are scheduled to be further reduced beginning in CY 2011. 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 Medicare 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 non-hospital based Medicare EPs, (including those additional EPs who may now qualify under the revised definition), who will demonstrate meaningful use of certified EHR technology over the period CYs 2011 through 2019 is as shown in Table 22.

TABLE 22: 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)	477.5	482.4	487.3	492.2	497.1	502.1	507.1	512.0	517.0
EPs that are both Medicare and Medicaid EPs (thousands)	95.5	96.5	97.5	98.4	99.4	100.4	101.4	102.4	103.4
Low Scenario:									
Percent of EPs who are Meaningful Users	10	13	15	18	21	24	28	32	36
Meaningful Users (thousands)	39.9	48.7	58.8	70.2	83.1	97.3	112.9	129.9	148.1
High Scenario:									
Percent of EPs who are Meaningful Users	36	40	44	49	53	58	62	66	70
Meaningful Users (thousands)	136.8	154.7	173.3	192.6	212.2	231.9	251.3	270.4	288.8

Under the HITECH Act, EPs can receive up to 5 years of Medicare incentive payments for the demonstration of 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 (2011 or 2012) 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, (with some limitations on switching programs) 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: of $63,750 versus $44,000 for Medicare. 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 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 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 organizations 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 use 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 started with the estimated rate of EHR adoption from the study with the most rigorous definition, but note that the meaningful criteria are not equivalent to a fully functional system as defined in this study. (DesRoches, CM, Campbell, EG, Rao, SR et al. (2008) "Electronic Health Records in Ambulatory Care—A National Survey of Physicians" New England Journal of Medicine 359(1): 50–60). For the low scenario, 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.

Given the revisions to the meaningful use criteria in this final rule and the nationwide implementation of the Regional Extension Center Program, the likelihood of reaching the high scenario has increased. However, actual adoption trends could be significantly different from these assumptions, given the elements of uncertainty we describe throughout this analysis.

Net costs for the low scenario of the Medicare EP portion of the HITECH Act are shown in Table 23.

TABLE 23: Estimated Costs (+) and Savings (–) for Medicare EPs Demonstrating Meaningful Use of Certified EHR Technology, Low Scenario (in billions)

Fiscal Year	Incentive Payments	Payment Adjustment Receipts	Benefit Payments	Net Total
2009	—	—	—	—
2010	—	—	—	—
2011	$0.2	—	—	$0.2
2012	$1.0	—	—	$1.0
2013	$0.9	—	—	$0.9
2014	$0.6	—	—	$0.6
2015	$0.5	–$0.6	—	–$0.1
2016	$0.3	–$1.0	—	–$0.6
2017	$0.1	–$1.4	—	–$1.3
2018	—	–$1.6	—	–$1.6
2019	—	–$1.6	—	–$1.6
Total, 2009-2014	$2.6	—	—	$2.6
Total, 2009-2019	$3.6	–$6.1	—	–$2.5

The estimated net costs for the high scenario of the Medicare EP portion of the HITECH Act are shown in Table 24.

TABLE 24: 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	$0.6	—	—	$0.6
2012	$2.3	—	—	$2.3
2013	$2.0	—	—	$2.0
2014	$1.3	—	—	$1.3
2015	$1.1	–$0.4	—	$0.7
2016	$0.7	–$0.6	—	$0.1
2017	$0.3	–$0.8	—	–$0.5
2018	—	–$0.8	—	–$0.8
2019	—	–$0.8	—	–$0.8
Total, 2009-2014	**$6.2**	**—**	**—**	**$6.2**
Total, 2009-2019	**$8.3**	**–$3.4**	**—**	**$5.0**

b. Medicare Eligible Hospitals and CAHs

In brief, the estimates of hospital adoption were developed by calculating projected incentive payments (which are driven by discharges), comparing them to projected costs of attaining meaningful use, and then making assumptions about how rapidly hospitals would adopt given the fraction of their costs that were covered. In addition, our estimates have been updated to reflect that the additional challenges likely to be experienced in the adoption of EHRs among CAHs will be partially ameliorated by supplements to Regional Extension Center funding to assist CAHs with EHR adoption.

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 $11,000 to a high of $12.9 million, with the median being $3.8 million. The potential Medicare incentive payments for each eligible hospital were compared with the hospital's expected cost of purchasing and operating certified EHR technology. Costs of adoption for each hospital were estimated using data from the 2008 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 final meaningful use definition will be the hardest one for hospitals to meet. Table 25 provides these proportions.

TABLE 25: Hospital IT Capabilities By Hospital Size

	Levels of Adoption							
	Any CPOE Meds		Lab Results		Neither		Total	
Hospital Size	Number of Hospitals	Percentage	Number of Hospitals	Percentage	Number of Hospitals	Percentage	Number of Hospitals	Percentage
CAHs	176	19%	440	48%	293	32%	909	23%
Small/Medium	817	31%	1,352	51%	462	18%	2,631	67%
Large (400+beds)	216	54%	163	41%	18	5%	397	10%
Total	1209	31%	1955	50%	773	20%	3,937	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 have updated these data to reflect the latest figures from the 2008 AHA Survey. Costs at these levels of adoption were significantly higher in 2008 than 2007. This may better reflect the costs of implementing additional functionalities. We have also updated the number of discharges using the most recent cost report data available. 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 first demonstrating meaningful use in FY 2016 or later are not eligible for incentive payments. Medicare 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 to illustrate the uncertainty, we are providing two scenarios for our estimates. Our high scenario estimated net costs for section 4102 of the HITECH Act are shown in Table 26: Estimated costs (+) and savings (−) for eligible hospitals adopting certified EHRs. This provision is estimated to increase Medicare hospital expenditures by a net total of $10.1 billion during FYs -2011 through 2019.

TABLE 26: 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	$0.5	—	([1])	$0.5
2012	$2.1	—	([1])	$2.1
2013	$2.2	—	([1])	$2.2
2014	$1.9	—	([1])	$1.9
2015	$2.1	-$0.3	([1])	$1.8
2016	$1.3	-$0.1	([1])	$1.2
2017	$0.5	-$0.1	([1])	$0.5
2018	—	([1])	([1])	([1])
2019	—	—	([1])	([1])
Total, 2009-2014	$6.7	—	–$0.1	$6.7
Total, 2009-2019	$10.7	–$0.5	–$0.2	$10.1

[1] Savings of less than $50 million.

We are also providing the estimates for a low scenario in Table 27.

TABLE 27: 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	$0.2	—	([1])	$0.2
2012	$0.9	—	([1])	$0.9
2013	$1.1	—	([1])	$1.1
2014	$1.2	—	([1])	$1.2
2015	$1.4	–$0.9	([1])	$0.5
2016	$1.2	–$0.6	([1])	$0.6
2017	$0.6	-$0.3	([1])	$0.3
2018	—	-$0.2	([1])	-$0.2
2019	—	-$0.1	([1])	-$0.1
Total, 2009-2014	$3.5	—	–$0.1	$3.5
Total, 2009-2019	$6.7	–$2.0	–$0.2	$4.6

[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 28, 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 28 shows the high scenario estimates:

TABLE 28: 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 two scenarios which are examples of what we believe are possible low rates and high rates of adoption.

Table 29 shows the low scenario estimates.

TABLE 29: 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	0.1	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 29, 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 30 shows our high scenario estimated percentages of the total potential incentive payments associated with eligible hospitals that could demonstrate meaningful use of EHR systems. Also shown are the estimated percentages of potential incentives that would actually be paid each year.

TABLE 30: 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	38.4%	38.4%
2012	53.5%	53.5%
2013	70.2%	70.2%
2014	82.6%	82.6%
2015	92.6%	54.2%
2016	96.9%	43.4%
2017	99.0%	—
2018	100.0%	—

For instance in FY 2012 under the high scenario, 53.5 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, 92.6 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 54.2 percent of all possible incentive payments actually paid in that year.

Table 31 shows the low scenario estimates.

TABLE 31: 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	16.8%	16.8%
2012	21.8 %	21.8%
2013	32.1%	32.1%
2014	47.6%	47.6%
2015	66.4 %	49.6%
2016	85.9%	64.1%
2017	91.4%	—
2018	95.6 %	—

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.

Comment: The AHA surveyed 795 hospitals in January 2010 asking whether their EHR systems could meet each of the meaningful use objectives now and in coming years: 45 percent reported they could meet all Stage 1 objectives by 2015 meaning that the remainder might be subject to penalties.

Response: Their survey was based on our proposed definition of meaningful use. The definition of meaningful use in this final rule offers more flexibility and lower thresholds which we believe will make it easier for eligible hospitals to qualify for incentives. However we do acknowledge that the meaningful use criteria described in this final rule may still challenge hospitals to use their IT in ways that improve patient care and outcomes. We also acknowledge that smaller, more rural hospitals could experience added burden in achieving meaningful use related to timing and costs of implementation. Supplemental funding to Regional Extension Centers to assist CAHs will work to lessen disparity between urban and rural hospitals. We also believe that the presence of incentive payments, market demands and rewards for data exchange, and future cost savings resulting from meaningful use will increase hospital adoption and meaningful use of EHRs.

c. Critical Access Hospitals (CAHs)

We estimate that there are 1,302 CAHs eligible to receive EHR incentive payments. Given the financial assistance available under HITECH for Regional Extension Centers, whose priorities include assisting CAHs in EHR adoption, we estimate that the 19 percent of CAHs with relatively advanced EHR systems will achieve meaningful use before 2016. We also estimate that most of the remaining CAHs that have already adopted some kind of EHR system (48 percent of CAHs) will also achieve meaningful use by 2016. Our estimates regarding the incentives that will be paid to CAHs are incorporated into the overall Medicare and Medicaid program costs.

We note that in response to comments this final rule amends the definition of acute care hospital for purposes of the Medicaid EHR incentive payment program to generally include critical access hospitals that meet the Medicaid patient volume criteria. Thus, the change in the definition has required that we update our tables to reflect the increased number of hospitals that now may qualify for the Medicaid EHR incentive payment program under this new definition. The numbers and percentages from the revised tables are reflected throughout this final impact analysis. Additionally, EHR adoption rates have been adjusted now that CAHs will be eligible for both Medicare and Medicaid EHR incentive payments.

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 qualify for a Medicaid incentive payment for adopting, implementing, or upgrading in their first participation year, or for meaningful use, and up to an additional 5 years of incentive payments for demonstrating meaningful use of certified EHR technology. Under Medicaid, EPs include physicians (including pediatricians), dentists, certified nurse-midwives, nurse practitioners, and certain physician assistants. Initial incentive payments are available through 2016, and incentive payments cannot be made after 2021. The Medicaid hospital incentives are similar to those specified in section 4102 of the HITECH Act for Medicare, except that they must be paid out over at least 3 years and are spread out over a maximum of 6 years, are based on the ratio of Medicaid inpatient days to total days, and are not phased down as quickly as the Medicare payments based on the first year of payment. Medicaid hospitals can begin incentive payments through 2016, and incentive payments cannot be made after 2021. 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 non-adoption 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 32 shows our high estimates for the net Medicaid costs for eligible hospitals and EP.

TABLE 32: Estimated Federal Costs (+) and Savings (–) under Medicaid, High Scenario (in $billions)

	Incentive payments			
Fiscal year	Hospitals	Eligible professionals	Benefit payments	Net total
2009	—	—	—	—
2010	—	—	—	—
2011	0.8	0.9	([1])	1.7
2012	0.3	1.1	([1])	1.4
2013	0.9	1.0	([1])	1.9
2014	0.7	0.9	([1])	1.6
2015	0.6	1.1	([1])	1.7
2016	0.5	1.1	([1])	1.7
2017	0.4	0.9	([1])	1.3
2018	0.2	0.6	([1])	0.7
2019	0.0	0.3	([1])	0.3
Total, 2009-14	2.5	4.0	0.0	6.5
Total, 2009-19	4.3	8.0	-0.1	12.2

[1] Less than $50 million impact

Table 33 shows the low estimates for Medicaid costs and savings.

TABLE 33: Estimated Federal Costs (+) and Savings (–) under Medicaid, Low Scenario (in $billions)

	Incentive Payments		Benefit Payments	
Fiscal Year	Hospitals	Eligible Professionals		Net Total
2009	—	—	—	—
2010	—	—	—	—
2011	0.4	0.2	([1])	0.6
2012	0.1	0.4	([1])	0.5
2013	0.4	0.4	([1])	0.8
2014	0.4	0.4	([1])	0.8
2015	0.5	0.5	([1])	1.0
2016	0.7	0.6	([1])	1.3
2017	0.8	0.5	([1])	1.3
2018	0.4	0.4	([1])	0.9
2019	0.1	0.3	([1])	0.4
Total, 2009-14	1.3	1.4	0.0	2.7
Total, 2009-19	3.8	3.8	0.0	7.6

[1] Less than $50 million impact.

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 use 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 34.

TABLE 34: Assumed Number of Nonhospital Based Medicaid EPs Who Will Be Meaningful Users of Certified EHR Technology, High Scenario (All population figures are in thousands)

	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	477.5	482.4	487.3	492.2	497.1	502.1	507.1	512.0	517.0
EPs who meet the Medicaid patient Volume Threshold	95.5	96.5	97.5	98.4	99.4	100.4	101.4	102.4	103.4
Medicaid Only EPs[1]	44.1	44.8	45.5	46.3	47.1	47.8	48.6	49.3	50.1
Total Medicaid	139.6	141.3	143.0	144.7	146.5	148.2	150.0	151.7	153.5
Percent of EPs receiving incentive payments during year	47.3%	66.3%	76.6%	82.2%	85.6%	88.8%	43.8%	25.0%	14.4%
Number of EPs receiving incentive payment during year	66.0	93.7	109.6	119.0	125.4	131.7	65.7	38.0	22.1
Percent of EPs who have ever received incentive payment	47.3%	66.3%	76.6%	82.2%	85.6%	88.8%	91.9%	94.7%	95.9%
Number of EPs who have ever received incentive payment	66.0	93.7	109.6	119.0	125.4	131.7	137.7	143.6	147.2

[1] Includes non hospital-based eligible pediatricians, dentists, certified nurse-midwives, nurse practitioners and physicians assistants. These numbers were not based on tabulated Medicaid data. Rather, a different methodology was used to estimate the EP counts for each group.

It should be noted that since the Medicaid EHR incentive payment program provides that a Medicaid EP can receive an incentive payment in their first year because he or she has demonstrated a meaningful use or because he or she has adopted, implemented, or upgraded certified EHR technology, these participation rates include not only meaningful users but eligible providers implementing certified EHR technology as well. Table 35 shows our low scenario estimates.

TABLE 35: Assumed Number of Nonhospital Based Medicaid EPs Who Will Be Meaningful Users of Certified EHR Technology, Low Scenario (All population figures are in thousands)

	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	477.5	482.4	487.3	492.2	497.1	502.1	507.1	512.0	517.0
EPs who meet the Medicaid patient Volume Threshold	95.5	96.5	97.5	98.4	99.4	100.4	101.4	102.4	103.4
Medicaid Only EPs[1]	44.1	44.8	45.5	46.3	47.1	47.8	48.6	49.3	50.1
Total Medicaid	139.6	141.3	143.0	144.7	146.5	148.2	150.0	151.7	153.5
Percent of EPs receiving incentive payments during year	15.1%	24.0%	30.8%	36.0%	40.5%	45.3%	30.7%	21.9%	15.1%
Number of EPs receiving incentive payment during year	21.1	34.0	44.0	52.1	59.4	67.2	46.0	33.2	23.1
Percent of EPs who have ever received incentive payment	15.1%	24.0%	30.8%	36.0%	40.5%	45.3%	50.4%	55.7%	59.9%
Number of EPs who have ever received incentive payment	21.1	34.0	44.0	52.1	59.4	67.2	75.5	84.4	91.9

[1] Includes non hospital-based eligible pediatricians, dentists, certified nurse-midwives, nurse practitioners, and physicians assistants. These numbers were not based on tabulated Medicaid data. Rather, a different methodology was used to estimate the EP counts for each group.

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 36. 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 spread aggregate Medicaid incentive payments over no less than 3 years, but no more than 6 years of payments, and acute care hospitals may qualify to receive both the Medicare and Medicaid incentive payments.

As stated previously, the estimated eligible hospital incentive payments were calculated based on the hospitals' qualifying status and individual incentive amounts payable under the statutory formula. The estimated savings in Medicaid benefit expenditures resulting from the use of 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 36: 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	39.1%	39.1%
2012	54.4%	54.4%
2013	70.9%	70.9%
2014	83.1%	44.0%
2015	92.9%	38.5%
2016	97.1%	26.2%
2017	99.0%	14.0%
2018	100.0%	4.2%
2019	100.0%	0.0%

Table 37 shows our low scenario estimates.

TABLE 37: 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	18.3%	18.3%
2012	23.3%	23.3%
2013	33.7%	33.7%
2014	49.2%	30.9%
2015	67.8%	44.5%
2016	86.5%	52.8%
2017	91.8%	37.3%
2018	95.9%	18.7%
2019	100.0%	0.0%

7. Benefits for All EPs and All Eligible Hospitals

In this final rule we have not quantified the overall benefits to the industry, nor to eligible hospitals, or EPs in the Medicare, Medicaid, or MA programs. 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.*)

Nonetheless, we believe there are benefits that can be obtained by eligible hospitals and EPs, including: reductions in medical record-keeping 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 Center *http://www.journalacs.org/article/S1072-7515%2807%2900390-0/abstract-article-footnote-1s.*) 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, the study states that EHRs can reduce the duplication of diagnostic tests, prompt providers to prescribe cost-effective generic medications, remind patients about preventive care reduce unnecessary office visits and assist in managing complex care. Further, the report claims 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 final 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.

Since the CBO study, additional research has emerged documenting the association of EHRs with improved outcomes among diabetics (Hunt, JS et al. (2009) "The impact of a physician-directed health information technology system on diabetes outcomes in primary care: a pre- and post-implementation study" Informatics in Primary Care 17(3):165–74; Pollard, C *et al.* (2009) "Electronic patient registries improve diabetes care and clinical outcomes in rural community health centers" Journal of Rural Health 25(1):77–84) and trauma patients (Deckelbaum, D. et al. (2009) "Electronic medical records and mortality in trauma patients "The Journal of Trauma: Injury, Infection, and Critical Care 67(3): 634–636), enhanced efficiencies in ambulatory care settings (Chen, C et al. (2009) "The Kaiser Permanente Electronic Health Record: Transforming and Streamlining Modalities Of Care."Health Affairs 28(2):323–333), and improved outcomes and lower costs in hospitals (Amarasingham, R. et al. (2009) "Clinical information technologies and inpatient outcomes: a multiple hospital study" Archives of Internal Medicine 169(2):108–14).

9. General Considerations

The estimates for the HITECH Act provisions were based on the economic assumptions underlying the President's 2011 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, CAHs and EPs will adopt EHRs and other HIT. Nonetheless, we believe that the Medicare incentive payments and the prospect of significant payment penalties for not demonstrating meaningful use 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 expect to administer the requirements in such a way as to encourage adoption of certified EHR technology and facilitate qualification for incentive payments, and expect to adopt progressively demanding standards at each stage year. Certified EHR technology has the potential to help reduce medical costs through efficiency improvements, such as prompter treatments, avoidance of duplicate or otherwise unnecessary services, and reduced administrative costs (once systems are in place), with most of these savings being realized by the providers rather than by Medicare or Medicaid. To the extent that this technology will have a net positive effect on efficiency, then more rapid adoption of such EHR systems 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 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.

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, Medicare payment adjustments will begin.

10. Summary

The total cost to the Medicare and Medicaid programs is estimated to be $9.7 billion in transfers under the low scenario, and $27.4 billion under the high scenario, over a 10-year timeframe. The main reasons for the changes from the proposed rule are revised definitions of hospital-based eligible professional and Medicaid acute care hospitals, and updated data on discharges and costs of adoption among hospitals. 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	$0.2	$0.2	$0.4	$0.2	$1.0
2012	$0.9	$1.0	$0.1	$0.4	$2.4
2013	$1.1	$0.9	$0.4	$0.4	$2.8
2014	$1.2	$0.6	$0.4	$0.4	$2.6
2015	$0.5	-$0.1	$0.5	$0.5	$1.4
2016	$0.6	-$0.6	$0.7	$0.6	$1.3
2017	$0.3	-$1.3	$0.8	$0.5	$0.3
2018	-$0.2	-$1.6	$0.4	$0.4	-$1.0
2019	-$0.1	-$1.6	$0.1	$0.3	-$1.3
TOTAL	**$4.6**	**-$2.5**	**$3.8**	**$3.8**	**$9.7**

Table 39 shows the total costs from 2011 through 2019 for the high scenario after which the payment adjustments will be invoked.

Table 39: 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	$0.5	$0.6	$0.8	$0.9	$2.8
2012	$2.1	$2.3	$0.3	$1.1	$5.8
2013	$2.2	$2.0	$0.9	$1.0	$6.1
2014	$1.9	$1.3	$0.7	$0.9	$4.8
2015	$1.8	$0.7	$0.6	$1.1	$4.2
2016	$1.2	$0.1	$0.5	$1.1	$2.9
2017	$0.5	-$0.5	$0.4	$0.9	$1.3
2018	—	-$0.8	$0.2	$0.6	0.0
2019	—	-$0.8	—	$0.3	-$0.5
TOTAL	**$10.1**	**$5.0**	**$4.3**	**$8.0**	**$27.4**

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, and the like, are still unable to be quantified at this time.

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 final rule. Monetary annualized benefits and nonbudgetary costs are presented as discounted flows using 3 percent and 7 percent factors. Additional expenditures that will be undertaken by eligible entities in order to obtain the Medicare and Medicaid incentive payments to adopt and demonstrate meaningful use of certified EHR technology, and to avoid the Medicare payment adjustments that will ensue if they fail to do so are noted by a placeholder in the accounting statement. We are not able to explicitly define the universe of those additional costs, nor specify what the high or low range might be to implement EHR technology in this final rule.

Expected qualitative benefits include improved quality of care, better health outcomes, reduced errors and the like. Private industry costs would include the impact of EHR activities such as temporary reduced staff productivity related to learning how to use the EHR, the need for additional staff to work with HIT issues, and administrative costs related to reporting.

TABLE 40: Accounting Statement: Classification of Estimated Expenditures CYs 2010 through 2019

	Category: Transfers	
Annualized Monetized	Low Estimate	High Estimate
7%	1,147.9 million	3,102.2 million
3%	1,038.7 million	2,902.4 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 final 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 amends 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 as follows:

■ A. Revising paragraph (d)(2)(i)(B).

■ B. Adding 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-fourths 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 as follows:
■ A. Revising paragraph (a)(1).
■ B. Adding new paragraphs (a)(5), (a)(6) and (a)(7).

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.

(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.

(7) There is no administrative or judicial review under section s1869 and 1878 of the Actor otherwise of the following:

(i) The methodology and standards for determining the amount of payment under paragraph (a)(5) of this section, including the calculation of reasonable costs under § 495.106(c) of this chapter.

(ii) The methodology and standards for determining the amount of payment adjustments made under paragraph (a)(6).

(iii) The methodology and standards for determining a CAH to be a qualifying CAH under § 495.106 of this chapter.

(iv) The methodology and standards for determining if the hardship exemption applies to a CAH under paragraph (a)(6)(ii) of this section.

(v) The specification of the cost reporting periods, payment years, or fiscal years as applied under this paragraph.

* * * * *

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 as follows:
■ 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.
■ C. Adding a new paragraph (b)(2)(iv).

The addition reads 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 as follows:
■ 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 as follows:
■ A. Adding paragraph (a)(3).
■ B. Revising paragraph (b).

The addition and revision read as follows:

§ 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, eligible hospitals, and 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.
495.110 Preclusion on administrative and judicial review.

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 MA-affiliated eligible hospitals.
495.206 Timeframe for payment to qualifying MA organizations.
495.208 Avoiding duplicate payment.
495.210 Meaningful EHR 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 FFP.
495.328 Request for reconsideration of adverse determination.
495.330 Termination of FFP for failure to provide access to information.
495.332 State Medicaid health information technology (HIT) plan requirements.
495.334 Reserved.
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 eligible professionals who adopt and meaningfully use certified electronic health record (EHR) technology.

(b) Section 1853(1) of the Act to provide incentive payments to Medicare Advantage organizations for certain 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 the Medicare FFS program.

(d) Section 1814(l) of the Act to provide an incentive payment to critical access hospitals that 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)(B)(ix)(I), 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 EHR technology, and for covered professional services furnished on or after January 1, 2015 to Medicare beneficiaries by certain professionals who are not meaningful users of certified EHR technology.

§ 495.4 Definitions.

In this part, unless otherwise indicated—

Certified electronic health record technology has the same definition as this term is defined at 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 eligible professional (EP)—

(i) For the first payment year, any continuous 90-day period within a calendar year;

(ii)(A) Except as specified in paragraph (1)(ii)(B) of this definition, for the second, third, fourth, fifth, or sixth payment year, the calendar year.

(B) For Medicaid providers who are demonstrating they are meaningful EHR users for the first time in their second payment year, the EHR reporting period during such second payment year is any continuous 90-day period within the calendar year.

(2) For an eligible hospital or a CAH—

(i) For the first payment year, any continuous 90-day period within a federal fiscal year; and

(ii)(A) Except as specified in paragraph (2)(ii)(B) of this definition, for the second, third, fourth, fifth, or sixth payment year, the Federal fiscal year.

(B) For Medicaid providers who are demonstrating they are meaningful EHR users for the first time in their second payment year, the EHR reporting period during such second payment year is any continuous 90-day period within the Federal 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.

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 a hospital setting in the year preceding the payment year. For Medicare, this will be calculated based on the Federal FY prior to the payment year. For Medicaid, it is at the State's discretion if the data is gathered on the Federal FY or CY prior to the payment year. A setting is considered a hospital setting if it is a site of service that would be identified by the codes used in the HIPAA standard transactions as an inpatient hospital, or emergency room setting.

Meaningful EHR user means:

(1) Subject to paragraph (3) of this definition, 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)(i) Except as specified in paragraph (2)(ii) of this definition, a Medicaid EP or Medicaid eligible hospital, that meets the requirements of 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.

(ii) An eligible hospital or CAH is deemed to be a meaningful EHR user for purposes of receiving an incentive payment under subpart D of this Part, if the hospital participates in both the Medicare and Medicaid EHR incentive programs, and the hospital meets the requirements of paragraph (1) of this definition.

(3) To be considered a meaningful EHR user, at least 50 percent of an EP's patient encounters during the EHR reporting period during the payment year must occur at a practice/location or practices/locations equipped with certified EHR technology.

Payment year means:

(1) For an EP, a calendar year beginning with CY 2011; and

(2) For a CAH or an eligible hospital, a Federal fiscal year beginning with FY 2011.

Qualified EHR has the same definition as this term is defined at 45 CFR 170.102.

First, second, third, fourth, fifth, or sixth payment years mean as follows:

(1) The first payment year is: with respect to an EP, the first calendar year for which the EP receives an incentive payment under this part; and with respect to an eligible hospital or CAH, the first FY for which the hospital receives an incentive payment under this part.

(2) The second, third, fourth, fifth, or sixth payment year is:

(i) With respect to a Medicare EP, the second, third, fourth or fifth successive CY immediately following the first payment year; and with respect to a Medicare eligible hospital or CAH, the second, third, or fourth successive Federal FY immediately following the first payment year. (Note: Medicare EPs are not eligible for a sixth payment year and Medicare eligible hospitals are not eligible for a fifth or sixth payment year.)

(ii)(A) With respect to a Medicaid EP, the second, third, fourth, fifth, or sixth CY for which the EP receives an incentive payment under subpart D, regardless of whether the year immediately follows the prior payment year; and

(B) With respect to a Medicaid eligible hospital, for years prior to FY 2017, the second, third, fourth, fifth, or sixth Federal FY for which the hospital receives an incentive payment under subpart D of this part, regardless of whether the year immediately follows the prior payment year. Beginning with FY 2017, payments to Medicaid eligible hospitals must be consecutive, and the hospital is not eligible for an incentive payment under subpart D of this part unless it received such incentive payment for the prior fiscal year.

§ 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 paragraphs (a)(2) and (a)(3) of this section, EPs must meet all objectives and associated measures of the Stage 1 criteria specified in paragraph (d) of this section and five objectives of the EP's choice from paragraph (e) of this section to meet the definition of a meaningful EHR user.

(2) *Exclusion for non-applicable objectives.* (i) An EP may exclude a particular objective contained in paragraphs (d) or (e) of this section, if the EP meets all of the following requirements:

(A) Must ensure that the objective in paragraph (d) or (e) of this section includes an option for the EP to attest that the objective is not applicable.

(B) Meets the criteria in the applicable objective that would permit the attestation.

(C) Attests.

(ii) An exclusion will reduce (by the number of exclusions applicable) the number of objectives that would otherwise apply. For example, an EP that has an exclusion from one of the objectives in paragraph (e) of this section must meet four (and not five) objectives of the EP's choice from such paragraph to meet the definition of a meaningful EHR user.

(3) *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 (d) and (e) 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 paragraphs (b)(2) and (b)(3) of this section, eligible hospitals and CAHs must meet all objectives and associated measures of

the Stage 1 criteria specified in paragraph (f) of this section and five objectives of the eligible hospital's or CAH's choice from paragraph (g) of this section to meet the definition of a meaningful EHR user.

(2) *Exclusions for nonapplicable objectives.* (i) An eligible hospital or CAH may exclude a particular objective that includes an option for exclusion contained in paragraphs (f) or (g) of this section, if the hospital meets all of the following requirements:

(A) The hospital meets the criteria in the applicable objective that would permit an exclusion.

(B) The hospital so attests.

(ii) An exclusion will reduce (by the number of exclusions received) the number of objectives that would otherwise apply. For example, an eligible hospital that is excluded from one of the objectives in paragraph (g) of this section must meet four (and not five) objectives of the hospital's choice from such paragraph to meet the definition of a meaningful EHR user.

(3) *Exception for Medicaid eligible hospitals that adopt, implement or upgrade in their first payment year.* For Medicaid eligible hospitals that 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 (f) and (g) of this section apply beginning with the second payment year, and do not apply to the first payment year.

(c) Many of the objective and associated measures in paragraphs (d) through (g) of this section rely on measures that count unique patients or actions.

(1) If a measure (or associated objective) in paragraphs (d) through (g) of this section references paragraph (c) of this section, then the measure may be calculated by reviewing only the actions for patients whose records are maintained using certified EHR technology. A patient's record is maintained using certified EHR technology if sufficient data was entered in the certified EHR technology to allow the record to be saved, and not rejected due to incomplete data.

(2) If the objective and associated measure does not reference this paragraph (c) of this section, then the measure must be calculated by reviewing all patient records, not just those maintained using certified EHR technology.

(d) *Stage 1 core criteria for EPs.* An EP must satisfy the following objectives and associated measures, except those objectives and associated measures for which an EP qualifies for an exclusion under paragraph (a)(2) of this section specified in this paragraph:

(1)(i) *Objective.* Use computerized provider order entry (CPOE) for medication orders directly entered by any licensed healthcare professional who can enter orders into the medical record per state, local and professional guidelines.

(ii) *Measure.* Subject to paragraph (c) of this section, more than 30 percent of all unique patients with at least one medication in their medication list seen by the EP have at least one medication order entered using CPOE.

(iii) *Exclusion in accordance with paragraph (a)(2) of this section* Any EP who writes fewer than 100 prescriptions during the EHR reporting period.

(2)(i) *Objective.* Implement drug-drug and drug-allergy interaction checks.

(ii) *Measure.* The EP has enabled this functionality for the entire EHR reporting period.

(3)(i) *Objective.* Maintain an up-to-date problem list of current and active diagnoses.

(ii) *Measure.* More than 80 percent of all unique patients seen by the EP have at least one entry or an indication that no problems are known for the patient recorded as structured data.

(4)(i) *Objective.* Generate and transmit permissible prescriptions electronically (eRx).

(ii) *Measure.* Subject to paragraph (c) of this section, more than 40 percent of all permissible prescriptions written by the EP are transmitted electronically using certified EHR technology.

(iii) *Exclusion in accordance with paragraph (a)(2) of this section* Any EP who writes fewer than 100 prescriptions during the EHR reporting period.

(5)(i) *Objective.* Maintain active medication list.

(ii) *Measure.* More than 80 percent of all unique patients seen by the EP have at least one entry (or an indication that the patient is not currently prescribed any medication) recorded as structured data.

(6)(i) *Objective.* Maintain active medication allergy list.

(ii) *Measure.* More than 80 percent of all unique patients seen by the EP have at least one entry (or an indication that the patient has no known medication allergies) recorded as structured data.

(7)(i) *Objective.* Record all of the following demographics:

(A) Preferred language.

(B) Gender.

(C) Race.

(D) Ethnicity.

(E) Date of birth.

(ii) *Measure.* More than 50 percent of all unique patients seen by the EP have demographics recorded as structured data.

(8)(i) *Objective.* Record and chart changes in the following vital signs:

(A) Height.

(B) Weight.

(C) Blood pressure.

(D) Calculate and display body mass index (BMI).

(E) Plot and display growth charts for children 2–20 years, including BMI.

(ii) *Measure.* Subject to paragraph (c) of this section, more than 50 percent of all unique patients age 2 and over seen by the EP, height, weight and blood pressure are recorded as structured data.

(iii) *Exclusion in accordance with paragraph (a)(2) of this section.* Any EP who either see no patients 2 years or older, or who believes that all three vital signs of height, weight, and blood pressure of their patients have no relevance to their scope of practice.

(9)(i) *Objective.* Record smoking status for patients 13 years old or older.

(ii) *Measure.* Subject to paragraph (c) of this section, more than 50 percent of all unique patients 13 years old or older seen by the EP have smoking status recorded as structured data.

(iii) *Exclusion in accordance with paragraph (a)(2) of this section.* Any EP who sees no patients 13 years or older.

(10)(i) *Objective.* Report ambulatory clinical quality measures to CMS or, in the case of Medicaid EPs, the States.

(ii) *Measure.* Subject to paragraph (c) of this section, successfully report to CMS (or, in the case of Medicaid EPs, the States) ambulatory clinical quality measures selected by CMS in the manner specified by CMS (or in the case of Medicaid EPs, the States).

(11)(i) *Objective.* Implement one clinical decision support rules relevant to specialty or high clinical priority along with the ability to track compliance with that rule.

(ii) *Measure.* Implement one clinical decision support rule.

(12)(i) *Objective.* Provide patients with an electronic copy of their health information (including diagnostics test results, problem list, medication lists, medication allergies) upon request.

(ii) *Measure.* Subject to paragraph (c) of this section, more than 50 percent of all patients who request an electronic copy of their health information are provided it within 3 business days.

(iii) *Exclusion in accordance with paragraph (a)(2) of this section.* Any EP that has no requests from patients or their agents for an electronic copy of patient health information during the EHR reporting period.

(13)(i) *Objective.* Provide clinical summaries for patients for each office visit.

(ii) *Measure.* Subject to paragraph (c) of this section, clinical summaries

provided to patients for more than 50 percent of all office visits within 3 business days.

(iii) *Exclusion in accordance with paragraph (a)(2) of this section.* Any EP who has no office visits during the EHR reporting period.

(14)(i) *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.

(ii) *Measure.* Performed at least one test of certified EHR technology's capacity to electronically exchange key clinical information.

(15)(i) *Objective.* Protect electronic health information created or maintained by the certified EHR technology through the implementation of appropriate technical capabilities.

(ii) *Measure.* Conduct or review a security risk analysis in accordance with the requirements under 45 CFR 164.308(a)(1) and implement security updates as necessary and correct identified security deficiencies as part of its risk management process.

(e) *Stage 1 menu set criteria for EPs.* An EP must meet five of the following objectives and associated measures, one of which must be either paragraph (e)(9) or (e)(10) of this section, except that the required number of objectives and associated measures is reduced by an EP's paragraph (a)(2) of this section exclusions specified in this paragraph:

(1)(i) *Objective.* Implement drug-formulary checks.

(ii) *Measure.* The EP has enabled this functionality and has access to at least one internal or external formulary for the entire EHR reporting period.

(2)(i) *Objective.* Incorporate clinical lab-test results into EHR as structured data.

(ii) *Measure.* Subject to paragraph (c) of this section, more than 40 percent of all clinical lab tests results ordered by the EP 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.

(iii) *Exclusion in accordance with paragraph (a)(2) of this section.* An EP who orders no lab tests whose results are either in a positive/negative or numeric format during the EHR reporting period.

(3)(i) *Objective.* Generate lists of patients by specific conditions to use for quality improvement, reduction of disparities, research, or outreach.

(ii) *Measure.* Subject to paragraph (c) of this section, generate at least one report listing patients of the EP with a specific condition.

(4)(i) *Objective.* Send reminders to patients per patient preference for preventive/follow-up care.

(ii) *Measure.* Subject to paragraph (c) of this section, more than 20 percent of all patients 65 years or older or 5 years old or younger were sent an appropriate reminder during the EHR reporting period.

(iii) *Exclusion in accordance with paragraph (a)(2) of this section.* An EP who has no patients 65 years old or older or 5 years old or younger with records maintained using certified EHR technology.

(5)(i) *Objective.* Provide patients with timely electronic access to their health information (including lab results, problem list, medication lists, and allergies) within 4 business days of the information being available to the EP.

(ii) *Measure.* At least 10 percent of all unique patients seen by the EP are provided timely (available to the patient within four business days of being updated in the certified EHR technology) electronic access to their health information subject to the EP's discretion to withhold certain information.

(iii) *Exclusion in accordance with paragraph (a)(2) of this section.* Any EP that neither orders nor creates any of the information listed at 45 CFR 170.304(g) during the EHR reporting period.

(6)(i) *Objective.* Use certified EHR technology to identify patient-specific education resources and provide those resources to the patient if appropriate.

(ii) *Measure.* More than 10 percent of all unique patients seen by the EP are provided patient-specific education resources.

(7)(i) *Objective.* The EP who receives a patient from another setting of care or provider of care or believes an encounter is relevant should perform medication reconciliation.

(ii) *Measure.* Subject to paragraph (c) of this section, the EP performs medication reconciliation for more than 50 percent of transitions of care in which the patient is transitioned into the care of the EP.

(iii) *Exclusion in accordance with paragraph (a)(2) of this section.* An EP who was not the recipient of any transitions of care during the EHR reporting period.

(8)(i) *Objective.* The EP who transitions their patient to another setting of care or provider of care or refers their patient to another provider of care should provide summary care record for each transition of care or referral.

(ii) *Measure.* Subject to paragraph (c) of this section, the EP who transitions or refers their patient to another setting of care or provider of care provides a summary of care record for more than 50 percent of transitions of care and referrals.

(iii) *Exclusion in accordance with paragraph (a)(2) of this section.* An EP who neither transfers a patient to another setting nor refers a patient to another provider during the EHR reporting period.

(9)(i) *Objective.* Capability to submit electronic data to immunization registries or immunization information systems and actual submission according to applicable law and practice.

(ii) *Measure.* Performed at least one test of certified EHR technology's capacity to submit electronic data to immunization registries and follow up submission if the test is successful (unless none of the immunization registries to which the EP submits such information has the capacity to receive the information electronically).

(iii) *Exclusion in accordance with paragraph (a)(2) of this section.* An EP who administers no immunizations during the EHR reporting period or where no immunization registry has the capacity to receive the information electronically.

(10)(i) *Objective.* Capability to submit electronic syndromic surveillance data to public health agencies and actual submission 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 and follow-up submission if the test is successful (unless none of the public health agencies to which an EP submits such information has the capacity to receive the information electronically).

(iii) Exclusion in accordance with paragraph (a)(2) of this section. An EP who does not collect any reportable syndromic information on their patients during the EHR reporting period or does not submit such information to any public health agency that has the capacity to receive the information electronically.

(f) *Stage 1 core criteria for eligible hospitals or CAHs.* An eligible hospital or CAH must meet the following objectives and associated measures except those objectives and associated measures for which an eligible hospital or CAH qualifies for a paragraph (b)(2) of this section exclusion specified in this paragraph:

(1)(i) *Objective.* Use CPOE for medication orders directly entered by any licensed healthcare professional who can enter orders into the medical

record per State, local, and professional guidelines.

(ii) *Measure.* Subject to paragraph (c) of this section, more than 30 percent of all unique patients with at least one medication in their medication list admitted to the eligible hospital's or CAH's inpatient or emergency department (POS 21 or 23) have at least one medication order entered using CPOE.

(2)(i) *Objective.* Implement drug-drug and drug-allergy interaction checks.

(ii) *Measure.* The eligible hospital or CAH has enabled this functionality for the entire EHR reporting period.

(3)(i) *Objective.* Maintain an up-to-date problem list of current and active diagnoses.

(ii) *Measure.* More than 80 percent of all unique patients admitted to the eligible hospital's or CAH's inpatient or emergency department (POS 21 or 23) have at least one entry or an indication that no problems are known for the patient recorded as structured data.

(4)(i) *Objective.* Maintain active medication list.

(ii) *Measure.* More than 80 percent of all unique patients admitted to the eligible hospital's or CAH's inpatient or emergency department (POS 21 or 23) have at least one entry (or an indication that the patient is not currently prescribed any medication) recorded as structured data.

(5)(i) *Objective.* Maintain active medication allergy list.

(ii) *Measure.* More than 80 percent of all unique patients admitted to the eligible hospital's or CAH's inpatient or emergency department (POS 21 or 23) have at least one entry (or an indication that the patient has no known medication allergies) recorded as structured data.

(6)(i) *Objective.* Record all of the following demographics;

(A) Preferred language.

(B) Gender.

(C) Race.

(D) Ethnicity.

(E) Date of birth.

(F) Date and preliminary cause of death in the event of mortality in the eligible hospital or CAH.

(ii) *Measure.* More than 50 percent of all unique patients admitted to the eligible hospital's or CAH's inpatient or emergency department (POS 21 or 23) have demographics recorded as structured data.

(7)(i) *Objective.* Record and chart changes in the following vital signs:

(A) Height.

(B) Weight.

(C) Blood pressure.

(D) Calculate and display body mass index (BMI).

(E) Plot and display growth charts for children 2–20 years, including BMI.

(ii) *Measure.* Subject to paragraph (c) of this section, for more than 50 percent of all unique patients age 2 and over admitted to the eligible hospital's or CAH's inpatient or emergency department (POS 21 or 23), height, weight, and blood pressure are recorded as structured data.

(8)(i) *Objective.* Record smoking for patients 13 years old or older.

(ii) *Measure.* Subject to paragraph (c) of this section, more than 50 percent of all unique patients 13 years old or older or admitted to the eligible hospital's inpatient or emergency department (POS 21 or 23) have smoking status recorded as structured data.

(iii) *Exclusion in accordance with paragraph (b)(2) of this section.* Any eligible hospital or CAH that admits no patients 13 years or older to their inpatient or emergency department (POS 21 or 23).

(9)(i) *Objective.* Report hospital clinical quality measures to CMS or, in the case of Medicaid eligible hospitals, the States.

(ii) *Measure.* Subject to paragraph (c) of this section, successfully report to CMS (or, in the case of Medicaid eligible hospitals or CAHs, the States) hospital clinical quality measures selected by CMS in the manner specified by CMS (or, in the case of Medicaid eligible hospitals or CAHs, the States).

(10)(i) *Objective.* Implement one clinical decision support rule related to a high priority hospital condition along with the ability to track compliance with that rule.

(ii) *Measure.* Implement one clinical decision support rule.

(11)(i) *Objective.* Provide patients with an electronic copy of their health information (including diagnostic test results, problem list, medication lists, medication allergies, discharge summary, procedures), upon request.

(ii) *Measure.* Subject to paragraph (c) of this section, more than 50 percent of all patients of the inpatient or emergency departments of the eligible hospital or CAH (POS 21 or 23) who request an electronic copy of their health information are provided it within 3 business days.

(iii) *Exclusion in accordance with paragraph (b)(2) of this section.* Any eligible hospital or CAH that has no requests from patients or their agents for an electronic copy of patient health information during the EHR reporting period.

(12)(i) *Objective.* Provide patients with an electronic copy of their discharge instructions at time of discharge, upon request.

(ii) *Measure.* Subject to paragraph (c) of this section, more than 50 percent of all patients who are discharged from an eligible hospital or CAH's inpatient or emergency department (POS 21 or 23) and who request an electronic copy of their discharge instructions are provided it.

(iii) *Exclusion in accordance with paragraph (b)(2) of this section.* Any eligible hospital or CAH that has no requests from patients or their agents for an electronic copy of the discharge instructions during the EHR reporting period.

(13)(i) *Objective.* Capability to exchange key clinical information (for example, problem list, medication list, medication allergies, and diagnostic test results), among providers of care and patient authorized entities electronically.

(ii) *Measure.* Performed at least one test of certified EHR technology's capacity to electronically exchange key clinical information.

(14)(i) *Objective.* Protect electronic health information created or maintained by the certified EHR technology through the implementation of appropriate technical capabilities.

(ii) *Measure.* Conduct or review a security risk analysis in accordance with the requirements under 45 CFR 164.308(a)(1) and implement security updates as necessary and correct identified security deficiencies as part of its risk management process.

(g) *Stage 1 menu set criteria for eligible hospitals or CAHs.* Eligible hospitals or CAHs must meet five of the following objectives and associated measures, one which must be specified in paragraph (g)(8), (g)(9), or (g)(10) of this section, except that the required number of objectives and associated measures is reduced by a hospital's paragraph (b)(2) of this section exclusions specified in this paragraph:

(1)(i) *Objective.* Implement drug-formulary checks.

(ii) *Measure.* The eligible hospital or CAH has enabled this functionality and has access to at least one internal or external formulary for the entire EHR reporting period.

(2)(i) *Objective.* Record advance directives for patient 65 years old or older.

(ii) *Measure.* Subject to paragraph (c) of this section, more than 50 percent of all unique patients 65 years old or older admitted to the eligible hospital's or CAH's inpatient (POS 21) have an indication of an advance directive status recorded as structured data.

(iii) *Exclusion in accordance with paragraph (b)(2) of this section.* An eligible hospital or CAH that admits no

patients age 65 years old or older during the EHR reporting period.

(3)(i) *Objective.* Incorporate clinical lab-test results into EHR as structured data.

(ii) *Measure.* Subject to paragraph (c) of this section, more than 40 percent of all clinical lab test results ordered by an authorized provider of the eligible hospital or CAH for patients admitted to its inpatient or emergency department (POS 21 and 23) during the EHR reporting period whose results are either in a positive/negative or numerical format are incorporated in certified EHR technology as structured data.

(4)(i) *Objective.* Generate lists of patients by specific conditions to use for quality improvement, reduction of disparities, research, or outreach.

(ii) *Measure.* Subject to paragraph (c) of this section, generate at least one report listing patients of the eligible hospital or CAH with a specific condition.

(5)(i) *Objective.* Use certified EHR technology to identify patient-specific education resources and provide those resources to the patient if appropriate.

(ii) *Measure.* More than 10 percent of all unique patients admitted to the eligible hospital's or CAH's inpatient or emergency department (POS 21 or 23) are provided patient-specific education resources.

(6)(i) *Objective.* The eligible hospital or CAH who receives a patient from another setting of care or provider of care or believes an encounter is relevant should perform medication reconciliation.

(ii) *Measure.* Subject to paragraph (c) of this section, the eligible hospital or CAH performs medication reconciliation for more than 50 percent of transitions of care in which the patient is admitted to the eligible hospital's or CAH's inpatient or emergency department (POS 21 or 23).

(7)(i) *Objective.* The eligible hospital or CAH that transitions their patient to another setting of care or provider of care or refers their patient to another provider of care should provide summary care record for each transition of care or referral.

(ii) *Measure.* Subject to paragraph (c) of this section, the eligible hospital or CAH that transitions or refers their patient to another setting of care or provider of care provides a summary of care record for more than 50 percent of transitions of care and referrals.

(8)(i) *Objective.* Capability to submit electronic data to immunization registries or immunization information systems and actual submission according to applicable law and practice.

(ii) *Measure.* Performed at least one test of certified EHR technology's capacity to submit electronic data to immunization registries and follow up submission if the test is successful (unless none of the immunization registries to which the eligible hospital or CAH submits such information has the capacity to receive the information electronically).

(iii) *Exclusion in accordance with paragraph (b)(2) of this section.* An eligible hospital or CAH that administers no immunizations during the EHR reporting period or where no immunization registry has the capacity to receive the information electronically.

(9)(i) *Objective.* Capability to submit electronic data on reportable (as required by State or local law) lab results to public health agencies and actual submission according to applicable law and practice.

(ii) *Measure.* Performed at least one test of certified EHR technology's capacity to provide electronic submission of reportable lab results to public health agencies and follow-up submission if the test is successful (unless none of the public health agencies to which an eligible hospital or CAH submits such information has the capacity to receive the information electronically).

(iii) *Exclusion in accordance with paragraph (b)(2) of this section.* No public health agency to which the eligible hospital or CAH submits such information has the capacity to receive the information electronically.

(10)(i) *Objective.* Capability to submit electronic syndromic surveillance data to public health agencies and actual submission 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 and follow-up submission if the test is successful (unless none of the public health agencies to which an eligible hospital or CAH submits information has the capacity to receive the information electronically).

(iii) *Exclusion in accordance with paragraph (a)(2) of this section.* No public health agency to which the eligible hospital or CAH submits information has the capacity to receive the information electronically.

(h) *Stage 2 criteria for EPs.* Beginning when final regulations for Stage 2 are effective, an EP must satisfy the following objectives and associated measures:

(1)(i) *Objective.* Use computerized provider order entry (CPOE) for medication orders directly entered by any licensed healthcare professional who can enter orders into the medical record per state, local and professional guidelines.

(ii) *Measure.* More than 60 percent of all unique patients with at least one medication in their medication list seen by the EP have at least one medication order entered using CPOE.

(iii) *Exclusion.* Any EP who writes fewer than 100 prescriptions during the EHR reporting period.

(2) [Reserved].

(i) *Stage 2 criteria for eligible hospitals or CAHs.* Beginning when final regulations for Stage 2 are effective, an eligible hospital or CAH must satisfy the following objectives and associated measures:

(1)(i) *Objective.* Use computerized provider order entry (CPOE) for medication orders directly entered by any licensed healthcare professional who can enter orders into the medical record per state, local and professional guidelines.

(ii) *Measure.* More than 60 percent of all unique patients with at least one medication in their medication list admitted to the eligible hospital's or CAH's inpatient or emergency department (POS 21 or 23) have at least one medication order entered using CPOE.

(2) [Reserved].

§ 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) *Attestation.* 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—

(A) Used certified EHR technology, and specify the technology used;

(B) Satisfied the required objectives and associated measures under § 495.6(d) and § 495.6(e) of this subpart;

(C) 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;

(ii) *Additional requirements for Medicaid EPs.* For Medicaid EPs, if, in accordance with § 495.316 and § 495.332, CMS has approved a State's revised definition for meaningful use, in addition to meeting paragraphs (a)(1)(i) through (ii) of this section, the EP must

also demonstrate meeting the State revised definition using the method approved by CMS; and

(iii) *Exception for Medicaid EPs.* If a Medicaid EP has adopted, implemented or upgraded certified EHR technology in the first payment year, the EP need not demonstrate meaningful use until the second payment year, as described in § 495.6 and § 495.8 of this subpart.

(2) For CY 2012 and subsequent years—

(i) *Attestation.* 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—

(A) Used certified EHR technology and specify the technology used.

(B) Satisfied the required objectives and associated measures under § 495.6(d) and § 495.6(e), except § 495.6(d)(10) "Report ambulatory clinical quality measures to CMS or, in the case of Medicaid EPs, the States."

(C) 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.

(ii) *Reporting of clinical quality information.* For § 495.6(d)(10), "Report ambulatory clinical quality measures to CMS or, in the case of Medicaid EPs, the States," report the ambulatory clinical quality measures selected by CMS electronically to CMS (or in the case of Medicaid EPs, the States) in the manner specified by CMS (or in the case of Medicaid EPs, the States).

(iii) *Additional requirements for Medicaid EPs.* For Medicaid EPs, if, in accordance with § 495.316 and § 495.332, CMS has approved a State's additional criteria for meaningful use, in addition to meeting paragraphs (a)(2)(i) through (iii), the EP must also demonstrate meeting such additional criteria using the method approved by CMS.

(iv) *Exception for Medicaid EPs.* If a Medicaid EP has adopted, implemented, or upgrade certified EHR technology in the first payment year, the EP need not demonstrate that it is a meaningful EHR user until the second payment year, as described in § 495.6 and § 495.8 of this subpart.

(3) For all CYs, an EP who practices in multiple physical locations, not all of which have certified EHR technology available, will demonstrate meaningful use using only the locations where the EP has certified EHR technology available. (See also § 495.4 regarding the definition of meaningful EHR user).

(b) *Demonstration by eligible hospitals and CAHs.* To successfully demonstrate that it is a meaningful EHR user, an eligible hospital or CAH must the following requirements:

(1) For FY 2011—

(i) *Attestation.* 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—

(A) Used certified EHR and specify the technology used.

(B) Satisfied the required objectives and associated measures under § 495.6(f) and § 495.6(g).

(C) Must specify the EHR reporting period and provide the result of each applicable measure for all patients admitted to the inpatient or emergency department (POS 21 or 23) of the hospital during the EHR reporting period for which a selected measure is applicable.

(ii) *Additional requirements for Medicaid eligible hospitals.* For Medicaid eligible hospitals, if, in accordance with § 495.316 and § 495.332, CMS has approved a State's revised definition for meaningful use, in addition to meeting paragraphs (b)(1)(i) through (ii) of this section, the eligible hospital must also demonstrate meeting the State's revised definition using the method approved by CMS.

(iv) *Exception for Medicaid eligible hospitals.* If a Medicaid eligible hospital has adopted, implemented or upgraded certified EHR technology in the first payment year, the eligible hospital need not demonstrate meaningful use until the second payment year, as described in § 495.6 and § 495.8 of this subpart.

(2) For FY 2012 and subsequent years—

(i) *Attestation.* 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—

(A) Used certified EHR and specify the technology used;

(B) Satisfied the required objectives and associated measures under § 495.6(f) and § 495.6(g), except § 495.6(f)(9) "Report hospital clinical quality measures to CMS or, in the case of Medicaid eligible hospitals, the States;"

(C) Must specify the EHR reporting period and provide the result of each applicable measure for all patients admitted to the inpatient or emergency department (POS 21 or 23) of the hospital during the EHR reporting period for which a selected measure is applicable.

(ii) *Reporting clinical quality information.* For § 495.6(f)(9) "Report hospital clinical quality measures to CMS or, in the case of Medicaid eligible hospitals, the States," report the hospital quality measures selected by CMS electronically to CMS (or in the case of Medicaid eligible hospitals, the States), in the manner specified by CMS (or in the case of Medicaid eligible hospitals, the States).

(iv) *Additional requirements for Medicaid eligible hospitals.* For Medicaid eligible hospitals if, in accordance with § 495.316 and § 495.332, CMS has approved a State's revised definition for meaningful use, in addition to meeting paragraphs (b)(2)(i) through (iii) of this section, the eligible hospital must also demonstrate meeting the State's revised definition using the method approved by CMS.

(v) *Exception for Medicaid eligible hospitals.* If a Medicaid eligible hospital has adopted, implemented, or upgraded certified EHR technology in the first payment year, the eligible hospital need not demonstrate that it is a meaningful EHR user until the second payment year, as described in § 495.6 and § 495.8 of this subpart.

(c) *Review of meaningful use.* (1) CMS (and in the case of Medicaid EPs and eligible hospitals, States) may review an EP, eligible hospital or CAH's demonstration of meaningful use.

(2) All EPs, eligible hospitals, and CAHs must keep documentation supporting their demonstration of meaningful use for 6 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.

(4) Such other information as specified by CMS.

(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) which may be the EP's Social Security Number

(SSN) 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, eligible hospital or CAH 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) After receiving at least one EHR incentive payment, may switch between the two EHR incentive programs only one time, and only for a payment year before 2015;

(3) Must, for each payment year, meet all of the applicable requirements, including applicable patient volume requirements, for the program in which he or she chooses to participate (Medicare or Medicaid);

(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; and

(5) Is placed in the payment year the EP would have been in had the EP begun in and remained in the program to which he or she has switched. 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.* (1) EPs are permitted to reassign their incentive payments to their employer or to an entity with which they have a contractual arrangement allowing the employer or entity to bill and receive payment for the EP's covered professional services.

(2)(i) Assignments in Medicare must be consistent with Section 1842(b)(6)(A) of the Act and 42 CFR part 424 subpart F.

(ii) Medicaid EPs may also assign their incentive payments to a TIN for an entity promoting the adoption of EHR technology, consistent with subpart D of this part.

(3) Each EP may reassign the entire amount of the incentive payment to only 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 (as specified in section 1848(k)(3) of the Act) services furnished by an EP for which payment is made under, or is based on, the Medicare physician fee schedule.

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, and excluding those hospital units specified in § 412.25 of this chapter.

Eligible professional (EP) means a physician as defined in section 1861(r) of the Act, which includes, with certain limitations, 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 a geographic 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 (qualifying 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, as determined for that payment year.

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 must be paid to a qualifying EP (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 to 75 percent of the estimated allowed charges for covered professional services furnished by the EP during the payment year.

(2) For purposes of this paragraph (a) of this section, 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 paragraphs (b)(2) and (c) of this section, the amount of the incentive payment under paragraph (a) of this section 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 EP 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 EP is 2014, then the payment limit for a payment year for the qualifying EP is the same as the amount specified in paragraph (b)(1) of this section 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 payment limit specified in this paragraph for such EP for such year and any subsequent year is $0.

(c) *Increase in incentive payment limit for EPs who predominantly furnish services in a geographic HPSA.* In the case of a qualifying EP 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 that is designated as of December 31 of such year, the incentive payment limit determined under paragraph (b) of this section is to be increased by 10 percent.

(d) *Payment adjustment effective in CY 2015 and subsequent years for nonqualifying EPs.*

(1) 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) of this section 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 EP is not subject to the payment adjustment for an EP who is not a successful electronic prescriber under section 1848(a)(5) of the Act, or 98 percent if the EP is subject to the payment adjustment

for an EP 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.* (i) 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.

(ii) The Secretary's determination to grant an EP an exemption under paragraph (d)(3)(i) of this section may be renewed on an annual basis, provided that in no case may an EP be granted an exemption under paragraph (d)(3)(i) of this section for more than 5 years.

§ 495.104 Incentive payments to eligible hospitals.

(a) *General rule.* A qualifying hospital (as defined in this subpart) must 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 paragraph (d) of this section and the payment formula specified in paragraph (c) 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 2016.

(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.

(iii) The transition factor determined under paragraph (c)(5) of this section.

(2) *Interim and final payments.* CMS uses data on hospital acute care inpatient discharges, Medicare Part A acute care inpatient-bed-days, Medicare Part C acute care inpatient-bed-days, and total acute care inpatient-bed-days, from the latest submitted 12-month hospital cost report as the basis for making preliminary incentive payments. Final payments are determined at the time of settling the first 12-month hospital cost report for the hospital fiscal year that begins on or after the first day of 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 acute care inpatient discharges or fewer, $2,000,000.

(ii) For each hospital with at least 1,150 but no more than 23,000 acute care inpatient discharges, $2,000,000 + [$200 × (n − 1,149)], where n is the number of discharges for the hospital.

(iii) For each hospital with more than 23,000 acute care inpatient discharges, $6,370,200.

(4) *Medicare share fraction*—(i) *General.* (A) CMS determines the Medicare share fraction for an eligible hospital by using the number of Medicare Part A, Medicare Part C, and total acute care 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 which are attributable to individuals with respect to whom payment may be made under Part A, including individuals enrolled in section 1876 Medicare cost plans; and

(*2*) The number of inpatient-bed-days which are attributable to individuals who are enrolled with a Medicare Advantage organization (as defined in § 422.2 of this chapter).

(B) A denominator which is the product of—

(1) The total number of acute care inpatient-bed-days; and

(2) The total amount of the eligible hospital's charges, not including any charges that are attributable to charity care, divided by the estimated total amount of the hospitals charges.

(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) For 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) For 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) For 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) For hospitals whose first payment year is FY 2015—

(A) ½ for FY 2015; and

(B) ¼ for FY 2016.

(d) No incentive payment for nonqualifying hospitals. After the first payment year, an eligible hospital will not receive an incentive payment for any payment year during which it is not a qualifying hospital.

§ 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)(4) 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 qualifying 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 addressee.

(3) Business phone number.

(4) Such other information as specified by CMS.

(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.

§ 495.110 Preclusion on administrative and judicial review.

There is no administrative or judicial review under sections 1869 or 1878 of the Act, or otherwise, of the following:

(a) For EPs—

(1) The methodology and standards for determining EP incentive payment amounts;

(2) The methodology and standards for determining the payment adjustments that apply to EPs beginning with 2015;

(3) The methodology and standards for determining whether an EP is a meaningful EHR user, including—

(i) The selection of clinical quality measures; and

(ii) The means of demonstrating meaningful EHR use.

(4) The methodology and standards for determining the hardship exception to the payment adjustments;

(5) The methodology and standards for determining whether an EP is hospital-based; and

(6) The specification of the EHR reporting period, as well as whether payment will be made only once, in a single consolidated payment, or in periodic installments.

(b) For eligible hospitals—

(1) The methodology and standards for determining the incentive payment amounts made to eligible hospitals, including—

(i) The estimates or proxies for determining discharges, inpatient-bed-days, hospital charges, charity charges, and Medicare share; and

(ii) The period used to determine such estimate or proxy;

(2) The methodology and standards for determining the payment adjustments that apply to eligible hospitals beginning with FY 2015;

(3) The methodology and standards for determining whether an eligible hospital is a meaningful EHR user, including—

(i) The selection of clinical quality measures; and

(ii) The means of demonstrating meaningful EHR use.

(4) The methodology and standards for determining the hardship exception to the payment adjustments; and

(5) The specification of the EHR reporting period, as well as whether payment will be made only once, in a single consolidated payment, or in periodic installments.

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 section 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 to a Medicare beneficiary.

Payment year means—

(1) For a qualifying MA EP, a calendar year (CY) beginning with CY 2011 and ending with CY 2016; and

(2) For an eligible hospital, a Federal fiscal year (FY) 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, for which at least two thirds of the Medicare hospital discharges (or bed-days) are of (or for) 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 must 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.

(5) Is not a "hospital-based EP" as that term is defined in § 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 2011 (for plan year 2012), 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. "Potentially qualifying MA EPs" and "potentially qualifying MA-affiliated eligible hospitals" are those EPs and hospitals that meet the respective definitions of "qualifying MA EP" and "qualifying MA-affiliated eligible hospital" in § 495.200 but who (or which) are not meaningful users of certified EHR technology.

(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 2012, 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 for the current plan year.

(2) A qualifying MA organization must provide CMS with the following for each MA EP or eligible hospital when reporting under either paragraph (b)(1) or (b)(3) of this section:

(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 within 60 days of the close 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 MA-affiliated eligible 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 60 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 section 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.

(iii) Methodological proposals must be submitted to CMS by June of the payment year and must be auditable by an independent third-party. CMS will review and approve or disapprove such proposals in a timely manner.

(5) For qualifying MA EPs who are not salaried, qualifying MA organizations may obtain attestations from such qualifying MA EPs (or from entities that the MA EPs are employed by or with which they have a partnership interest) as to the amount of compensation received by such EPs for MA plan enrollees of the MA organization. The organizations may submit to CMS compensation information for each such MA EP based on such attestations.

(6) For qualifying MA EPs who are not salaried, qualified MA organizations may have qualifying MA EPs (or from entities that the MA EPs are employed by or with which they have a partnership interest) send MA organization compensation information directly to CMS. CMS will use the information provided in this subparagraph or paragraph (b)(5) of this section for no other purpose than to compute the amount of EHR incentive payment due the MA organization.

(c) *Amount payable to qualifying MA organization for qualifying MA-affiliated eligible hospitals.* (1)(i) 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.

(ii) 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 EHR users 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 6 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 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 § 495.202(b) is provided to CMS.

§ 495.210 Meaningful EHR 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 60 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 60 days after close of the FY whether each qualifying MA-affiliated eligible hospital is a meaningful EHR 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 authorize States, at their option, to provide for incentive payments to Medicaid providers for adopting, implementing, or upgrading certified EHR 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 or 1300–1399

Adopt, implement or upgrade means—

(1) Acquire, purchase, or secure access to certified EHR technology;

(2) Install or commence utilization of certified EHR technology capable of meeting meaningful use requirements; or

(3) Expand the available functionality of certified EHR technology capable of meeting meaningful use requirements at the practice site, including staffing, maintenance, and training, or upgrade from existing EHR technology to certified EHR technology per the ONC EHR certification criteria.

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 certified EHR technology 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 eligible providers.

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. (or a Medicaid or CHIP demonstration project approved under section 1115 of the Act).

(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 (as described at § 495.304(c) through (e)) that is estimated through a numerator and denominator, consistent with the SMHP, and that meets the requirements of § 495.306.

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 an EHR incentive payment is limited to the following when consistent with the scope of practice regulations, as applicable for each professional (§ 440.50, § 440.60, § 440.100; § 440.165, and § 440.166):

(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 (FQHC) led by a physician assistant or a rural health clinic (RHC), that 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, for each year for which the EP seeks an EHR incentive payment, not be hospital-based as defined at § 495.4 of this subpart, and meet one of the following criteria:

(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) of this section 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) *General rule.* A Medicaid provider must annually meet patient volume requirements of § 495.304, as these requirements are established through the State's SMHP in accordance with the remainder of this section.

(b) *State option(s) through SMHP.* A State must submit through the SMHP the option or options it has selected for measuring patient volume. A State must select the methodology described in either paragraph (c) or paragraph (d) of section (or both methodologies). In addition, or as an alternative, a State may select the methodology described in paragraph (g) of this section.

(c) *Methodology, patient encounter.*

(1) *EPs.* To calculate Medicaid patient volume, an EP must divide:

(*i*) The total Medicaid patient encounters in any representative, continuous 90-day period in the preceding calendar year; by

(*ii*) The total patient encounters in the same 90-day period.

(2) *Eligible hospitals.* To calculate Medicaid patient volume, an eligible hospital must divide—

(i) The total Medicaid encounters in any representative, continuous 90-day period in the preceding fiscal year; by

(ii) The total encounters in the same 90-day period.

(3) *Needy individual patient volume.* To calculate needy individual patient volume, an EP must divide—

(*i*) The total needy individual patient encounters in any representative, continuous 90-day period in the preceding calendar year; by

(ii) The total patient encounters in the same 90-day period.

(d) *Methodology, patient panel.*

(1) *EPs.* To calculate Medicaid patient volume, an EP must divide:

(i) (A) The total Medicaid patients assigned to the EP's panel in any representative, continuous 90-day period in the preceding calendar year when at least one Medicaid encounter took place with the Medicaid patient in the year prior to the 90-day period; plus

(B) Unduplicated Medicaid encounters in the same 90-day period; by

(ii)(A) The total patients assigned to the provider in that same 90-day period with at least one encounter taking place with the patient during the year prior to the 90-day period; plus

(B) All unduplicated patient encounters in the same 90-day period.

(2) *Needy individual patient volume.* To calculate needy individual patient volume an EP must divide—

(i)(A) The total Needy Individual patients assigned to the EP's panel in any representative, continuous 90-day period in the preceding calendar year when at least one Needy Individual encounter took place with the Medicaid patient in the year prior to the 90-day period; plus

(B) Unduplicated Needy Individual encounters in the same 90-day period, by

(ii)(A) The total patients assigned to the provider in that same 90-day period with at least one encounter taking place with the patient during the year prior to the 90-day period, plus

(B) All unduplicated patient encounters in the same 90-day period.

(e) For purposes of this section, the following rules apply:

(1) For purposes of calculating EP patient volume, a Medicaid encounter means services rendered to an individual on any one day where—

(i) Medicaid (or a Medicaid demonstration project approved under section 1115 of the Act) paid for part or all of the service; or

(ii) Medicaid (or a Medicaid demonstration project approved under section 1115 of the Act) paid all or part of the individual's premiums, co-payments, and cost-sharing.

(2) For purposes of calculating hospital patient volume, both of the following definitions in paragraphs (e)(2)(i) and (e)(2)(ii) of this section may apply:

(i) A Medicaid encounter means services rendered to an individual per inpatient discharge where—

(A) Medicaid (or a Medicaid demonstration project approved under section 1115 of the Act) paid for part or all of the service; or

(B) Medicaid (or a Medicaid demonstration project approved under section 1115 of the Act) paid all or part of the individual's premiums, co-payments, and/or cost-sharing.

(ii) A Medicaid encounter means services rendered in an emergency department on any one day where—

(A) Medicaid (or a Medicaid demonstration project approved under section 1115 of the Act) paid for part or all of the service; or

(B) Medicaid (or a Medicaid demonstration project approved under section 1115 of the Act) paid all or part of the individual's premiums, co-payments, and cost-sharing.

(3) For purposes of calculating needy individual patient volume, a needy patient encounter means services rendered to an individual on any one day where—

(i) Medicaid or CHIP (or a Medicaid or CHIP demonstration project approved under section 1115 of the Act) paid for part or all of the service;

(ii) Medicaid or CHIP (or a Medicaid or CHIP demonstration project approved under section 1115 of the Act) paid all or part of the individual's premiums, co-payments, or cost-sharing;

(iii) The services were furnished at no cost; and calculated consistent with § 495.310(h); or

(iv) The services were paid for at a reduced cost based on a sliding scale determined by the individual's ability to pay.

(f) *Exception.* A children's hospital is not required to meet Medicaid patient volume requirements.

(g) *Establishing an alternative methodology.* A State may submit to CMS for review and approval through the SMHP an alternative from the options included in paragraphs (c) and (d) of this section, so long as it meets the following requirements:

(1) It is submitted consistent with all rules governing the SMHP at § 495.332.

(2) Has an auditable data source.

(3) Has received input from the relevant stakeholder group.

(4) It does not result, in the aggregate, in fewer providers becoming eligible than the methodologies in either paragraphs (c) and (d) of this section.

(h) *Group practices.* Clinics or group practices will be permitted to calculate patient volume at the group practice/clinic level, but only in accordance with all of the following limitations:

(1) The clinic or group practice's patient volume is appropriate as a patient volume methodology calculation for the EP.

(2) There is an auditable data source to support the clinic's or group practice's patient volume determination.

(3) All EPs in the group practice or clinic must use the same methodology for the payment year.

(4) The clinic or group practice uses the entire practice or clinic's patient volume and does not limit patient volume in any way.

(5) If an EP works inside and outside of the clinic or practice, then the patient volume calculation includes only those encounters associated with the clinic or group practice, and not the EP's outside encounters.

§ 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, implementation or upgrade 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) *Rules for Medicaid EPs.* The Medicaid EP's incentive payments are subject to all of the following limitations:

(1) *First payment year.* (i) For the first payment year, payment under this subpart may not exceed 85 percent of the maximum threshold of $25,000, which equals $21,250.

(ii) Medicaid EPs are responsible for payment for the remaining 15 percent of the net average allowable cost of certified EHR technology, or $3,750 for the first payment year.

(iii) An EP may not begin receiving payments any later than CY 2016.

(2) *Subsequent annual payment years.*

(i) For subsequent payment years, payment may not exceed 85 percent of the maximum threshold of $10,000, which equals $8,500.

(ii) Medicaid EPs are responsible for payment for the remaining 15 percent of the net average allowable cost of certified EHR technology, or $1,500 per payment year.

(iii) Payments after the first payment year may continue for a maximum of 5 years.

(iv) Medicaid EPs may receive payments on a non-consecutive, annual basis.

(v) No payments may be made after CY 2021.

(3) *Maximum incentives.* In no case may a Medicaid EP participate for more than a total of 6 years, and 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 payment is limited as follows:

(i) The maximum payment in the first payment year is further reduced by two-thirds, which equals $14,167.

(ii) The maximum payment in subsequent payment years is further reduced by 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) *Limitation to only one EHR incentive program.* An EP may only receive an incentive payment from either Medicare or Medicaid in a payment year, but not both.

(d) *Exception for EPs to switch programs.* An EP may change his or her EHR incentive payment program election once, consistent with § 495.10 of this part.

(e) *Limitation to one State only.* A Medicaid EP or eligible 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 FY 2016, and after FY 2016, a hospital may not receive an incentive payment unless it received an incentive payment in the prior fiscal year.

(6) Prior to FY 2016, payments can be made to an eligible hospital on a non-consecutive, annual basis for the fiscal year.

(7) 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 ending in the Federal fiscal year before the hospital's fiscal year that serves as the first 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 paragraph (g)(2)(i) of this section, 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 provider'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) of this section 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 in the payment year.

(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 reassign 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 reassigning annual payments and includes information about the verification mechanism the State will use to ensure that the reassignment 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 verification of eligibility for the payment year.

(2) *Medicaid eligible hospitals.* States disburse payments consistent with the Federal fiscal year on a rolling basis following verification of eligibility 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 payment year, it has adopted, implemented, or upgraded certified EHR technology, as defined in § 495.302.

(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 § 495.352 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, or 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 demonstrating that they are meaningful users 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) Subject to § 495.332, the State may propose a revised definition of meaningful use of certified EHR technology, subject to CMS prior approval, but only with respect to the following objectives:

(i) Generate lists of patients by specific conditions to use for quality improvement, reduction of disparities, research or outreach.

(ii) Capability to submit electronic data to immunization registries or immunization information systems and actual submission in accordance with applicable law and practice.

(iii) Capability to provide electronic submission of reportable (as required by State or local law) lab results to public health agencies and actual submission in accordance with applicable law and practice; and

(iv) Capability to provide electronic syndromic surveillance data to public health agencies and actual transmission in accordance with applicable law and practice.

(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 HHS, 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) Is 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 meaningful 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 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 of Health and Human Services, prior to release of the request for proposal or prior to execution of a contract.

(3) For contract amendments, unless specifically exempted by HHS, before execution of the contract amendment, involving contract cost increases exceeding $100,000 or contract time extensions of more than 60 days.

(4) The State Medicaid HIT plan.

(c) Failure to submit any of the information specified in paragraph (b) of this section to the satisfaction of HHS may result in disapproval or suspension of project funding.

(d) A State must obtain prior written approval from HHS 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 FFP.

If the HHS 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, suspension would occur in the same manner as 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 FFP for failure to provide access to information.

(a) HHS 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 health information technology (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) and other requirements included in ARRA.

(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; and

(iv) 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 or eligible hospital is a provider who meets patient volume consistent with the criteria in § 495.304 and § 495.306 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 a methodology for verifying such information.

(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 including meaningful use, efforts to adopt, implement, or upgrade and any information added to the CMS Single Provider Repository including all information related to patient volume, NPI, Tax identification number (TIN), 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 EHR reporting period, and that they have adopted, implemented, or upgraded certified EHR technology 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 their participation year and a methodology for verifying such information.

(6) A list of the specific actions planned to implement the 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 by the State 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.

(8) A description of the process in place to ensure that no amounts higher than 90 percent of FFP will be claimed by the State for administrative expenses in administering the certified EHR technology incentive payment program and a methodology for verifying such information.

(9) A description of the process and methodology for ensuring and verifying 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 incentive payment reassignments 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 EP 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.* For payments, States 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 the methodology for verifying such information.

(4) The process in place and the methodology for verifying that information is available in order to ensure that Medicaid EHR incentive payments are made for no more than a total of 6 years; that no EP or eligible hospital begins receiving payments after 2016; that incentive payments cease after 2021; and that an eligible hospital does not receive incentive payments after FY 2016 unless the hospital received an incentive payment in the prior fiscal year.

(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.

(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.

(7) The process in place to provide for the timely and accurate payment of incentive payments to EPs and eligible hospitals, including the timeframe 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.

(9) The process in place and the methodology for verifying that EPs meet their responsibility for 15 percent of the net average allowable cost for certified EHR technology.

(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(g).

(2)(i) A revised definition of meaningful use of certified EHR technology consistent with § 495.4 and § 495.316(d)(2) of this part.

(ii) Any revised definition of meaningful use may not require additional functionality beyond that of certified EHR technology and conform with CMS guidance on Stage 1. See also § 495.316(d)(2).

§ 495.334 [Reserved]

§ 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 including:

(1) Planned annual payment amounts;

(2) Total of planned payment amounts; and

(3) Calendar year of each planned annual payment amount.

(4) 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.

§ 495.344 Approval of the State Medicaid HIT plan, the HIT PAPD and update, the HIT IAPD and update, and the annual HIT IAPD.

HHS will not approve the State Medicaid HIT plan, HIT PAPD and update, HIT–IAPD and update, or annual IAPD if any of these documents do not include all of the information required under this subpart.

§ 495.346 Access to systems and records.

The State agency must allow HHS 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 sub agreements.

(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 offer or 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 offer or 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 2 CFR part 376.

(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 HHS 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.

§ 495.352 Reporting requirements.

Each State must submit to HHS 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 CFR 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.* HHS reserves a royalty-free, non-exclusive, and irrevocable license to reproduce, publish or otherwise use and to authorize others to use for Federal government purposes, the software, modifications, and documentation designed, developed or installed with FFP under this Subpart.

(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 § 495.312, 495.314, and § 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.

(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 that Medicaid EHR incentive payments are made for no more than 6 years; that no EP or eligible hospital begins receiving payments after 2016; that incentive payments cease after 2021; and that an eligible hospital does not receive incentive payments after FY 2016 unless the hospital received an incentive payment in the prior fiscal 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 § 455.15 and § 455.21 of this chapter, 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.* For any forms on which a provider submits information necessary to the determination of eligibility to receive EHR payments, the State must obtain a statement that meets the following requirements:

(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 of 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.

Authority: 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: June 16, 2010.

Marilyn Tavenner,

Acting Administrator, Centers for Medicare & Medicaid Services.

Approved: July 9, 2010.

Kathleen Sebelius,

Secretary.

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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; 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 (ONC), Department of Health and Human Services.

ACTION: Final rule.

SUMMARY: The Department of Health and Human Services (HHS) is issuing this final rule to complete the adoption of an initial set of standards, implementation specifications, and certification criteria, and to more closely align such standards, implementation specifications, and certification criteria with final meaningful use Stage 1 objectives and measures. Adopted certification criteria establish the required capabilities and specify the related standards and implementation specifications that certified electronic health record (EHR) technology will need to include to, at a minimum, support the achievement of meaningful use Stage 1 by eligible professionals, eligible hospitals, and/or critical access hospitals (hereafter, references to "eligible hospitals" in this final rule shall mean "eligible hospitals and/or critical access hospitals") under the Medicare and Medicaid EHR Incentive Programs. Complete EHRs and EHR Modules will be tested and certified according to adopted certification criteria to ensure that they have properly implemented adopted standards and implementation specifications and otherwise comply with the adopted certification criteria.

DATES: *Effective Date:* This final rule is effective August 27, 2010. The incorporation by reference of certain publications listed in the rule is approved by the Director of the Federal Register as of August 27, 2010.

FOR FURTHER INFORMATION CONTACT: Steven Posnack, Director, Federal Policy Division, Office of Policy and Planning, Office of the National Coordinator for Health Information Technology, 202–690–7151.

SUPPLEMENTARY INFORMATION:

Acronyms

ANSI American National Standards Institute
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
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 International Classification of Diseases, 9th Revision, Clinical Modification
ICD–10–PCS International Classification of Diseases, 10th Revision, Procedure Coding System
ICD–10–CM International Classification of Diseases, 10th Revision, Clinical Modification
IHS Indian Health Service
LOINC Logical Observation Identifiers Names and Codes
NCPDP National Council for Prescription Drug Programs
NLM National Library of Medicine
OCR Office for Civil Rights
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
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
XML eXtensible Markup Language

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I. Background

A. Legislative History

The Health Information Technology for Economic and Clinical Health (HITECH) Act, Title XIII of Division A and Title IV of Division B of the American Recovery and Reinvestment Act of 2009 (ARRA) (Pub. L. 111–5), was enacted on February 17, 2009. The HITECH Act amended the Public Health Service Act (PHSA) and established "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 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. Section 3004(b)(1) of the PHSA also permits the Secretary to adopt the initial set of standards, implementation specifications, and certification criteria on an interim, final basis.

B. Regulatory History

1. Initial Set of Standards, Implementation Specifications, and Certification Criteria for EHR Technology Interim Final Rule

On December 30, 2009, the **Federal Register** made available for public inspection, an interim final rule (the Interim Final Rule) with a request for comments, which adopted an initial set of standards, implementation specifications, and certification criteria. As noted in this rulemaking (75 FR 2014), we described how Congress fundamentally tied the adopted standards, implementation specifications, and certification criteria 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 included 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.

The initial set of standards, implementation specifications, and certification criteria adopted in the Interim Final Rule established the capabilities that Certified EHR Technology would need to include to, at a minimum, support eligible professionals' and eligible hospitals' efforts to achieve what had been proposed for meaningful use Stage 1 under the Medicare and Medicaid EHR Incentive Programs proposed rule.

2. Interdependencies With Other HITECH Provisions and Relationship to Other Regulatory Requirements

In addition to our discussion of how the standards, implementation specifications, and certification criteria adopted in the Interim Final Rule correlated with the Medicare and Medicaid EHR Incentive Programs proposed rule, we also discussed our approach to align adopted standards, implementation specifications, and certification criteria with new and pending HITECH Act regulatory actions and with other already established regulatory requirements. We also explained our approach for aligning these standards, implementation specifications, and certification criteria with: the adopted standard and certification criterion related to the Health Insurance Portability and Accountability Act of 1996 (HIPAA) Privacy Rule Accounting of Disclosures Regulation under the HITECH Act; alignment with the HIPAA Privacy and Security Regulations; the Medicare Part D Electronic Prescribing Regulations; and the HIPAA Transactions and Code Sets Standards Regulations.

II. Overview of the Final Rule

We are amending part 170 of title 45 of the Code of Federal Regulations (CFR) to complete the adoption of the initial set of standards, implementation specifications, and certification criteria as required by section 3004(b)(1) of the PHSA and realign them with the final objectives and measures established for meaningful use Stage 1. After reviewing and considering public comments on our adopted standards, implementation specifications, and certification criteria, we have made several revisions to support the final meaningful use objectives and measures, clarify certain certification criteria to resolve identified technical challenges related to some of the standards and implementation specifications we adopted, and to provide for additional flexibility.

III. Section-by-Section Discussion of the Final Rule and Response to Comments

A. Introduction

This section summarizes the nearly 400 timely comments received by ONC related to the Interim Final Rule. In some cases, due to the simultaneous publication and topical similarity of the notice of proposed rulemaking for meaningful use Stage 1, commenters inadvertently submitted comments to our regulation docket on *regulations.gov* instead of the Centers for Medicare & Medicaid Services (CMS) regulation docket, and vice versa. Recognizing this oversight, CMS and ONC shared misplaced comments between the offices and we included within our review all comments that could be reasonably identified as comments on the Interim Final Rule.

We have organized the preamble of this final rule along the following lines. First, we respond to general comments, including those related to the scope and applicability of the final rule that we believe are necessary to clarify upfront. Next, we respond to comments regarding the definitions of certain defined terms. We then respond to public comments on each certification criterion, and where an adopted certification criterion also references standards and implementation specifications, we include our response to public comments on the related standards and implementation specifications. These concepts were separately discussed in the Interim Final Rule and we believe that discussing the certification criteria together with associated standards and implementation specifications will improve the clarity of the final rule and will allow us to more fully address public comments in a broader context. We include the following table at the beginning of the discussion of each certification criterion section to illustrate the final meaningful use Stage 1 objectives for eligible professionals and eligible hospitals and to show how we have revised adopted certification criteria in response to the revised meaningful use objectives and measures and public comments.

Meaningful use Stage 1 objective	Meaningful use Stage 1 measure	Certification criterion
Eligible Professional and/or Eligible Hospital & Critical Access Hospital Objective.	Eligible Professional and/or Eligible Hospital & Critical Access Hospital Measure.	Interim Final Rule Text: Certification Criterion. Final Rule Text: Certification Criterion.

Finally, in considering public comments on the Interim Final Rule, we analyzed whether we had structured the regulation text in an optimal and understandable manner. For several provisions, we received comments requesting additional clarification and we felt that the original regulatory structure contributed to the commenters' confusion. Because of those comments and in an effort to better structure the regulation text for future revisions, we have revised the structure conceptually to group content exchange standards and associated

implementation specifications and vocabulary standards, and separated them into different sections. In line with this "conceptual" restructuring, we have determined that specifying how a Complete EHR or EHR Module must comply with an adopted standard should be solely reflected in the certification criteria. As a result, several certification criteria have been revised to more clearly reflect how a Complete EHR or EHR Module must comply with adopted standards and, where applicable, the relevant adopted implementation specifications.

B. General Comments

Some commenters appear to have misinterpreted or misunderstood the scope of the Interim Final Rule and the applicability of the adopted standards, implementation specifications, and certification criteria. We would therefore like to clarify these concepts at the beginning of this final rule and are providing the following responses to the relevant comments.

Comments. Some commenters seem to have construed the adoption of standards, implementation specifications, and certification criteria as including requirements that apply to the health care providers that will use the Certified EHR Technology, rather than as required capabilities of the Certified EHR Technology itself. These commenters, for instance, questioned whether entities using Certified EHR Technology must comply with adopted standards and implementation specifications when electronically using or transmitting health information within or among components of the legal entity or alternatively whether the standards apply solely to transmissions between legal entities. Other commenters specifically requested clarification regarding the adopted standards that are required to be used internally within each provider's office, institution, or closed system and which standards are required for purposes of electronically exchanging health information among such entities. Some comments implied that the Interim Final Rule should have specified when an eligible professional or eligible hospital would be required to use adopted standards. One commenter specifically requested that the adopted standards apply only to the electronic exchange of health information between legal entities.

Response. As stated in § 170.101, we specify that "[t]he 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." In §§ 170.200 and 170.300, we further specify that "[t]he standards and implementation specifications adopted in this part apply with respect to Complete EHRs and EHR Modules" and that "[t]he certification criteria adopted in this subpart apply to the testing and certification of Complete EHRs and EHR Modules."

The purpose of this final rule, therefore, is to adopt standards, implementation specifications, and certification criteria to test and certify that a Complete EHR or EHR Module provides certain capabilities, and where applicable, to require that those capabilities be implemented in accordance with adopted standards and implementation specifications. The adopted standards, implementation specifications, and certification criteria were not intended to impose independent requirements on the entities using Certified EHR Technology. Unlike certain other regulatory requirements to which eligible professionals or eligible hospitals may be subject, it is not within the intended scope of this final rule to specify the requirements for entities using Certified EHR Technology.

We understand the commenters' point though that an adopted standard and implementation specification could apply equally to electronic transactions between legal entities as well as to transmissions within an entity. This final rule, however, is not intended to specify the conditions under which adopted standards and implementation specifications must be used, only that a Complete EHR or EHR Module, in order to be certified, must include specified capabilities that are implemented in accordance with those standards, implementation specifications, and certification criteria. We anticipate that other regulations, as well as the clinical and business needs of HIT users, anticipated efficiencies and desired quality improvements, and technical, architectural, and enterprise limitations will determine when entities will utilize the capabilities required of Certified EHR Technology. Additionally, we would note that Complete EHRs and EHR Modules will, in many cases, be tested and certified independent of the environment within which they will be implemented. Consequently, specifying when an entity that implements Certified EHR Technology must utilize a particular capability in its operating environment exceeds the scope of this rule.

To further demonstrate this point, Certified EHR Technology implemented by an eligible professional will need to possess the capability to generate an electronic prescription according to one of the standards we have adopted. To specify the contexts in which an electronic prescription (generated according to the adopted standard) must be transmitted would go beyond the scope of certification. Moreover, it would raise a more serious and practical consideration. Attempting to specify when entities must utilize the capabilities of Certified EHR Technology would add an unnecessary level of complexity to this rule and create the potential for conflicts with other regulations promulgated by the HHS. For instance, HHS has already promulgated at least two sets of regulations identifying when health care providers need to use specific standards and the contexts in which those standards must be used. Under the HIPAA Transactions and Code Sets Standards regulations, HHS specifies at 45 CFR 162.923(a) that "[e]xcept as otherwise provided in this part, if a covered entity conducts with another covered entity (*or within the same covered entity*), using electronic media, a transaction for which the Secretary has adopted a standard under this part, the covered entity must conduct the transaction as a standard transaction." (Emphasis added.) Consequently, in the HIPAA context, covered entities must use adopted transaction standards for covered transactions both within the covered entities and with outside entities. The Medicare Part D electronic-prescribing (e-prescribing) regulations implement a different approach for certain e-prescribing transactions. Health care providers that electronically prescribe Part D drugs for Part D eligible individuals under 42 CFR 423.160(a)(3)(iii), "may use either HL7 messages or the NCPDP SCRIPT Standard to transmit prescriptions or prescription-related information internally when the sender and the recipient are part of the same legal entity. If an entity sends prescriptions outside the entity (for example, from an HMO to a non-HMO pharmacy), it must use the adopted NCPDP SCRIPT Standard or other applicable adopted standards." Therefore, we believe that it is unnecessary and outside of the intended scope of this rule to specify the contexts or circumstances under which adopted standards and implementation specifications must be utilized.

Moreover, we anticipate that future meaningful use objectives and measures will specify, as necessary and appropriate, the conditions under which certain health care providers will need

to use adopted standards and implementation specifications. The context, for instance, governing when a standard must be used will, in some cases, be directly related to whether and how an eligible professional or eligible hospital must meaningfully use Certified EHR Technology. For example, a final meaningful use Stage 1 objective requires that eligible professionals and eligible hospitals use Certified EHR Technology to record demographics including, among other fields, race and ethnicity. While we have adopted the race and ethnicity codes published by the Office of Management and Budget (OMB), in the context Medicare and Medicaid EHR incentive programs, the *meaningful use of Certified EHR Technology* will dictate whether such codes must be used "inside" an organization. Another example of when a meaningful use objective establishes the context in which a standard must be used is the objective that requires eligible professionals and eligible hospitals to use Certified EHR Technology to maintain an up-to-date problem list of current and active diagnoses. The measure associated with this objective requires that entries be recorded in "structured data" and in this context we adopted ICD–9 or SNOMED–CT® to provide that structure. As a result, Certified EHR Technology must be capable of using ICD–9 or SNOMED–CT® when an eligible professional or eligible hospital seeks to maintain an up-to-date problem list.

In other instances, the Department does not specify explicitly in regulation the context for certain meaningful use objectives and whether meaningful use of Certified EHR Technology would require the use of a standard for electronic transactions solely between two different legal entities, or for all transactions, or for most transactions with certain exemptions.

Comments. Several commenters requested that we provide more information about the standards we expect the Secretary to adopt in order to support future stages of meaningful use. These commenters noted, along with referencing the timelines for making changes to HIT, that it would benefit the HIT industry if we could provide a roadmap, framework, or more descriptive "glide path" for future standards adoption activities.

Response. We anticipate that future stages of meaningful use will require us to adopt additional standards, implementation specifications, and certification criteria. We also expect that standards we have adopted will continue to be revised and updated over time, to reflect current technology, changing medical practice and regulatory requirements. We will therefore need to continue to harmonize those adopted standards with other standards to support interoperability. We anticipate that the standards required to support future stages of meaningful use will need a framework that supports harmonization across different meaningful use scenarios and that supports early real world testing. We plan to work closely with the HIT Standards Committee to develop a forward looking agenda and to make known in advance the types of standards, implementation specifications, and certification criteria on which we will seek recommendations from the HIT Standards Committee. We believe this will benefit the HIT industry by providing greater transparency of the standards adoption activities and will serve as an early indication for the public of candidate standards that are being identified for possible adoption.

C. Definitions—§ 170.102

In this section, we respond to public comment on the definitions adopted in the Interim Final Rule. We address the definition of Certified EHR Technology last after we provide clarifications related to the definitions of Complete EHR and EHR Module.

1. Definition of Disclosure

Comments. A few commenters noted that the definition of *disclosure* was too broad or asked that we refine the adopted definition to be more limited and to only apply in certain circumstances. One commenter noted that this was a new definition.

Response. As we explained in the preamble of the Interim Final Rule, this definition repeated the text specified at 45 CFR 160.103 (the General Provisions section for the HIPAA regulations). Because the Interim Final Rule created a new part in Title 45 of the CFR, the definition of disclosure as it is used in the HIPAA regulations would not necessarily have applied to our use of the term in this rule. Therefore, to prevent unnecessary ambiguity for the regulated community, we adopted the definition of the term as it is defined at 45 CFR 160.103.

In light of public comment and to prevent any future regulatory inconsistency that would require rulemaking to correct, we have revisited our approach of repeating the text of the definition of disclosure from 45 CFR 160.103 and have decided to cross reference 45 CFR 160.103 in the definition of disclosure. The final definition will read: disclosure is defined as it is in 45 CFR 160.103.

2. Definition of Standard

Comment. A commenter stated that our definition of standard was comprehensive from a technical perspective, but believed the definition was incomplete from a policy perspective. The commenter argued that for interoperability to be successful, it was essential that standards be created through collaborative, consensus-based processes that take into consideration the needs and concerns of all interested stakeholders. For that reason, the commenter suggested, in order for the definition to be whole from both a technical and policy perspective, we should add to the definition the phrase "developed through the use of open, collaborative, consensus-based processes."

Response. While we appreciate the commenter's point, we believe that the proposed language is unnecessary and potentially problematic. Federal agencies are already required under the National Technology Transfer and Advancement Act of 1995 (NTTAA) (15 U.S.C. 3701 *et seq.*) and OMB Circular A–119 [1] to use, wherever practical, technical standards that are developed or adopted by voluntary consensus standards bodies to carry out policy objectives or activities, with certain exceptions. In drafting the Interim Final Rule, we briefly discussed relevant provisions of the NTTAA and OMB Circular A–119, our compliance with the statute and the Circular, and we requested comments on our approach to the selection of standards. We also explained that both the NTTAA and OMB Circular A–119 provide for certain exceptions to selecting only standards developed or adopted by voluntary consensus standards bodies, namely when doing so would be "inconsistent with applicable law or otherwise impractical." In the Interim Final Rule, we identified those instances in which we had and had not adopted voluntary consensus standards. In the instances in which we had not adopted voluntary consensus standards, we provided two principal reasons: first, that in most cases a voluntary consensus standard that could meet the requisite technical goals was simply unavailable; and second, that to the extent 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 industry. In

[1] *http://www.whitehouse.gov/omb/circulars_a119.*

this final rule, we have adopted only voluntary consensus standards, except for two government-unique standards (CMS Physician Quality Reporting Initiative (PQRI) 2009 Registry XML Specification and the Office of Management and Budget Standards for Maintaining, Collecting, and Presenting Federal Data on Race and Ethnicity), a functional standard relating to vocabularies included in RxNorm, and the specified standards to protect electronic health information. We are aware of no voluntary consensus standards that would serve as alternatives to these standards for the purposes that we have identified. We encourage the HIT Standards Committee to obtain public input, hold hearings on, and recommend to the National Coordinator standards that have been developed or adopted by voluntary consensus standards bodies.

3. Definition of Implementation Specification

We did not receive any comments applicable to the definition of implementation specification and consequently did not make any changes to the definition.

4. Definition of Certification Criteria

Comments. One commenter expressly stated its support for our definition of certification criteria.

Response. We appreciate the commenter's support for our definition of certification criteria and have not made any changes to the definition in this final rule.

5. Definition of Qualified EHR

Comments. A couple of commenters asserted that there is uncertainty in the industry with respect to what constitutes an EHR due both to the seemingly inconsistent definitions of terms in the HITECH Act and to the alternative definitions published by different organizations and associations. The commenters made specific reference to the definition of "Qualified Electronic Health Record" ("Qualified EHR") at section 3000 of the PHSA and to the term "EHR" found in the HITECH Act at section 13400 of Subtitle D. The latter defines EHR as "an electronic record of health-related information on an individual that is created, gathered, managed, and consulted by authorized clinicians and staff." The former defines Qualified EHR as "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." Both commenters recommended that the definition of Qualified EHR be clarified with one commenter suggesting that the definition should follow the definition of EHR as it relates to health care providers.

Response. We appreciate these comments and recognize that the existence of multiple terms that include the word "EHR" can be confusing. However, we believe that Congress intended for HHS to apply the definition of a Qualified EHR found in section 3000 of the PHSA to this regulation for specific reasons that cannot be overlooked. As a result, we have decided not to adopt the recommendation to follow the definition of the term EHR that is found in Subtitle D of the HITECH Act. We discuss additional responses to comments on the definition of Qualified EHR below.

Comments. A few commenters requested that we expand the definition of Qualified EHR to include a variety of additional functionality and that a Qualified EHR be able to comply with business or legal requirements. These comments requested that we add required elements for an EHR to constitute a Qualified EHR, including that the EHR: Have a record-keeping capability for legal purposes; include certain requirements for usability; enable health care providers to perform several other actions not specified in the definition; and that certain elements of patient demographic information be specified.

Response. We understand the rationale behind these commenters' suggestions, but we do not believe that it is necessary to add more prerequisite capabilities to the definition of Qualified EHR. We believe Congress defined Qualified EHR to include a minimum level of capabilities. Furthermore, to meet the definition of Certified EHR Technology, a Qualified EHR must be certified in accordance with a certification program established by the National Coordinator. As a result, we believe that any additional capabilities a Qualified EHR would need to possess to allow an eligible professional or eligible hospital to be in a position to qualify for incentive payments under the Medicare and Medicaid EHR incentive programs will be more appropriately addressed through the Secretary's adoption of additional standards, implementation specifications, and certification criteria.

Comments. Some commenters requested that we clarify some of the terms in the definition of Qualified EHR such as "capture," "query," "other sources," and "relevant to health care quality" with respect to how they related to Certified EHR Technology. Another commenter expressly stated that if we only intended to repeat the statutory definition of Qualified EHR without modification, we should at least clarify the meaning of demographic information.

Response. We do not believe that additional clarity is needed or desirable for such terms because the meanings are context specific. The intended meanings of these terms will depend significantly on the contexts in which the terms are used and the associated capabilities of the Certified EHR Technology. The terms' meanings may also be affected by any standards and implementation specifications that are associated with those capabilities and adopted. In certain circumstances, for instance, the meaning of the phrase "other sources" as used in the definition of Qualified EHR will depend on the specific context in which electronic health information is being integrated or exchanged, and perhaps on whether the source is external to or internal within the Complete EHR or the EHR Module. Similarly, the meanings of the terms or phrases "capture," "query," "relevant to health care quality" and "demographic" information may vary according the context of the required capabilities of the EHR technology. In each of these instances, we believe that the adopted certification criteria and meaningful use objectives and measures will provide these contexts, identify the associated required capabilities, and consequently clarify the intended meanings of these terms.

6. Definition of Complete EHR

Comments. Some commenters supported our definition of Complete EHR and believed that it was understandable, sufficient, and reasonable. Other commenters, however, suggested that the definition of Complete EHR was too narrow, because the term is tied to only those certification criteria adopted by the Secretary. These commenters argued that the Complete EHR and the adopted certification criteria should be more comprehensive and should include functionality that is not presently required for a Complete EHR to achieve certification. Many of these commenters referenced the Health Level Seven (HL7) EHR System Functional Model (EHR–S

FM) and contended that what we had defined as a Complete EHR did not align with or include all of the functionality specified in the EHR–S FM. One commenter requested that we clarify what we meant by "we fully expect some EHRs to have capabilities beyond those addressed by certification criteria" when we made this point during our discussion of the definition of Complete EHR in the preamble of the Interim Final Rule. Other commenters recommended specific wording changes to the definition.

Response. In the Interim Final Rule we defined Complete EHR to mean "EHR technology that has been developed to meet all applicable certification criteria adopted by the Secretary." We clarified that the term Complete EHR 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 believe that commenters misunderstood the scope and purpose of the regulatory definition and believe that the definition effectively fulfills its regulatory purpose. We intend for the definition of Complete EHR to be used to clearly identify EHR technology as being able to perform, at a minimum, all of the applicable capabilities required by certification criteria adopted by the Secretary, and thereby, as providing eligible professionals or eligible hospitals with the technical capabilities they need to support their achievement of meaningful use of Certified EHR Technology. It is in this context that we view such EHR technology as "complete."

We recognize that many commenters recommended a definition of "Complete EHR" that would be more comprehensive than the definition we provided. Many commenters contended that HIT exists and is available for eligible professionals and eligible hospitals to implement, and much of it includes a myriad of capabilities far surpassing the capabilities required to meet the definition of Complete EHR. We do not dispute that point. We also understand that the capabilities included in a Complete EHR, as defined for the purposes of this regulation, may not encompass all of the capabilities a specific eligible professional or eligible hospital or for that matter any health care provider, may deem essential to meet their unique business needs and use cases.

This definition, however, *does not* in any way preclude any additional capabilities from being included in a Complete EHR or implemented in a complementary fashion. The definition sets forth a floor, not a ceiling, and serves to signify that once tested and certified to all applicable certification criteria, a Complete EHR meets the definition of Certified EHR Technology. For this reason, we did not seek to craft this definition in a way that signified that a Complete EHR would be able to provide all of the capabilities a health care provider desired or deemed necessary, or that the entity's EHR could only include the capabilities for which the Secretary has adopted certification criteria. Nor did we define Complete EHR according to a particular functional model, because doing so would have been inconsistent with the regulatory purpose of the definition.

In light of public comment and to further clarify the regulatory purpose of the definition of Complete EHR as well as make clear that a Complete EHR should not be misinterpreted to mean EHR technology that is any more comprehensive than the certification criteria to which it was tested and certified, we have added the phrase "at a minimum" to the definition. The final definition of Complete EHR will therefore read "EHR technology that has been developed to meet, at a minimum, all applicable certification criteria adopted by the Secretary."

As a related point, we would also note that an eligible professional or eligible hospital would need to use a capability that is included among the adopted certification criteria to meet the associated meaningful use objective or measure. The eligible professional or eligible hospital therefore could not attempt to use a capability that is superfluous to certification to demonstrate the meaningful use of "Certified EHR Technology." We understand that the Medicare and Medicaid EHR Incentive Programs final rule discusses this issue more fully in several places, and we defer to those discussions concerning the requirements for achieving meaningful use of Certified EHR Technology.

Comment. In the context of the definition of Complete EHR, one commenter asked for clarification regarding how many certification criteria a Complete EHR must be developed to meet.

Response. For the purposes of meeting the definition of Complete EHR, EHR technology designed for an ambulatory setting (to be used by eligible professionals) must be certified to all of the certification criteria adopted at 45 CFR 170.302 and 45 CFR 170.304, and EHR technology designed for an inpatient setting (to be used by eligible hospitals) must be certified to all of the certification criteria adopted at 45 CFR 170.302 and 45 CFR 170.306.

7. Definition of EHR Module

Comments. Numerous commenters strongly supported our inclusion of a modular approach to meet the definition of Certified EHR Technology. Many of these commenters saw this approach as a way to spur greater innovation in the HIT marketplace, provide more choices for health care providers, and generally broaden the appeal of HIT and expedite its adoption. Some commenters noted, however, that they believed the definition needed further clarification with respect to what would constitute an EHR Module. In most cases, these commenters provided examples of technologies that they believed should meet the definition of EHR Module and they sought confirmation that these technologies would meet the definition. Included among these technologies were radiology information systems (RIS), picture archiving and communication systems (PACS), PHRs, speech recognition software, electrocardiogram systems, remote patient monitoring (RPM) devices, and other electronic devices including non-health care devices.

Response. In the Interim Final Rule, we defined an 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." Consequently, EHR Modules, by definition, must provide a capability that can be tested and certified in accordance with at least one certification criterion adopted by the Secretary. Therefore, if an EHR Module does not provide a capability that can be tested and certified at the present time, it is *not* HIT that would meet the definition of EHR Module. We stress "at the present time," because as new certification criteria are adopted by the Secretary, other HIT could be developed and then tested and certified in accordance with the new certification criteria as EHR Modules.

We encourage eligible professionals and eligible hospitals to use any and all HIT they believe will help make the health care they deliver more effective and efficient. However, unless the HIT is tested and certified to at least one certification criterion for use as part of Certified EHR Technology, it does not constitute an EHR Module for the purposes of this regulation. Eligible professionals and eligible hospitals are not prohibited from using or implementing this HIT, but again, at the present time, such HIT cannot

constitute an EHR Module and serve as a necessary component of Certified EHR Technology for eligible professionals or eligible hospitals to use when seeking to achieve meaningful use as defined in the Medicare and Medicaid EHR Incentive Programs final rule.

In response to these comments, we would also like to clarify our conceptualization of an EHR Module. An EHR Module could provide a single capability required by one certification criterion or it could provide all capabilities but one, required by the certification criteria for a Complete EHR. In other words, we would call HIT tested and certified to one certification criterion an "EHR Module" and HIT tested and certified to nine certification criteria an "EHR Module," where ten certification criteria are required for a Complete EHR. We have not made any changes to the definition of EHR Module as a result of these comments or the comments addressed below.

Comment. One commenter asked whether we meant to include in the definition of EHR Module "interfaces" that perform data mapping or transformation. The commenter raised this question while noting that some organizations use multiple interfaces to interconnect their HIT systems and that it would be an arduous task for these organizations to ensure that all individual interfaces are certified. Another commenter sought clarification regarding what we meant when we stated as an example in the Interim Final Rule that EHR Modules could be "an interface or other software program that provides the capability to exchange electronic health information."

Response. As discussed above, to meet the definition of EHR Module, HIT would need to provide a capability that could be tested and certified to at least one certification criterion. If a certification criterion has therefore been adopted that requires a particular capability for exchanging electronic health information, an interface or other software program that provides that capability could be tested and certified as an EHR Module. In many circumstances, an interface or program may provide valuable functionality, but not a capability for which a certification criterion has been adopted. For example, software implemented by an eligible professional that performs data translation or mapping between two databases or data sets may provide critical functionality, yet that software would not constitute an EHR Module. Similarly, interfaces between "HIT systems" may be critical to the functionality of the separate systems, but they themselves would not be EHR Modules.

In those circumstances in which an interface or other software program is an integral component of an EHR Module without which it would not be able to be tested and certified, then such interface or other software program, though not itself an EHR Module, would function as a critical piece of the overall EHR Module presented for testing and certification. For example, a software program that would permit an eligible professional or eligible hospital to electronically exchange health information with other eligible professionals or eligible hospitals could be tested and certified as an EHR Module, if it provides the capability to electronically exchange health information according to standards adopted by the Secretary. In this example, whatever comprises the software program would be considered part of the EHR Module that is tested and certified.

Finally, in situations where an eligible professional or eligible hospital believes that it has multiple HIT systems that would each meet the definition of EHR Module, we suggest that the eligible professional or eligible hospital evaluate whether these systems could be combined with other systems to constitute a Complete EHR. If they are capable of being combined to form a Complete EHR, it may be more expeditious and beneficial for an eligible professional or eligible hospital to simply seek Complete EHR testing and certification.

Comments. A few commenters requested that we clarify how EHR Modules would be tested and certified to adopted privacy and security certification criteria. Other commenters asked whether we meant to allow for there to be EHR Modules that provided only privacy and security capabilities.

Response. These comments pertain to the certification programs rule, and are outside of the scope of this rule. We therefore respond to these comments in the Temporary Certification Program final rule (75 FR 36158).

8. Definition of Certified EHR Technology

Comments. Multiple commenters commended ONC for recognizing the need to certify EHR Modules and enabling certified EHR Modules to be used in combination to meet the definition of Certified EHR Technology. These commenters noted that this approach makes it clear that eligible professionals and eligible hospitals will have the flexibility to select certified EHR modules that are the most useful to them, and can achieve meaningful use either with combinations of certified HIT or a single EHR system. However, some commenters mentioned that the definition is unnecessarily ambiguous, and subject to possible alternative interpretations. Some commenters also commented on certain statements in the preamble regarding EHR Modules and queried how a proper combination of EHR Modules could be used to meet the definition of Certified EHR Technology. Other commenters, while acknowledging that adopted certification criteria will determine in part what constitutes Certified EHR Technology, urged ONC to revise the definition to include only patient care functionality. Finally, a few commenters offered specific word changes for the definition to improve its clarity.

Response. In the Interim Final Rule, we 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." With respect to a combination of EHR Modules, we clarified in the preamble of the Interim Final Rule that:

> As long as each EHR Module has been separately tested and certified in accordance with the certification program established by the National Coordinator * * * 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.

Many commenters appeared to be confused by the inclusion of "each of which" in the definition of Certified EHR Technology. Other commenters also stated that "each of which" was awkwardly placed, making it difficult to interpret how the combination of EHR Modules must satisfy the subsequent requirements of the definition. This confusion also made it difficult to understand the clarifying remarks reiterated above regarding our intention to avoid implying that a combination of certified EHR Modules had to be certified a second time when a proper combination had been created. We generally agree with these comments and are revising the definition slightly

to avoid this ambiguity and to clarify that the definition of Certified EHR Technology can be met in either of two ways.

The first way that the definition of Certified EHR Technology can be met is for a Complete EHR to: (1) Meet the requirements included in the definition of a Qualified EHR, and (2) be 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. The second way that the definition of Certified EHR Technology can be met is if each constituent EHR Module of a combination of EHR Modules 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 and the resultant combination also meets the requirements included in the definition of a Qualified EHR.

As previously written, it was unclear to many commenters that the comma preceding "each of which" was meant to separately apply a Complete EHR and "combination of EHR Modules" to the subsequent requirements. Our intention was that a combination of EHR Modules would have to provide the capabilities necessary to meet the definition of a Qualified EHR and that the EHR Modules combined would have *each* been tested and certified in accordance with the certification criteria applicable to each EHR Module.

In response to commenters, we have decided to revise the definition of Certified EHR Technology to state explicitly the two distinct ways the definition can be met. The revised definition will read as follows. *Certified EHR Technology* means:

(1) A Complete EHR that meets the requirements included in the definition of a Qualified EHR and has been tested and certified in accordance with the certification program established by the National Coordinator as having met all applicable certification criteria adopted by the Secretary; or

(2) A combination of EHR Modules in which each constituent EHR Module of the combination has been tested and certified in accordance with the certification program established by the National Coordinator as having met all applicable certification criteria adopted by the Secretary, and the resultant combination also meets the requirements included in the definition of a Qualified EHR.

As discussed in the Temporary Certification Program final rule, a pre-coordinated integrated bundle of EHR Modules would fall under the second definition of Certified EHR Technology, although each EHR Module of the bundle would be tested and certified at the same time rather than separately. Therefore, provided that a proper combination of EHR Modules has been created, combinations of EHR Modules could be tested and certified either at the same time or at separate times, to meet the definition of Certified EHR Technology.

Finally, we believe that commenter suggestions to revise the definition of Certified EHR Technology to reference specific certification criteria are misguided. The definition, regardless of the certification criteria that must be included in a Complete EHR or combination of EHR Modules, must be able to accommodate changes in certification criteria over time. Accordingly we believe that the final definition meets this intended goal and conveys a clear meaning.

Comments. Some commenters appeared to interpret our definition as providing that EHR Modules must be used to meet the definition of Certified EHR Technology. Of these commenters, some requested that we clarify whether health care providers would be required to obtain certification of EHR Modules that no vendors support. Other commenters asked whether non-certified "EHR modules" could be used in combination with a Complete EHR or in combination with EHR Modules that are used to meet the definition of Certified EHR Technology.

Response. We would like to make clear that eligible professionals and eligible hospitals are *not* required to use EHR Modules in order to meet the definition of Certified EHR Technology. The use of EHR Modules is completely voluntary and provides an alternate avenue for eligible professionals and eligible hospitals who seek to implement more customized HIT solutions while still meeting the definition of Certified EHR Technology. Commenters who expressed concerns about their responsibility for seeking certification for EHR Modules for which no vendor supports did not provide specific examples, and we are uncertain as to the basis for their concerns. Regardless, we reiterate that the use of EHR Modules is voluntary and we believe that most eligible professionals and eligible hospitals that are adopting HIT for the first time will have a variety of Complete EHRs available from which to choose.

We also clarify that only those EHR Modules that provide capabilities necessary to meet the definition of Certified EHR Technology will need to be tested and certified. That being said, eligible professionals and eligible hospitals are free to utilize any other type of HIT to complement or in combination with Certified EHR Technology, including HIT that provides capabilities for other purposes not related to meaningful use.

Comments. Some commenters suggested that our definition was too broad. Most of these commenters argued that we should permit eligible professionals to adopt only Complete EHRs and EHR Modules that were certified as including only those capabilities applicable to their specialty or practice. In other words, these commenters sought for the definition of Certified EHR Technology to be interpreted in such a way as to permit different specialty-oriented variations of Certified EHR Technology to exist.

Response. At the present time, we believe that the definition of Certified EHR Technology already includes some of the flexibility these commenters request. We permit, for example, a Complete EHR designed for an ambulatory setting and a Complete EHR designed for an inpatient setting both to meet the definition of Certified EHR Technology, even though each is compliant with a slightly different set of applicable certification criteria. In that regard, we believe we have integrated a balanced and appropriate amount of flexibility into the definition of Certified EHR Technology, which will also allow us to make additional refinements over time. We believe that it is possible based on industry need for us to specify in a future rulemaking sets of applicable certification criteria for Complete EHRs and EHR Modules designed for particular clinical settings.

9. Definition of Human Readable Format

Comments. A number of commenters across several certification criteria requested that we clarify the meaning of "human readable format." These commenters questioned what human readable format meant when it was used in the certification criteria and offered examples of what they thought would constitute human readable format such as, style sheets and PDFs. A couple of commenters suggested that human readable format should consider patients' linguistic needs. A commenter requested we discuss the compliance requirements associated with the Americans with Disabilities Act and the relevant sections of the Rehabilitation Act of 1973 to ensure human readable format was meant to include an obligation to provide people with disabilities alternative formats such as large print or Braille.

Response. In the Interim Final Rule, we discussed the meaning of human readable format and provided examples of what we believe would constitute human readable format. We reiterate that discussion below.

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 * * * 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).

The term human readable format is used in two contexts, when coded health information should be displayed to an eligible professional or (to a health care professional within) an eligible hospital using Certified EHR Technology and in the circumstances where Certified EHR Technology must be capable of generating an electronic copy of health information for individuals. Each context may dictate a different human readable format. For example, the use of a style sheet may be appropriate for both health care professionals that are interacting with Certified EHR Technology as well as individuals who receive an electronic copy of their health information to access at a later time. In other circumstances it may be more appropriate for a health care professional to view health information in human readable format on their handheld device while an individual may seek an electronic document, such as a PDF. Given the requests for additional clarity regarding the meaning of human readable format, we have decided to define the term in this final rule as follows: Human readable format means a format that enables a human to read and easily comprehend the information presented to him or her regardless of the method of presentation (*e.g.,* computer screen, handheld device, electronic document).

We noted in the Interim Final Rule that the standards, implementation specifications, and certification criteria adopted by the Secretary applied to Complete EHRs and EHR Modules, not to persons or entities. We also stated that nothing required by the Interim Final Rule should be construed as affecting existing legal requirements under other Federal laws. Accordingly, this final rule does not affect an eligible professional or eligible hospital's requirements to comply with other Federal laws in the event health information is provided in human readable format and persons with disabilities require reasonable accommodations.

10. Definition of User

Comments. A number of commenters commenting on several certification criteria requested that we clarify the meaning of the term "user."

Response. We recognize that the term user is referenced in the certification criteria and at times could be interpreted differently. We believe this flexibility is necessary because a user may be different depending on the certification criterion and the context within which the capability it specifies is used. Accordingly, we believe a user could be a health care professional or office staff, someone who might interact directly with Certified EHR Technology or that it could also be software program or service.

D. Final Rule Amendments to Adopted Standards, Implementation Specifications, and Certification Criteria §§ 170.202, 170.205, 170.207, 170.210, 170.302, 170.304, 170.306

1. Flexibility and Innovation

Comments. Many commenters requested that we provide more flexibility in the final rule to accommodate new developments in HIT. These commenters agreed with our approach to identify minimum standards for certain code sets and they recommended a similar approach for other standards. Some commenters suggested alternative approaches to adopting standards, such as adopting standards at a higher level of abstraction (*e.g.,* HL7 2.x, where "x" could be any version within the version 2 family) and accompanying the adopted standards with detailed implementation specifications or guidance outside of the rulemaking process.

Response. We appreciate commenters' support for the "minimum standard" approach that we established in the Interim Final Rule. We believe that code sets are an appropriate type of standard to set as a "minimum." In the Temporary Certification Program final rule, we discuss the approaches available to the Secretary to identify and accept newer versions of adopted minimum code set standards. Below, we discuss how we have added flexibility into this final rule and how we can add flexibility in future rulemakings.

In many cases, however, our flexibility may be limited due to legal requirements to adopt substantive requirements through following the procedures of the Administrative Procedure Act (APA). Depending upon the circumstances and subject matter, we may not be able to alter the substantive standards that apply to Certified EHR Technology solely through guidance. In addition, a real and practical need to ensure consistency among various standards regulations constrains the amount of flexibility we can incorporate into the standards we adopt.

In addition, in accordance with Office of the Federal Register regulations related to "incorporation by reference," which we follow for this final rule, the publications we reference are "limited to the edition of the publication that is approved" and do not include "[f]uture amendments or revisions of the publication." Consequently, we do not include regulatory language that refers, for instance, to "Version 1.X" when "X" remains a variable.

We do believe, however, that additional flexibility can be added into this and future rulemakings through at least one of four currently identified means:

- *Alternative Standards.* In the Interim Final Rule and in this final rule, we have adopted "alternative" standards (and applicable implementation specifications) for several certification criteria. As a general rule, when an adopted certification criterion refers to two or more standards as alternatives, use of at least one of the alternative standards will be considered compliant with the certification criterion. For the certification criterion at § 170.302(k)(1), for instance, we have adopted HL7 2.3.1

and HL7 2.5.1 as alternatives, and the use of either standard (and the applicable implementation specifications) would be sufficient to comply with the certification criterion. In each of these instances, we have tried to balance the need for flexibility with the goal of advancing interoperability, while also taking into account that the HIT industry has not yet migrated to a single specific standard for certain purposes. In some cases, this balancing has required the adoption of certification criteria that requires certain EHR technology to be capable of receiving electronic health information formatted according to a standard that it is not natively capable of generating. For example, with respect to patient summary records, we have adopted the Continuity of Care Document and Continuity of Care Record standards as alternatives. As a condition of certification, section 170.304(i)(1) provides as an additional requirement that upon receipt of a patient summary record formatted in the alternative standard, the EHR technology must be capable of displaying the patient summary record in human readable format. We believe this final rule correctly balances at this stage of EHR adoption our goal of promoting interoperability with the HIT industry's ability to comply with the certification criteria and its need for flexibility. Consistent with our long-term goals for interoperability, we anticipate that this balance will need to change as the HIT industry migrates to single specific standards for particular purposes.

• *Minimum Code Set Standards.* As previously discussed in the Interim Final Rule, we adopted several minimum code set standards. It is important to note that these code set standards set the floor, not the ceiling, for testing and certification. If, and when, the Secretary accepts a newer version of an adopted minimum standard code set, the Secretary will, in effect, raise the ceiling for what is permitted for testing and certification as well as whether Certified EHR Technology can be upgraded to that newer version without adversely affecting the Certified EHR Technology's certified status. For context purposes we repeat a portion of the Interim Final Rule's preamble that discussed our approach to minimum code set standards.

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.

We would note that consistent with this approach the Secretary has proactively identified and deemed acceptable newer versions of the following adopted "minimum standard" code sets:

(1) LOINC version 2.3, released on February 26, 2010; and

(2) CVX—Vaccines Administered, March 17, 2010.

We are consequently using this opportunity to inform Complete EHR and EHR Module developers, prospective ONC-Authorized Testing and Certification Bodies, and the rest of the public of the Secretary's recognition of these newer versions of certain adopted "minimum standard" code sets. We reiterate that use of these newer versions is voluntary. We also note in accordance with 45 CFR 170.455(b)(2) that Certified EHR Technology may be upgraded to comply with these newer versions at any time without adversely affecting the certification status of the Certified EHR Technology.

• *Optional Standards, Implementation Specifications, and Certification Criteria.* We believe that additional flexibility and specificity can be introduced into this and future cycles of rulemaking through the adoption and designation of "optional" standards, implementation specifications, and certification criteria. Optional standards, implementation specifications, and certification criteria would be *voluntary* and would *not be required* for testing and certifying a Complete EHR or EHR Module. We believe that optional standards, implementation specifications, and certification criteria will also help better prepare the HIT industry for future mandatory certification requirements.

• *Standards and Backwards Compatibility.* In previous rulemakings, specifically the Secretary's adoption of electronic prescribing (e-prescribing) standards (70 FR 67579) related to the Medicare Part D prescription drug program, HHS discussed a process to improve flexibility in regulatory requirements which involves "backwards compatibility." HHS described backwards compatibility as meaning that a newer version of a standard retains at a minimum the full functionality of the version previously adopted in regulation, and that the newer version would permit the successful completion of the applicable transaction(s) with entities that continue to use the older version(s). HHS discussed that if a newer version of a standard were backward compatible with an adopted standard, it would be possible to pursue a more expedited approach to permit the utilization of the newer version while still remaining in compliance with the law. We believe that the approach established in the e-prescribing rulemaking could be leveraged in many situations for the standards and implementation specifications adopted for HIT certification. However, we note that this approach can only be implemented when a newer version of a standard is technically capable of fully functioning with the adopted version of the standard to conduct the specified transaction.

Much like minimum code set standards, we could foresee possibly adopting a backward compatible version of a previously adopted standard and allowing entities to voluntarily use the newer version for a period of time. In such cases, much like a minimum code set standard, Complete EHR and EHR Module developers would be permitted to have their Complete EHR or EHR Module certified according to the adopted backward compatible version, and eligible professionals and eligible hospitals in possession of Certified EHR Technology would be permitted to upgrade voluntarily their Certified EHR Technology to include the adopted backwards compatible version. Given that we anticipate adopting new or modified standards, implementation specifications, and certification criteria every two years in sync with the initiation of a new meaningful use stage, we believe that the Secretary's adoption of backward compatible versions of standards would generally be limited to intermediate years (*i.e.,* 2012 and 2014). To accomplish the adoption of a backwards compatible version, we would take an approach very similar to the approach described in the final e-prescribing regulation.

We would first review whether the new version of an adopted standard retains at a minimum the full functionality of the adopted version of the standard as well as whether it enables the successful completion of the applicable transaction(s) with entities that continue to use the older version(s). We would then review whether a standard should be updated with a new version and whether use of either the new version or the older version would be considered compliant as well as whether use of the new version would conflict with any already existing regulatory requirements. If we believe that the Secretary's adoption of a newer version of a standard on a voluntary

basis would be appropriate, we would then seek the advice of the HIT Standards Committee to evaluate the newer version of the standard and to solicit relevant public input. The Secretary would then recognize or adopt for voluntary use the new version of the standard in a **Federal Register** publication. At that point, use of either the new or old version would be considered compliant. Entities that would voluntarily adopt the later backward compatible version of the standard would remain obligated to accommodate the earlier adopted version without modification. Prior to the Department formally retiring the older version of the standard and mandating the use of the later version, the Department would engage in notice and comment rulemaking.

2. Transport Standards

Comments. Generally, commenters echoed one of two responses: Some urged for the complete removal of SOAP and REST and others requested that we provide detailed implementation specifications for SOAP and REST along with the identification of the transactions to which SOAP and REST were applicable. Some commenters also stated that neither standard was sufficiently specified in order to ensure interoperability, while others pointed out that it appeared that we had globally applied the usage of SOAP or REST to all adopted standards, which, if true, would cause conflicts with several adopted standards (*e.g.,* it was noted that the HL7 standards we adopted utilize Minimum Lower Layer Protocol (MLLP) as the transport standard and not SOAP or REST).

Response. We have considered the public comments received on this matter and we are convinced that it is prudent to remove the adopted standards, SOAP and REST. We did not intend for the significant potential conflicts identified by commenters to occur as a result of our adoption of SOAP and REST. We have determined that it would be more appropriate and reasonable for us not to require at the present time specific transport standards as a condition of certification. We hope that this will reduce some of the burden on Complete EHR and EHR Module developers and provide greater opportunities for innovation. With that said, we plan to carefully watch the impact of this decision and its affect on interoperability. We encourage Complete EHR and EHR Module developers to utilize transport standards that will help the industry coalesce around common methods for electronic health information exchange, and we plan to examine this decision in future rulemakings.

3. Certification Criteria and Associated Standards and Implementation Specifications

We have organized our discussion of the final certification criteria according to the order in which they are currently specified at 45 CFR 170 subpart C. We note that the final regulatory citations will have changed for many certification criteria and encourage the public to review, in full, the final regulatory text specified in subpart C of part 170 in the regulation text of this final rule. We begin with the certification criteria at 45 CFR 170.302 (general certification criteria for Complete EHRs and EHR Modules), move on to 45 CFR 170.304 (specific certification criteria for Complete EHRs and EHR Modules designed for an ambulatory setting) and end with 45 CFR 170.306 (specific certification criteria for Complete EHRs or EHR Modules designed for an inpatient setting). We also include, where appropriate, a discussion of the adopted standard(s) and implementation specifications associated with each certification criterion. For each final certification criterion, we start with an overview of the final version and then discuss and respond to public comments.

a. General Certification for Complete EHRs or EHR Modules—§ 170.302

Section 170.302(a)—Drug-Drug, Drug-Allergy, Drug-Formulary Checks

Meaningful use Stage 1 objective	Meaningful use Stage 1 measure	Certification criterion
Implement drug-drug and drug-allergy interaction checks.	The EP/eligible hospital/CAH has enabled this functionality for the entire EHR reporting period.	Interim Final Rule Text: (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). (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. Final Rule Text: § 170.302(a). (1) *Notifications.* Automatically and electronically generate and indicate in real-time, notifications at the point of care for drug-drug and drug-allergy contraindications based on medication list, medication allergy list, and computerized provider order entry (CPOE). (2) *Adjustments.* Provide certain users with the ability to adjust notifications provided for drug-drug and drug-allergy interaction checks.

Meaningful use Stage 1 objective	Meaningful use Stage 1 measure	Certification criterion
Implement drug-formulary checks ...	The EP/eligible hospital/CAH has enabled this functionality and has access to at least one internal or external drug formulary for the entire EHR reporting period.	Interim Final Rule Text: (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). Final Rule Text: § 170.302(b). *Drug-formulary checks.* Enable a user to electronically check if drugs are in a formulary or preferred drug list.

Comments. Based on the example given in the preamble of the Interim Final Rule, several commenters believed that we required real-time alerts to utilize a pop-up message or sound. Commenters stated that the method of delivering real-time alerts should not be included in the regulation as it would restrain innovation. One commenter expressed concern that the requirements of this certification criterion were overly specific with respect to how the Certified EHR Technology needed to perform the tasks rather than focusing on the desired result. The commenter recommended the certification criterion be modified to ensure that such alerts are clearly visible to the physicians at the point-of-care. Some commenters recommended that the term "notification" should replace the term "alert" for this and other certification criterion because the term alert implied a particular implementation whereas notification was more neutral.

Response. Unfortunately, many of the commenters who reacted to our example also believed that it was a requirement. We simply added the example of a pop-up message or sound in the preamble of the Interim Final Rule to make the requirement clear. The use of a pop-up message or sound was not a specified requirement in the regulation text. We agree with the commenters who explained that there may be better ways to provide alerts. For the purposes of testing and certification, we leave it entirely up to Complete EHR and EHR Module developers to innovate in this area and provide capabilities that are both easy to use and prevent medical errors. Additionally, we agree with the commenters who suggested that we replace "alert" with "notification," and we have made that change globally across all certification criteria that used the term alert.

Comments. A few commenters requested clarification of the requirement to track and report on the number of alerts responded to by a user. A commenter requested clarification on why the number of alerts is captured but not what the user did with the alert and if this data is going to be used to rate providers based upon the number of alerts they received. Two commenters requested that "responded to by a user" be clarified and asked whether it meant that a user had taken a different action as a result of the alert. One commenter recommended removing the alert requirement unless it is more clearly specified. One commenter recommended deleting the requirement on alert statistics because it could lead to alert fatigue. A few commenters expressed concern about the ability to deactivate, modify, and add rules for drug-drug and drug-allergy checking. These commenters recommended that this capability be removed because of the risk to patient safety. A commenter noted that treating physicians should have the ability to ignore alerts in light of other clinical facts about the patient and felt that providing the ability to delete or modify alerts in a way that would be inconsistent with current medical standards would be irresponsible and contrary to the meaningful use goal of preserving the health and safety of patients. Other commenters requested clarification as to whether the ability to "deactivate" rules implied the ability to remove specific rules or drug pairs as they exist in commercially-available clinical decision support (CDS) databases; the ability to "modify" rules implied that an administrator would be able to change the rules as they exist in these commercially-available CDS databases; and the ability to "add" new rules implied that the administrator could create new rules in commercially-available CDS databases. The commenters interpreted "modify" to mean, for example, the ability to override or change severity setting; and "add" to mean activating a category of CDS, such as drug-drug interactions, but not individual rules; and "deactivate" as the ability to "turn off" specific types of rules. Another commenter requested clarification as to whether the requirement for customization would be met if a system administrator were to set the selected severity level to reflect the collective decision of a practice or if alerts must be tailored on an EP-by-EP basis. A commenter requested clarification on what qualifies as a "response" to an alert. One commenter recommended that the rule clarify that "responded to by a user" means in a way which meaningfully addresses the alerts. A couple of commenters stated that centrally hosted services would have problems complying with the customization requirements because the hosting vendor takes responsibility for the administration, maintenance and updating of the clinical decision support rules including alerts for drug interactions alerts, including drug-drug, drug-allergy and drug-problem. These commenters were concerned that allowing each of their clients to create local drug-interaction rules would slow their ability to provide important updates to their client base, since this would require navigation of a complex hierarchy of preferred local rules. These local rules would also introduce clinical risk if old local rules could create a conflict with a clinically appropriate global, updated rule.

Response. Based on the significant number of comments presenting diverse interpretations of these provisions, we determined that this certification criterion needed further clarification and have revised it accordingly. Our intention related to the alert statistics capability had been to mirror the clinical decision support capability. With respect to customization, we sought to provide users of Certified EHR Technology with a way to adjust the severity level for which alerts are presented. In response to public comment, and to clarify what we believe Certified EHR Technology must include as a condition of certification, we have removed the "alert statistics" part of the certification criterion altogether and revised the "customization" part of the certification criterion to more clearly specify this capability. Our revisions focus on Certified EHR Technology's capability to allow certain users (*e.g.,* those with administrator rights) with the ability to adjust notifications provided for drug-drug and drug-allergy checks (*e.g.,* set the level of severity for which notifications are presented).

Comment. A commenter stated that use of age as a required data element in this certification criterion is a problem

because drug databases handle age in non-standard ways. It was also stated that for geriatric patients weight is also considered along with age.

Response. We agree with this commenter. After considering this comment, particularly in light of the potentially divergent interpretations of this certification criterion we noted above, we have removed "age" from the certification criterion. It was never our intention, as could have been anticipated, to require that Certified EHR Technology be capable of performing checks that relate type or dosage of drugs to the patient's age, or "drug-age checks."

Comment. A commenter encouraged ONC to add adverse drug events to the certification criterion and to identify candidate standards for its inclusion to support meaningful use Stage 2.

Response. We appreciate the suggestion and believe that identifying adverse drug events is important. Because the final meaningful use Stage 1 requirements under the Medicare and Medicaid EHR incentive programs do not include such a requirement, though, we do not believe that it would be appropriate at the present time to add such a requirement as a condition of certification. This does not preclude Complete EHR or EHR Module developers from including such functionality.

Comment. A couple of commenters requested clarification on what CPOE means in the certification criterion. A commenter requested that ONC clarify that this certification criterion applies only to the order-entry workflow and is not applicable to other office processes or workflows which might involve the same clinical data but which would not necessarily generate these alerts.

Response. We clarify for commenters that our inclusion of CPOE in the certification criterion is meant to indicate that notifications should occur based on new medication orders, in addition to a patient's current medications and medication allergies, as they are being entered. In response to the other commenter's request for clarification, we believe that notifications will occur during the order-entry workflow.

Comment. A commenter requested that the rule be clarified to explicitly require that drug-drug, drug-allergy, and drug formulary checks occur based on information and medication lists in an individual's complete medical record derived from all relevant providers, not only the drug list of the specific provider.

Response. We clarify that we expect Certified EHR Technology to perform drug-drug and drug-allergy checks based on medication list and medication allergy list information included within Certified EHR Technology as structured data. We recognize that Certified EHR Technology may also store health information in scanned documents, images, and other non-interoperable non-computable formats and, consequently, do not expect Certified EHR Technology to be capable of reading or accessing the information in these other formats for the purposes of performing drug-drug and drug-allergy checks.

Comment. A commenter requested that ONC clarify that EHR vendors will not be required to remove the option to disable drug-drug and drug-allergy checks.

Response. While we do not require that the option to disable drug-drug and drug-allergy checks be removed as a condition of certification, we note that in order for an eligible professional or eligible hospital to become a meaningful user of Certified EHR Technology this capability must be enabled.

Comments. Several commenters noted that the NCPDP Formulary and Benefits standard is not used in an inpatient setting. The commenters consequently requested clarification as to how the standard can be used in an inpatient setting. Some of the commenters noted that for inpatient settings, hospitals typically relied on their own formularies for performing the types of checks specified. Another commenter requested clarification whether the correct content exchange standard was National Council for Prescription Drug Programs (NCPDP) Formulary and Benefits Standard version 1.0 and that if it was, the commenter recommended its adoption. Another commenter noted that some State Medicaid formularies are not yet available via nationwide e-prescribing networks and recommended that ONC encourage the implementation of State Medicaid formularies within the NCPDP Formulary and Benefits Standard via a nationwide e-prescribing network.

Response. We agree with those commenters who identified the inconsistency of applying the Formulary and Benefits standard to the inpatient setting. Because the CMS proposed meaningful use objectives applied to both eligible professionals and eligible hospitals, we did not make the distinction as to when a Complete EHR or EHR Module would need to include the Formulary and Benefits standard. However, in light of these comments and to support the final meaningful use measure, we have determined that it would be appropriate to adopt a more general certification criterion that would be applicable to both Complete EHRs and EHR Modules designed for ambulatory and inpatient settings. Accordingly, we have removed any reference to a particular standard because an eligible professional or eligible hospital that does not have external access to a drug formulary would be able to satisfy this meaningful use measure by checking an internally managed drug formulary. Although the Formulary and Benefits standard is no longer required as a condition of certification, we note that eligible professionals who seek to comply with the electronic prescribing requirements associated with Medicare Part D eligible individuals will need to use this standard as they do today. Additionally, we do not agree that it is within the scope of this rulemaking to address State Medicaid Agencies' participation in nationwide e-prescribing networks.

Comments. Many commenters noted that the drug-formulary requirement should not apply to Complete EHRs and EHR Modules designed for an inpatient setting because there was no proposed requirement for meaningful use Stage 1 for eligible hospitals to electronically prescribe. Many of the commenters recommended removing this as a requirement for eligible hospitals while retaining it with the criteria for eligible professionals. A few commenters specifically recommended adding it to the criterion for electronic prescribing. Several commenters recommended that if the requirement were kept for hospitals it should be written as a separate criterion to address the query of a hospital's drug formulary during the order entry process and not the NCPDP Formulary and Benefits standard. A commenter stated that current industry practice among vendors of EHR technology is to provide a "generic" national formulary rather than the formulary for a particular plan. The commenter recommended that the functionality require that a user actually perform an eligibility check before access is provided and, in response to that check, the functionality show the correct formulary and benefits information, rather than just generic data.

Response. We believe that our discussion above regarding the removal of the standard associated with this certification criterion addresses many of the concerns raised by commenters. However, we disagree with the suggestion that Complete EHRs and EHR Modules designed for an inpatient setting should not be required to include this capability. This capability is required to be enabled for the

purposes of meeting the meaningful use Stage 1 measure. Consistent with the final meaningful use Stage 1 objectives which separated drug-drug and drug-allergy checks from drug-formulary checks, we have separated out these capabilities into two different certification criteria.

Comments. A commenter stated a concern that this criterion, combined with future meaningful use requirements, will shift providers' focus from prescribing the best drug for the patient to prescribing what is covered by the patient's insurance plan or generic brands. Another commenter stated that adding formulary checks to the workload of physicians will decrease physicians' efficiency and increase their costs.

Response. In this rule, the Secretary is completing the adoption of the initial set of standards, implementation specifications, and certification criteria for the certification of Complete EHRs and EHR modules. The certification criteria ensure that Certified EHR Technology includes certain capabilities. The extent to which health care providers must use those capabilities and how they integrate EHR technology into their practice falls outside the scope of this rule. We therefore do not believe that these concerns are within the scope of this rulemaking.

Comment. A commenter recommended that "drug-test checks" should be added. The commenter stated that many drugs require some form of laboratory testing to ensure that drugs are prescribed appropriately. The commenter stated, for example, that an anticoagulant medication should not be prescribed unless there is a test result on record that shows that giving this drug would not cause harm.

Response. Presently, drug-test checking is not a required capability for eligible professionals and eligible hospitals to use in order to successfully meet the requirements of meaningful use Stage 1. Accordingly, we do not believe that it would be appropriate to require Certified EHR Technology to be capable of performing drug-test checks as a condition of certification at the present time.

Section 170.302(b)—Maintain Up-To-Date Problem List

Meaningful use stage 1 objective	Meaningful use stage 1 measure	Certification criterion
Maintain an up-to-date problem list of current and active diagnoses.	More than 80% of all unique patients seen by the EP or admitted to the eligible hospital's or CAH's inpatient or emergency department (POS 21 or 23) have at least one entry or an indication that no problems are known for the patient recorded as structured data.	Interim Final Rule Text: *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). Final Rule Text: § 170.302(c). Final rule text remains the same as Interim Final Rule text, except for references to adopted standards, which have been changed.

Comments. Several commenters expressed concerns about the use of ICD–9–CM because it is primarily used for billing and administrative purposes and may not accurately represent the true clinical meaning of a problem or condition when it is documented at the point of care. One commenter stated a concern that the problem list standards do not allow for capturing of free text that health care providers use when an appropriate code is in neither SNOMED–CT® nor ICD–9–CM.

Response. The comments are correct in that ICD–9–CM is primarily used for billing and administrative purposes. SNOMED–CT® is offered as an alternative standard that will support more clinical descriptions of patient problems or conditions. We believe that with the adoption of both SNOMED–CT® and ICD–9–CM, healthcare providers should have adequate coverage for patient diagnoses and conditions. We are discouraging the use of free text for documenting problem lists since this will limit the usefulness of problem lists for clinical reminders, decision support and other patient safety and quality reporting.

Comments. Several commenters recommended that only SNOMED–CT® be adopted, or alternatively, that we expressly indicate an intention to move away from ICD–9CM and ICD–10 in the future. Another commenter recommended against the adoption of SNOMED–CT® because the commenter felt that our adoption of SNOMED–CT® would require eligible professionals and eligible hospitals to use both ICD–9–CM and SNOMED–CT®. One commenter recommended that a publicly vetted and HHS approved standard mapping between ICD–9–CM and SNOMED CT® should be made available at the public's expense.

Response. We agree conceptually that a single standard for clinical information would be desirable in the long term. However, presently both ICD–9–CM and SNOMED–CT® are used by EHR technology to code clinical information, and adopting both would provide users with additional flexibility. Moreover, we anticipate that as meaningful use objectives and measures evolve over time, we will receive additional public input and experience related to these standards and may eventually be able to adopt only one standard.

Comments. A few commenters asked for clarification as to whether SNOMED–CT® or ICD–9CM codes needed to be included within Certified EHR Technology or if these standards were only necessary when electronic health information is exchanged. Some of these commenters also requested that we permit any coding system to be used as long as it can be mapped to the appropriate format when electronic health information is to be exchanged.

Response. As previously discussed, meaningful use requirements will typically specify whether an adopted standard will have to be used among components of a business organization or solely for the electronic exchange of health information with other legal entities. The measure for this final meaningful use objective provides that entries be recorded as structured data. The certification criterion specifies that ICD–9CM or SNOMED–CT® are the code sets which must be included in Certified EHR Technology, and are therefore the code sets that would be used to record entries as structured data.

Comments. A few commenters recommended the removal of "longitudinal care" in the certification criterion. These commenters cited our clarification in the preamble that by longitudinal care we meant "over multiple office visits." These commenters questioned how this language would be applicable to an inpatient setting since patients are typically treated for acute episodes and not over multiple office visits.

Response. The reference to longitudinal care is intended to convey that the problem list must be comprehensive in the sense that it must be capable of including entries provided over an extended period of time. Consequently, for Complete EHRs and EHR Modules to be certified for an ambulatory setting, they will need to be designed to enable the user to electronically record, modify, and retrieve a patient's problem list over multiple encounters. For an inpatient setting, they will need to enable the user to electronically record, modify, and retrieve a patient's problem list for the duration of an entire hospitalization. This clarification was also requested in relation to the medication list and medication allergy list certification criteria and we have not repeated our response. As a result, we have retained "longitudinal care" in each certification criterion where the term is referenced and only make this clarification once.

Comment. A commenter suggested that we include a reasonable expectation of what constitutes "up-to-date" in the reference to "up-to-date" problem list.

Response. We referred this comment to CMS, and it is addressed in the final rule on the Medicare and Medicaid EHR Incentive Programs.

Section 170.302(c)—Maintain Active Medication List

Meaningful use Stage 1 objective	Meaningful use Stage 1 measure	Certification criterion
Maintain active medication list	More than 80% of all unique patients seen by the EP or admitted to the eligible hospital's or CAH's inpatient or emergency department (POS 21 or 23) have at least one entry (or an indication that the patient is not currently prescribed any medication) recorded as structured data.	Interim Final Rule Text: *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). Final Rule Text: § 170.302(d). *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.

Comments. A few commenters agreed with the certification criterion. One commenter requested that we provide more clarity on the use of term "retrieve." The commenter questioned whether we intended to use the word "retrieve" in the certification criterion to mean solely the retrieval of information available to Certified EHR Technology or if we intended for it to also include the interactive retrieval of medication list information from external sources. The commenter suggested we clarify that "retrieve" meant retrieval of only information internally available to Certified EHR Technology. Other commenters, similar to their comments on the problem list certification criterion, stated that there needed to be more clarity with respect to how the reference to "longitudinal care" applied to a Complete EHR or EHR Module used by an eligible hospital.

Response. We clarify that for this certification criterion, and all other certification criteria, the term "retrieve" means the retrieval of information directly stored and managed by Certified EHR Technology and that it does not mean the retrieval of information from external sources, unless explicitly stated otherwise. We also take this opportunity, in the context of our response regarding "longitudinal care" above, to clarify that "medication history" is intended to include a record of prior modifications to a patient's medications.

Comment. A commenter stated that there needs to be more clarity with respect to whether an EHR Module must maintain a list of all active medications or if a specialty system, such as a cardiology system, could maintain a list of medications specific to its specialty use and provide the list to the enterprise EHR.

Response. If an EHR Module developer seeks to have its "medication list EHR Module" certified, the EHR Module must provide the capabilities specified by the certification criterion. We do not intend to limit how the EHR Module could appropriately provide these capabilities (*i.e.,* whether the EHR Module must itself enable the user to electronically record, modify, and retrieve a patient's active medication list for longitudinal care, or whether the EHR Module could be designed to provide those capabilities through its interaction with a device or devices at the enterprise level).

Comment. One comment stated that this criterion should include a provision to include the ability to transmit this information to public health entities as required by law.

Response. Nothing we adopt in this final rule precludes such a capability from being included in a Complete EHR or EHR Module. That is not, however, currently a necessary requirement for certification.

Comments. One commenter stated that it would need to perform extensive reprogramming to accommodate the standard we adopted if it meant modifying underlying medication databases. This commenter suggested that this standard as it applied to the maintenance of medication lists be deferred. Along those lines, a couple of commenters stated that more clarification was needed with respect to whether RxNorm identifiers needed to be stored internally within Certified EHR Technology or only needed to be used upon the electronic exchange of health information. Other commenters expressly stated that the mapping of the vocabulary be limited to instances where the electronic exchange of health information would take place.

Response. We understand these commenters' concerns and agree that it would be premature to require the use of the adopted standard in this context. In that regard, we seek to clarify for commenters our intention, which was solely to associate this adopted standard (as some commenters suggested) with the certification criteria that require the capability to electronically exchange health information. We recognize that continuing to associate this standard with the adopted certification criterion could potentially impose a significant burden on the industry, which we did not intend. Accordingly, we have removed from this certification criterion the requirement to use this standard. We discuss our response to comments on the standard itself in the context of the patient summary record certification criterion.

Section 170.302(d)—Maintain Active Medication Allergy List

Meaningful use Stage 1 objective	Meaningful use Stage 1 measure	Certification criterion
Maintain active medication allergy list.	More than 80% of all unique patients seen by the EP or admitted to the eligible hospital's or CAH's inpatient or emergency department (POS 21 or 23) have at least one entry (or an indication that the patient has no known medication allergies) recorded as structured data.	Interim Final Rule Text: *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. Final Rule Text: Unchanged Now § 170.302(e).

Comments. Much like the prior certification criterion, many commenters signaled their support for this certification criterion. Other commenters raised the same points related to this certification criterion as they did for the medication list certification criterion.

Response. We believe our responses to the problem list and medication list certification criteria are applicable to these repeated comments.

Comments. Many commenters suggested that non-medication allergies be added to this certification criterion. A few commenters stated that it could jeopardize patient safety if not all allergens were included in Certified EHR Technology.

Response. Patient safety is one of HHS's top priorities. At the present time, the final meaningful use objective and measure focus on medication allergies. Accordingly, we have adopted a certification criterion to support this objective and measure. We would like to reiterate, however, that a certification criterion sets the floor not the ceiling for the capabilities Certified EHR Technology must include. We encourage Complete EHR and EHR Module developers to provide more comprehensive capabilities than those currently required for achieving certification.

Section 170.302(e)—Record and Chart Vital Signs

Meaningful use Stage 1 objective	Meaningful use Stage 1 measure	Certification criterion
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 more than 50% of all unique patients age 2 and over seen by the EP or admitted to eligible hospital's or CAH's inpatient or emergency department (POS 21 or 23), height, weight and blood pressure are recorded as structured data.	Interim Final Rule Text: (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. Final Rule Text: § 170.302(f). (1) *Vital signs.* Enable a user to electronically record, modify, and retrieve a patient's vital signs including, at a minimum, height, weight, and blood pressure. (2) Unchanged (3) Unchanged

Comment. One commenter noted that the units of measurement should be specified in the EHR with regards to vital signs. For example that height should be specified in inches or centimeters.

Response. We do not believe that this level of specificity is necessary. We expect that Complete EHR and EHR Module developers will include the units of measure that their customers believe are necessary to meet their needs, which in many cases will include those that patients routinely request. We also expect that many Complete EHR and EHR Module developers will offer both metric units and U.S. units of measurement, as a standard business practice.

Comments. In what appeared to be a reaction to the proposed meaningful use objective and measure, some commenters requested that we remove BMI as part of the certification criterion for Complete EHR or EHR Modules designed for an inpatient setting. The rationale provided was that acute care providers would not be required to track BMI.

Response. While we can understand these commenters' concern, we believe that BMI is a simple mathematical calculation that Certified EHR Technology should be capable of performing regardless of the setting for which it is designed.

Comment. One commenter recommended that BMI and age components should be used to create an alert when an unhealthy BMI is indicated for a patient and that Certified EHR Technology should record whether the patient was informed of the unhealthy BMI status.

Response. We believe that this recommendation is overly specific, is more germane to meaningful use, and exceeds the type of capability we believe should be specified as a condition of certification.

Comments. A few commenters noted this certification criterion applies more directly to specialties that predominantly treat children. For other specialties, this criterion would add unnecessary cost and complexity to many HIT products that they would use. Many commenters suggested that a growth chart component should not be required for EHR technology designed for an inpatient setting, as it is not feasible to track this data in a meaningful way over a long enough period of time in an inpatient setting (which is typically of a short and

infrequent duration). A couple of commenters suggested that non-traditional forms of growth charts should be accepted. One commenter suggested that the certification criterion establish a baseline, but should not limit the expansion of this capability to other ages. Other commenters made specific suggestions for different age ranges, such as including children under the age of two and lowering the upper age to ages less than 20 years old (*e.g.,* 18).

Response. As we stated above with respect to the calculation of BMI, we believe that Certified EHR Technology should be capable of performing this capability regardless of the setting for which it is designed. Moreover, with respect to whether growth charts should be applicable to Complete EHRs and EHR Modules designed for an inpatient setting, we remind commenters that children's hospitals qualify as eligible hospitals under the Medicaid EHR incentive program and will also need to demonstrate meaningful use of Certified EHR Technology. We do not preclude Complete EHR and EHR Module developers from designing novel approaches to displaying growth charts. Finally, we concur with the commenter that suggested this certification criterion should be a baseline. We reiterate that this certification criterion establishes a floor, not a ceiling, and we encourage Complete EHR and EHR Module developers to include additional functionality where it will enhance the quality of care that eligible professionals and eligible hospitals can provide.

Comments. Similar to the comments above, many commenters suggested the growth chart requirement should include children under age 2. The charting would then include: weight, length, pulse oximetry, head circumference, and blood pressure (with percentiles based on age and weight).

Response. For Stage 1, the related meaningful use objective addresses ages 2–20. In order to remain consistent with and support this objective, we do not believe that it is necessary at this time to require a capability for charting any additional ages as a condition of certification.

Comment. One commenter requested that we clarify whether "plot and electronically display" means to plot height, weight, and BMI over time or against national norms.

Response. We clarify that we expect a growth chart to plot the height, weight, and BMI over time, as compared to national norms. While the regulation text does not specifically require comparison to national norms, we understand that this type of information is typically provided along with the growth chart itself to provide greater relevance and meaning for the growth charts. We encourage Complete EHR and EHR Module developers to include this feature.

Comment. A commenter suggested that SNOMED–CT® be used for designation of BMI.

Response. Although we agree that SNOMED–CT® could be used to code BMI, we only require that Certified EHR Technology be capable of calculating BMI. We do not believe that it is necessary, as a condition of certification, to specify how BMI should be coded. That being said, we do not preclude the use of SNOMED–CT® to code BMI.

Comment. One commenter suggested that the certification criterion should be better aligned with the final meaningful use objective and measure. The commenter noted that the criterion includes temperature and pulse, which is not included in the meaningful use objective and measure.

Response. We agree with the comment and have removed temperature and pulse from the certification criterion.

Section 170.302(f)—Smoking Status

Meaningful use Stage 1 objective	Meaningful use Stage 1 measure	Certification criterion
Record smoking status for patients 13 years old or older.	More than 50% of all unique patients 13 years old or older seen by the EP or admitted to the eligible hospital's or CAH's inpatient or emergency department (POS 21 or 23) have smoking status recorded as structured data.	Interim Final Rule Text: *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. Final Rule Text: § 170.302(g). *Smoking status.* Enable a user to electronically record, modify, and retrieve the smoking status of a patient. Smoking status types must include: current every day smoker; current some day smoker; former smoker; never smoker; smoker, current status unknown; and unknown if ever smoked.

Comments. Several commenters stated that the smoking status certification criterion was overly prescriptive because it specified certain status variables. These commenters agreed that recording smoking status is crucial to health improvement efforts, but contended that mandating certain fields was the wrong approach. Many of these commenters stated that they were unaware of defined industry standard value set for smoking terminology and other suggested that our reference to specific types of smokers be removed. Others asked whether these variables were examples or the only responses allowed. A few commenters agreed with this certification criterion as reasonable and appropriate because it would provide value for both clinical care and public health. Commenters recommended that besides what we had specified, the certification criterion should also reference packs per day history information, secondhand smoke exposure, and alcohol consumption information. Other commenters recommended that the certification criterion be changed to reflect tobacco use rather than smoking.

Response. We have adopted this certification criterion to fully support the final meaningful use objective and measure, which in response to comments has been revised to further clarify the purpose of the objective and measure. We therefore disagree with those commenters who stated that this certification criterion is too prescriptive. Concurring with CMS, we believe that the fields associated with this measure should mirror those expressed in the Centers for Disease Control and Prevention, National Center for Health Statistics, National Health Interview Survey related to smoking status recodes.[2] Accordingly, the final certification criterion further specifies and slightly broadens the smoking statuses we expect Certified EHR Technology to be capable of recording. Generally speaking, we understand that a "current every day smoker" or "current some day smoker" is an individual who has smoked at least 100 cigarettes during his/her lifetime and still

[2] Smoking status recodes: *http://www.cdc.gov/nchs/nhis/tobacco/tobacco_recodes.htm.*

regularly smokes everyday or periodically, yet consistently; a "former smoker" would be an individual who has smoked at least 100 cigarettes during his/her lifetime but does not currently smoke; and a "never smoker" would be an individual who has not smoked 100 or more cigarettes during his/her lifetime.[3] The other two statuses (smoker, current status unknown; and unknown if ever smoked) would be available if an individual's smoking status is ambiguous. The status "smoker, current status unknown" would apply to individuals who were known to have smoked at least 100 cigarettes in the past, but their whether they currently still smoke is unknown. The last status of "unknown if ever smoked" is self-explanatory.

Section 170.302(g)—Incorporate Laboratory Test Results

Meaningful use Stage 1 objective	Meaningful use Stage 1 measure	Certification criterion
Incorporate clinical lab-test results into certified EHR technology as structured data.	More than 40% of all clinical lab tests results ordered by the EP or by an authorized provider of the eligible hospital or CAH for patients admitted to its inpatient or emergency department (POS 21 or 23) during the EHR reporting period whose results are either in a positive/negative or numerical format are incorporated in certified EHR technology as structured data.	Interim Final Rule Text: (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. Final Rule Text: § 170.302(h). (1) Unchanged. (2) *Display test report information.* Electronically display all the information for a test report specified at 42 CFR 493.1291(c)(1) through (7). (3) *Incorporate results.* Electronically attribute, associate, or link a laboratory test result to a laboratory order or patient record.

Comments on 170.302(g)(1)

Comments. A few commenters suggested that we specify in the regulation that the reference to receiving clinical laboratory test results in a "structured format" means in HL7 version 2.3.1 format. These commenters further recommended that we refer to HL7 version 2.3.1 within the certification criterion. These commenters stated that many Complete EHR and EHR Module developers already use HL7 2.3.1 and that adopting it as a standard would spur industry-wide adoption and also set the stage for driving adoption of future HL7 standards, like HL7 2.5.1, in the later stages of meaningful use. A commenter in support of including HL7 2.3.1 stated that it was concerned that if we did not specify a standard for this requirement that there could be confusion regarding which version of the standard should be used, and that laboratories would have to continue to support multiple standards. Another commenter also noted that we did not specify a standard format for the laboratory results that Certified EHR Technology must be capable of receiving. This commenter, however, stated that many EHRs are compliant with HL7 2.5.1 for the purposes of receiving laboratory results. The commenter also recommended that we apply this certification criterion differently for ambulatory and inpatient settings by requiring that Complete EHRs and EHR Modules designed for an ambulatory setting be required to receive HL7 2.5.1 formatted laboratory test results and those designed for an inpatient setting be required to receive HL7 2.3.1 formatted laboratory test results. One commenter suggested that our objectives could be better supported if we stated that in this certification criterion a requirement that laboratory results must be received electronically using HL7 transactions with implementation guidance.

Response. While we understand the intent of these commenters' suggestions, we do not believe that it is within the scope of this rule to dictate the standard by which laboratories transmit test results. The scope of this rule is the adoption of certification criteria that specify required capabilities of Certified EHR Technology (in this case, receiving laboratory information in structured format) and not, in this instance, specifying the standard by which laboratories must transmit test results.

Comment. A commenter requested that we clarify how this certification criterion is applicable to hospital settings. The commenter asked whether we intended for the capability of receiving laboratory test results to include results obtained during a patient's stay at the hospital or if we meant to also include the receipt of laboratory test results from other time periods. They suggested requiring only those laboratory test results obtained during the patient stay.

Response. For the purposes of demonstrating compliance with this certification criterion, we do not specify the contexts (*e.g.,* a patient stay) under which laboratory test results are received. Rather, consistent with the meaningful use objective and measure and the capabilities required by this certification criterion, we specify that when laboratory test results are received in structured format by Certified EHR Technology, that the results can be incorporated.

Comment. One commenter requested that we clarify whether the structured data requirement applies to all laboratories (including reference labs, hospital labs, physician office labs, and physicians performing their own lab tests).

Response. This certification criterion requires Complete EHRs and EHR Modules to provide the capability to receive clinical laboratory test results in a structured format as a condition of certification. It does not speak to how laboratories must send the test results.

[3] *ftp://ftp.cdc.gov/pub/Health_Statistics/NCHS/datasets/DATA2010/Focusarea27/O2701a.pdf.*

Comments on 170.302(g)(2)

Comments. Some commenters requested clarification on this specific capability within the certification criterion regarding what needed to be displayed in the context of LOINC codes. These commenters suggested that we not require the display of the actual LOINC code, but the description associated with the LOINC code. A commenter suggested that we identify a subset of common LOINC codes instead of requiring that tens of thousands of LOINC codes be supported for the purposes of certification. Other commenters suggested that we offer guidance in the form of a "starter set" of LOINC codes to encourage the use of the standard. One commenter requested that we confirm its understanding of this specific part of the certification criterion, which is that Certified EHR Technology must demonstrate the capability to import LOINC coded results from an external source. Finally, one commenter noted that the heading for the standard at § 170.205(a)(2)(iii) should just refer to "laboratory test results" and not "laboratory orders and results."

Response. We clarify that we do not expect Certified EHR Technology to natively (or internally) support LOINC in its entirety, which is why we do not believe that it is necessary to specify a subset of common LOINC codes. Given the diverse comments and requests for clarification on this specific aspect of the certification criterion, we agree with commenters that we should not require a LOINC code that has been received, to then be displayed. Accordingly, we have decided to remove this requirement from the certification criterion. We do, however, wish to further clarify our current approach to Certified EHR Technology's use of LOINC codes. Presently, we expect Certified EHR Technology to be able to reuse a LOINC code once it has been received and is accessible to Certified EHR Technology. We do not expect, as we mention above, that Certified EHR Technology will have to crosswalk or map internal or local codes to LOINC codes. This clarification is applicable to the standard that we have adopted regarding LOINC codes now specified at § 170.207. This response is applicable to similar comments we received on other certification criteria that also referenced the use of LOINC codes. Finally, we agree with the commenter who suggested that we revise the heading of the standard at § 170.205(a)(2)(iii). We have done this as part of the overall restructuring of the regulation text.

Comments on 170.302(g)(3)

Comments. Some commenters agreed with the capability specified in 170.302(g)(3). One noted a concern that modifications to either a certified Complete EHR or certified EHR Module could potentially result in the failure of Certified EHR Technology to display the test report information as required by the regulations and, thereby, put the laboratory in technical violation of the CLIA regulations. These commenters reasoned that because a Complete EHR or EHR Module must be tested and certified to be in compliance with 42 CFR 493.1291(c)(1) through (7) that certification should replace any requirement for the laboratory to confirm that the information has been properly transmitted and meets the CLIA requirements. These commenters also asserted that a laboratory should be relieved of any further regulatory responsibility under 42 CFR 493.1291(c)(1) through (7) for the display of the required report information to the physician or subsequent viewers of the information if the Certified EHR Technology has been implemented by an eligible professional or eligible hospital. One commenter reiterated the point by stating that because Certified EHR Technology would be required to display the required CLIA report elements, laboratories should not be unfairly held accountable for any elements that may be removed or altered by other parties from the test report before received by the physician.

Response. While we can understand the concern expressed by these commenters, we reiterate that the scope of our authority under this final rule only applies to capabilities that Certified EHR Technology must include. As a result, we cannot provide the regulatory relief that these commenters seek.

Comments on 170.302(g)(4)

Comments. A couple of commenters questioned whether we intended for the "updates" to be manual updates of electronic records. If that were true, some commenters were concerned that would create workflow problems and reduce the availability of results. Other commenters suggested that either the user be able to create an additional record, rather than be permitted to change the "official" record or that an adequate audit trail be preserved of the existing data and any updates, since an update may result in disparities with the official record of test results. These commenters wanted to ensure that the laboratory's record would be the same as the record maintained in the EHR. One commenter stated that paragraph (g)(4) could imply process and system behavior that we did not intend to require. The commenter stated that it is common practice in a hospital setting for lab results to be transmitted in high volume from a lab system to an EHR and made available for review to the clinician through the EHR, without a need for a user to review each transaction before updating the EHR to make the results available. Another commenter made a similar point and questioned whether an "update" meant manual intervention, which they stated would be impracticable in a hospital setting. One commenter stated that most EHR technology already links orders to lab results in an established way. The commenter also indicated that the certification criterion we adopted requires changes to a process that most EHR developers have already implemented and introduces inefficiencies for both EHR developers and health care providers.

Response. We appreciate the issues raised by commenters on this specific capability and have revised this part of the certification criterion to more clearly express our expectation for Certified EHR Technology and to be responsive to and consistent with commenters' suggestions. We intended for an update to mean, as indicated by the meaningful use objective and measures, that a laboratory test result would be incorporated in Certified EHR Technology with the originating laboratory order or with a patient's record in any one of the methods specified. Accordingly we have revised this specific capability to more clearly reflect our intent. We believe this addresses commenters' concerns and requests for clarification and would permit batches of laboratory test results to be electronically linked to laboratory orders or patient records without manual intervention.

Comments. Some commenters noted that small and medium size practices have had a difficult time working with commercial laboratory vendors to provide interfaces from which they can receive lab test results. These commenters noted that laboratory vendors typically charge too much for their services and do not prioritize establishing connections with small and medium size practices because they do not have the same volume of laboratory referrals as large practices.

Response. This certification criterion requires as a condition of certification that Certified EHR Technology be capable of supporting electronic laboratory interfaces. We understand the

concerns raised by commenters pertaining to the difficulty of certain practices being able to obtain laboratory interfaces and note that the meaningful use Stage 1 measure associated with this certification criterion is included in the "menu set" specified by CMS which we believe should help assuage some commenters' concerns. We do not believe that the ability of a practice (regardless of size) to obtain an interface or other type of connection is an issue that is within the scope of this final rule to address.

Comment. One commenter recommended that we revise this certification criterion to require that laboratory domain expertise be exhibited when laboratory information is displayed. The commenter further elaborated by stating that laboratory results are not homogeneous, and that specific laboratory domain expertise is necessary to design the ways in which the data associated with certain laboratory results (*e.g.,* microbiology, molecular pathology) are displayed in EHR systems to ensure appropriate presentation and interpretation.

Response. With the exception of displaying the required elements specified at 42 CFR 493.1291(c)(1) through (7), we do not require as a condition of certification any additional display requirements. Accordingly, we do not preclude Complete EHR and EHR Module developers from designing more specific displays of laboratory results that may need to be displayed in a more complex fashion.

Comment. One commenter requested that we clarify that Certified EHR Technology did not need to enable the EHR Technology user to receive voluminous raw or pre-final-report lab data, and further, that not providing this capability would not disqualify a Complete EHR or EHR Module from becoming certified.

Response. Enabling a Complete EHR or EHR Module to receive "raw or pre-final-report lab data" is not required under this or any other adopted certification criterion.

Comment. One commenter suggested that we modify this certification criterion to require transmission of cancer related lab tests and results to cancer registries as required by law.

Response. Because this certification criterion is about incorporating lab test results in Complete EHRs and EHR Modules and does not require any electronic transmissions, we do not believe that this is an appropriate requirement to consider.

Section 170.302(h)—Generate Patient Lists

Meaningful use Stage 1 objective	Meaningful use Stage 1 measure	Certification criterion
Generate lists of patients by specific conditions to use for quality improvement, reduction of disparities, research or outreach.	Generate at least one report listing patients of the EP, eligible hospital or CAH with a specific condition.	Interim Final Rule Text: *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. Final Rule Text: § 170.302(i). *Generate patient lists.* Enable a user to electronically select, sort, retrieve, and generate lists of patients according to, at a minimum, the data elements included in: (1) Problem list; (2) Medication list; (3) Demographics; and (4) Laboratory test results.

Comments. Several commenters requested clarification regarding the set of variables that should be included in the demographic information for the patient lists. Some of these commenters suggested that the gender, race, ethnicity and preferred language of the patient should be included in this data set. One commenter suggested that the final rule should explicitly adopt and incorporate the recommendations of a report published by the Institute of Medicine in mid-2009 entitled, "Race, Ethnicity and Language Data: Standardization for Health Care Quality Improvement."

Response. We appreciate the commenters' suggestions, and we have used them to clarify this certification criterion. It was our intention that Certified EHR Technology would be able to leverage the information, specifically the structured data it has available to it, to assist eligible professionals and eligible hospitals to generate patient lists. We have clarified this certification criterion to express this intent. Accordingly, we expect that Certified EHR Technology will be able to generate patient lists according to certain data elements for which structured data will be available: Medical problems; medications; demographics; and laboratory test results. While we respect the work completed by the Institute of Medicine, we do not believe that the public has had an adequate opportunity to consider its recommendations related to demographics in the context of certification, and we are therefore not including them as a condition of certification at this time. We encourage the HIT Standards Committee to consider this report as it recommends standards to the National Coordinator.

Comments. Several commenters requested further clarification regarding the meaning of "patient's clinical information." Other commenters stated that this phrase was too vague and was not included as part of the proposed meaningful use objective or measure and should therefore be removed. Some commenters requested further definition of the term "specific conditions," particularly to clarify whether this term refers to problems and diagnoses. Clarification was also requested regarding whether this information includes: a patient summary; the patient's entire medical history; and patient encounter notes. One commenter recommended that we clarify how the lists must be structured and suggested that we specify time periods for patient histories. One commenter requested clarification of the term "output," and suggested that it should mean to produce a list for internal use and that it does not refer to exporting the patient list to a system or destination external to the office of an eligible professional.

Response. We appreciate the concerns raised by these commenters and after further consideration agree that the terms referenced by commenters could be interpreted in multiple ways. Accordingly we have removed "patient's clinical information" and "specific conditions" from the certification criterion, and have reframed the certification criterion to more directly

align with the meaningful use measure by changing "output" to "generate." We sought to clarify that we intended that Certified EHR technology would be capable of electronically producing or "generating" patient lists for an eligible professional or eligible hospital's subsequent use. We do not require as a condition of certification that time periods be associated with a patient list, but presumably time (*i.e.,* the age of the information) could be one factor an eligible professional or eligible hospital could also use to sort their lists (*e.g.,* patients with XYZ problem recorded in the past 3 months). We believe that these revisions make this certification criterion clearer while addressing these commenters' concerns.

Section 170.302(i)—Report Quality Measures

Meaningful use Stage 1 objective	Meaningful use Stage 1 measure	Certification criterion
Eligible Professionals: Report ambulatory clinical quality measures to CMS or the States.	For 2011, provide aggregate numerator, denominator, and exclusions through attestation as discussed in section II(A)(3) of [the Medicare and Medicaid EHR Incentive Programs final rule].	Interim Final Rule Text: (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).
Eligible Hospitals and CAHs: Report hospital clinical quality measures to CMS or the States.	For 2012, electronically submit the clinical quality measures as discussed in section II(A)(3) of [the Medicare and Medicaid EHR Incentive Programs final rule].	Final Rule Text: § 170.304(j). (1) *Calculate.* (i) Electronically calculate all of the core clinical measures specified by CMS for eligible professionals. (ii) Electronically calculate, at a minimum, three clinical quality measures specified by CMS for eligible professionals, in addition to those clinical quality measures specified in paragraph (1)(i). (2) *Submission.* Enable a user to electronically submit calculated clinical quality measures in accordance with the standard and implementation specifications specified in § 170.205(f). § 170.306(i). (1) *Calculate.* Electronically calculate all of the clinical quality measures specified by CMS for eligible hospitals and critical access hospitals. (2) *Submission.* Enable a user to electronically submit calculated clinical quality measures in accordance with the standard and implementation specifications specified in § 170.205(f).

Comments. Many commenters stated that the Physician Quality Reporting Initiative (PQRI) 2008 Registry XML specifications apply only in the context of eligible professionals. Some of these commenters went on to state that hospitals are not familiar with PQRI and have been submitting quality measurement data to CMS under a separate program. A few commenters recommended that this standard requirement be removed while several others stated we should adopt both Quality Reporting Document Architecture (QRDA) and the PQRI XML Registry specification in this rulemaking and move to a single standard in the next rulemaking. Other commenters recommended that QRDA not be adopted in this rulemaking. Several commenters suggested that an implementation specification for eligible hospitals be created if we intend to continue to require that quality measure be reported in the PQRI Registry XML format. One commenter expressed a concern that if the PQRI 2008 Registry XML standard is maintained as the adopted standard that there is a danger that the certification Complete EHR and EHR Module developers obtain may become obsolete before Stage 1 has run its course. Finally, a couple of commenters suggested that ONC consider deferring the naming of a standard for submission of clinical quality measures until Stage 2 and instead only require what is necessary to support clinical quality measure submission in Stage 1.

Response. Many commenters misinterpreted our intent with respect to the adoption of the PQRI 2008 Registry XML specification as the standard for electronically submitting quality reporting data to CMS. Presently, CMS requires the submission of aggregate, summary level data for the purposes of meaningful use and not data at the patient-specific level. It is our understanding that the PQRI 2008 Registry XML specification is capable of serving as the "envelope" for aggregate, summary level data. Accordingly, we do not believe that, as some commenters suggested, an eligible hospital's familiarity with the PQRI program is relevant to the adoption of this standard for this specified purpose. Nor do we believe that a specific implementation of this standard is necessary for hospital settings as the standard's purpose and the type of data it will transmit to CMS will be the same—aggregate, summary level data. Through recent discussions with CMS since the publication of the Interim Final Rule we have determined that the PQRI 2009 Registry XML specification, a more recent version of the standards we adopted in the Interim Final Rule is a suitable replacement for 2008 version, and accordingly, we have adopted the 2009 version in its place. We believe this revision should assuage some commenters' concerns about the obsolescence of the adopted standard and reduce concerns that a wholly different standard would be adopted in the near future. If adopting a different standard for Certified EHR Technology becomes necessary, we would do so only after engaging in subsequent rulemaking.

Comments. A few commenters stated that many of the clinical quality measures proposed by CMS do not have electronic specifications and contended that it would be difficult for any vendor to have embedded these measures in their EHR products in a timely manner. But, these same commenters stated that when the specifications become available, that HHS should ensure through the certification process that the products are capable of generating accurate data. Many commenters expressed concerns that the certification criterion was too vague or too broad (because it implicitly referenced all of

the quality measures CMS had proposed). Some of the commenters recommended that this certification criterion be removed, while others recommended that it focus on a subset of measures in order to constrain the amount of electronic measure specifications a Complete EHR or EHR Module developer would need to address in order to be certified. At least one of these latter commenters indicated that our adopted certification criteria created uncertainty for Complete EHR and EHR Module Developers. This commenter asked that we clarify what clinical quality measures would need to be tested in order to satisfy this certification criterion and if there would be a baseline for eligible hospital measures as well as some identified core set of measures for eligible professionals. Along these same lines, another commenter recommended that EHR technology should be tested and certified only to the clinical quality measures applicable to the medical specialties of the eligible professionals that the EHR technology is intended to support and to whom it is marketed. Other commenters expressed concerns about timing and that a significant amount of effort would be required to reprogram Complete EHRs and EHR Modules to capture, calculate, and report the final meaningful use Stage 1 measures. Many commenters also stated that the proposed quality measures are not yet ready for automated reporting, that a significant amount of work is still required by the measure developer community, and that the value sets for these quality measures have not been validated. Several commenters objected to the reference to "States" in the certification criterion and recommended that it be removed. These commenters contended that the certification criterion should be limited to the "federal requirements" and further that it was unrealistic to expect Complete EHR and EHR Module developers to also comply with 50 separate State requirements as a condition of certification.

Response. We understand that CMS has worked to significantly increase the availability of a number of electronic measure specifications that are associated with specific clinical quality measures. In light of the final approach CMS has taken with respect to clinical quality measures for meaningful use Stage 1, we have revised this certification to better align it with the Medicare and Medicaid EHR Incentive Programs final rule requirements. We also agree with those commenters that requested we explicitly focus the report of clinical quality measures certification criterion, and the certification criteria in general, on Federal requirements and have removed the reference to "or States" in this certification criterion.

To better align this certification criterion with the final approach to clinical quality measures in the Medicare and Medicaid EHR Incentive Programs final rule, we have determined that it is no longer sufficient to specify one general certification criterion for both Complete EHRs and EHR Modules designed for either an ambulatory or inpatient setting. Accordingly, the final rule in §§ 170.304 and 170.306 will include a specific certification criterion for each setting. Complete EHRs and EHR Modules designed for an ambulatory setting will be required to be tested and certified as being compliant with all 6 of the core (3 core and 3 alternate core) clinical quality measures specified by CMS for eligible professionals (Section II(A)(3) of the Medicare and Medicaid EHR Incentive Programs final rule). Complete EHRs and EHR Modules designed for an ambulatory setting will also be required to be tested and certified as being compliant with, at a minimum, 3 of the additional clinical quality measures CMS has identified for eligible professionals (Section II(A)(3)of the Medicare and Medicaid EHR Incentive Programs final rule). We believe this revision provides clarity and flexibility and reduces the potential burden for Complete EHR and EHR Module developers (who may have been unfamiliar with certain clinical quality measures because of the type of eligible professional they serve) to become compliant with this certification criterion. As a result, Complete EHR and EHR Module developers for the ambulatory setting may provide Certified EHR Technology with a certain level of variability in terms of clinical quality measure capabilities. To provide further transparency for potential eligible professionals regarding the clinical quality measures to which a Complete EHR or EHR Module has been tested and certified, we specified that an ONC–Authorized Testing and Certification Body would need to report such information to the National Coordinator, and further, that the Complete EHR or EHR Module developer would need to make sure this information is available and communicated to prospective purchasers as part of the Complete EHR or EHR Module's certification.

Complete EHRs and EHR Modules designed for an inpatient setting will be required to be tested and certified as being compliant with all of the clinical quality measures specified by CMS (Section II(A)(3) of the Medicare and Medicaid EHR Incentive Programs final rule) for eligible hospitals. Again, we believe this revision provides greater clarity and reduces the potential burden for Complete EHR and EHR Module developers.

Comments. One commenter suggested that we separate the calculation and the submission parts of this certification criterion into two separate certification criteria.

Response. We disagree. We see no basis for separating these two parts of this certification criterion into two separate certification criteria. However, we believe that it is necessary to specify two different certification criteria to account for the different clinical quality measures that eligible professionals and eligible hospitals will need to report. Accordingly, we have adopted separate certification criteria for Complete EHRs and EHR Modules designed for ambulatory and inpatient settings and referenced the respective quality measures for each in the appropriate certification criterion.

Comments. One commenter suggested that all approved PQRI registries be automatically certified as an EHR Module.

Response. We do not believe that it is prudent or appropriate to automatically deem certain HIT as certified. That being said, if a PQRI registry can adequately perform the capability specified by the certification criterion, it could be certified as an EHR Module.

Comments. Several commenters stated that Certified EHR Technology should be capable of collecting quality measurement data and calculating results for reporting to avoid having eligible professionals and eligible hospitals perform these processes manually. These commenters also stated that Certified EHR Technology should be capable of accurately and reliably reporting quality measurement data. Some commenters recommended that a Complete EHR or EHR Module only be required to be certified to existing e-measure specifications.

Response. We agree that the collection of clinical quality measurement data and the calculation of results for submission to CMS should be performed by Certified EHR Technology. We also agree that Complete EHRs or EHR Modules should only be required to be tested and certified to developed electronic measure specifications. This is why CMS has only specified clinical quality measures for eligible professionals and eligible hospitals in the Medicare and Medicaid EHR Incentive Programs final rule for which electronic measure

specifications have been developed. Complete EHR and EHR Module developers should follow these electronic measure specifications in order to accurately calculate clinical quality measures.

Comments. Several commenters recommended that the certification criterion should be revised to include the word "accurately."

Response. We expect that clinical quality measures would be accurately calculated and do not see a need to specifically include the word in the certification criterion.

Section 170.302(j)—Check Insurance Eligibility and § 170.302(k)—Submit Claims

Meaningful use Stage 1 objective	Meaningful use Stage 1 measure	Certification criterion
Removed from final rule	Removed from final rule	Interim Final Rule Text: 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). Final Rule Text: Removed.

Meaningful use Stage 1 objective	Meaningful use Stage 1 measure	Certification criterion
Removed from final rule	Removed from final rule	Interim Final Rule Text: 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). Final Rule Text: Removed.

Comments. Many commenters recommended that the certification criteria for administrative transactions be removed because they considered the administrative capabilities that we required to be outside of the scope of an electronic health record and stated further that their inclusion did not align with the HIT industry's common view of what constituted EHR technology. A large number of commenters conveyed specific challenges including: These functions are usually handled by practice management systems which generally are separate from an EHR, although on occasion some vendors include these functionalities in their EHRs; practice management systems adoption is already very high and requiring certification for these products would be unnecessary and burdensome, given the wide variety and number of vendors and significant potential for increasing costs for providers; providers interested in achieving meaningful use would have to abandon a working practice management system if their practice management vendors were unwilling or unable to get certified; and many providers currently use clearinghouses to convert paper claims into electronic claims to submit to CMS and other payers. Several commenters recommended retaining the administrative transactions certification criteria because it would eventually reduce administrative costs across the health care system. Many commenters requested that we clarify several aspects of these certification criteria while some other commenters noted that significant progress has been made in using electronic eligibility inquires and claims transactions outside of an EHR context. Those commenters expressed concern that the inclusion of administrative transaction capability in this rule would create confusion, ambiguity, and potentially duplicate efforts. A couple of commenters noted that some payers do not accept electronic claims and eligibility checks. One commenter expressly noted that including the administrative functionalities would decrease innovation by creating a large barrier to entry for EHR innovators. Finally, a couple of commenters noted that health care providers would face significant challenges in the transition to ASC X12N 5010 and ICD–10 and lost productivity.

Response. In concert with CMS, we have considered commenters' rationale for and against the inclusion of these certification criteria. We have tried to summarize above several technical and programmatic challenges commenters identified if administrative transaction capability were included within the certification requirements. Due to the removal of these objectives from the meaningful use Stage 1 requirements, we do not believe that it would be appropriate to continue to require, as a condition of certification, that Complete EHRs and EHR Modules include these capabilities. Accordingly, we have removed the adopted standards, implementation specifications, and certification criteria related to these administrative transactions from this final rule.

As CMS explains in more detail in the Medicare and Medicaid EHR Incentive Programs final rule, the subsequent inclusion of administrative simplification requirements as part of meaningful use Stage 2 is an important long-term policy goal. Administrative simplification can improve the efficiency and reduce unnecessary costs in the health care system as a whole; the small percentage of paper claims submitted represents a disproportionately high administrative cost for health plans; the reconciliation of billing charges for services not eligible for payment creates a significant burden for providers, health plans, and most significantly, for patients. Moreover, we believe that the integration of administrative and clinical information systems is necessary to support effective management and coordinated care in physician practices. For example, the ability to: leverage clinical documentation in support of appropriate charge capture (*e.g.,* for preventive counseling, or immunizations provided); link lists of patients needing clinical reminders with patient contact information; stratify quality measures by patient demographic factors (*e.g.,* race/ethnicity) and insurer status (*e.g.,* Medicare beneficiaries).

Additionally, we believe that important benefits can be recognized through the future adoption of administrative transactions standards and certification criteria for Complete EHRs and EHR Modules. Through the

use of EHR Modules, eligible professionals and eligible hospitals have the opportunity to use practice management systems or clearinghouses that provide the capability to conduct administrative transactions as components of Certified EHR Technology. In that regard, we recognize the concerns expressed by some commenters that the developers of some practice management systems may not be prepared to seek certification for these legacy systems in 2010 or 2011. We also acknowledge that the required compliance date of January 1, 2012 for ASC X12N version 5010 transactions would further complicate the certification process associated with meaningful use Stage 1. However, we believe that after the ASC X12N version 5010 transition has occurred, and we approach the October 1, 2013 compliance date for HIPAA covered entities to use ICD–10, our decision to delay the adoption of administrative transactions certification criteria will prove beneficial for the adoption of Certified EHR Technology.

In order to meet upcoming administrative simplification deadlines, most health care providers will have to upgrade their practice management systems or implement new ones. This will provide an important opportunity to align EHR technology capabilities and standards for administrative transactions with the administrative simplification provisions that the Affordable Care Act provides for health plans and clearinghouses. Therefore, we intend to include for adoption, administrative transactions standards and certification criteria to support meaningful use Stage 2 rulemaking, and expect health care providers and Complete EHR and EHR Module developers to take this into consideration leading up to 2013.

Comments. Many commenters recommended that we remove the implementation specification, CORE Phase 1 (CORE), which we previously adopted. Several commenters noted that CORE is only useful if it has also been adopted by health plans, and they explained that not all health plans had adopted CORE. A few commenters expressed concern with CORE stating that it adds requirements to the HIPAA Standard Transactions and did not follow the work of the standards development organization that maintains administrative transactions. A few commenters also believed that following CORE results in non-compliant ASC X12N 4010 transactions. Other commenters noted that it appeared that we had required CORE for both ASC X12N 4010 and 5010 standard transactions, but that CORE Phase 1 is only applicable to ASC X12N 4010 standard transactions and cannot be used with ASC X12N 5010 standard transactions. A few commenters requested that we clarify whether providers and vendors will be required to receive CORE certification. Several commenters recommended ONC retain CORE Phase 1. A few commenters noted that CORE promotes uniformity and can provide significant reduction in transaction costs. A couple commenters recommended that ONC adopt subsequent CORE standards in future stages.

Response. As previously mentioned, we have decided to align our revisions with the changes made in the Medicare and Medicaid EHR Incentive Programs final rule and to remove, as noted above, the standards, implementation specifications, and certification criteria associated with administrative transactions. Consistent with that approach, we are removing the CORE Phase 1 implementation specification for the reasons submitted in comments.

Section 170.302(l)—Medication Reconciliation

Meaningful use Stage 1 objective	Meaningful use Stage 1 measure	Certification criterion
The EP, eligible hospital or CAH who receives a patient from another setting of care or provider of care or believes an encounter is relevant should perform medication reconciliation.	The EP, eligible hospital or CAH performs medication reconciliation for more than 50% of transitions of care in which the patient is transitioned into the care of the EP or admitted to the eligible hospital's or CAH's inpatient or emergency department (POS 21 or 23).	Interim Final Rule Text: *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. Final Rule Text: § 170.302(j) *Medication reconciliation.* Enable a user to electronically compare two or more medication lists.

Comments. Many commenters suggested that for this certification criterion we clarify whether we intended for the process of medication reconciliation to be automatic or to support an eligible professional or eligible hospital in performing this task. Many saw the former as a potential risk to patient safety. Although several different reasons were given, many commenters recommended that we revise the certification criterion to indicate that two or more medication lists be simultaneously displayed in order to permit an eligible professional or eligible hospital to then reconcile the medication lists.

Response. We have reviewed commenters' concerns and intend to clarify the language in this certification criterion. We recognize that the technical foundation and safety checks are not currently in place for automated medication reconciliation. We did not intend to imply that automated reconciliation needed to occur through our use of the word "electronically." We used the term "electronically" to express our expectation that eligible professionals and eligible hospitals would be able to use Certified EHR Technology to complete this task. Accordingly, we have revised this certification criterion to require that Certified EHR Technology be capable of providing a user with the ability to electronically compare two or more medication lists (*e.g.,* between an externally provided medication list and the current medication list in Certified EHR Technology). We expect that this could be done in a number of ways and we do not want to preclude Complete EHR and EHR Module developers from innovating, provided that the desired outcome is reached. For example, a user could be presented with two electronic lists side-by-side and move medications from one list to the other and then select the final current list. Alternatively, a user could view one list and two PDFs of other medications and use this capability to update the current medication list. We do, however, see great promise in making this capability more comprehensive and anticipate exploring ways to improve the utility of this capability before we adopt a subsequent round of certification criteria.

Comments. Several commenters supported this certification criterion, but wanted clarification regarding how

we expected testing and certification to be accomplished, especially if only one medication list was in use.

Response. We believe that the clarifications and revisions to the certification criterion and the discussion above clarify how we intend for this certification criterion to be tested.

Comments. Several commenters requested that we clarify the meanings of "medication reconciliation," "transitions of care," and "relevant encounter."

Response. These terms are not used in the certification criterion. We encourage commenters to review the Medicare and Medicaid EHR Incentive Programs final rule to see how these terms have been clarified in response to public comments.

Section 170.302(m)—Submission to Immunization Registries

Meaningful use Stage 1 objective	Meaningful use Stage 1 measure	Certification criterion
Capability to submit electronic data to immunization registries or Immunization Information Systems and actual submission in accordance with applicable law and practice.	Performed at least one test of certified EHR technology's capacity to submit electronic data to immunization registries and follow up submission if the test is successful (unless none of the immunization registries to which the EP, eligible hospital or CAH submits such information have the capacity to receive the information electronically).	Interim Final Rule Text: *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. Final Rule Text: § 170.302(k). *Submission to immunization registries.* Electronically record, modify, retrieve, and submit immunization information in accordance with: (1) The standard (and applicable implementation specifications) specified in § 170.205(e)(1) or § 170.205(e)(2); and (2) At a minimum, the version of the standard specified in § 170.207(e).

Comments. A significant majority of commenters recommended that we remove paragraph (m)(2) related to the applicable state-designated format. These commenters contended that such a requirement was vague, could be problematic from an interoperability perspective, and would make certification impracticable.

Response. We agree with those commenters that requested we explicitly focus the certification criterion and certification in general on Federal requirements. We have therefore removed the reference to "applicable stated-designated standard format" in the certification criterion. Additionally, we have reviewed this certification criterion and have determined that our reference to "immunization registries" is unnecessary. We are primarily concerned with Certified EHR Technology's ability to transmit the immunization information in a standardized format, and do not believe that it is necessary to specify a particular recipient in the certification criterion.

Comments. Many commenters supported our adoption of both HL7 2.3.1 and HL7 2.5.1. Some commenters acknowledged that HL7 2.3.1 was more commonly used for the purpose of submitting information to immunization registries while other commenters suggested that we only adopt HL7 2.5.1. Some commenters recommended that we keep our adopted standards the way they are. Others recommended that we only adopt HL7 2.3.1 because most immunization registries cannot comply with HL7 2.5.1.

Response. We appreciate that commenters support our adoption of both HL7 2.3.1 and HL7 2.5.1. We understand that both standards are currently in use and for that reason we have permitted either to be used for purposes of certification. We also understand that eligible professionals and eligible hospitals will have to use the standard that the immunization registry or Immunization Information System in their jurisdiction can receive and, as a result, we have adopted the two most common standards utilized for the transmission of immunization information.

Comment. One commenter noted that it would be very helpful to provide a source for mapping from the NDC code on the vaccine packaging to the CVX/MVX codes used for interoperability, in anticipation of supporting barcode scanning of vaccines. Another commenter noted that while some mapping has occurred between CPT and CVX, they were not aware of a translation map from NDC to CVX. They also stated that even though a list of CVX codes is available, they were not aware of a downloadable immunization database using CVX codes. They considered this lack of a database a significant burden and impediment to compliance. The commenter concluded by suggesting that CPT codes be used instead of CVX codes, because CPT codes are used for billing purposes and would be readily available.

Response. The CDC maintains an openly available list of updated CVX codes as well as a mapping of CVX codes to CPT codes on their Web site.[4] Moreover, we believe that CVX codes are more appropriate than CPT codes because as the commenter referenced, CPT codes are used for billing purposes. In that regard, we believe that because there is a publicly available mapping between CVX and CPT, it would not be difficult or burdensome to map CPT codes to CVX codes. NDC codes were not adopted as a standard to represent immunizations and we do not believe that requiring their use for the purposes of demonstrating compliance with this certification criterion would be appropriate.

Comment. One commenter recommended that we revise the certification criterion combined with associated standards to state, "For the purposes of electronically submitting information to immunization registries Certified EHR Technology must be capable of using a certified EHR module or portal provided by a state immunization registry which is capable of submitting and retrieving coded immunization information or 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 as the vocabulary standard." The basis for this commenter's suggestion was that providers in its state link to the state's

[4] *http://www.cdc.gov/vaccines/programs/iis/stds/cpt.htm.*

immunization module through EHRs and that all immunization data are stored immediately in the state's registry. The commenter further clarified that since the data resides in the state registry natively, there is no need to transmit this information.

Response. In light of this commenter's suggestion, we have revised the certification criterion to replace the word "transmit" with "submit" to better align this certification criterion with the meaningful use objective and measure. We believe that submission of immunization data would encompass this commenter's existing method.

Comment. One commenter stated that they believed the use of CVX is neither mature nor widespread.

Response. We disagree. Our information indicates that CVX codes are widely used for reporting to immunization registries.

Comment. Some commenters identified implementation specifications that are available for the standards we had adopted for transmitting immunization information. A couple of these commenters specifically recommended using implementation specifications that would identify message types necessary for transmissions to immunization registries. Commenters also suggested using the CDC's implementation guides, and explicitly recommended that we adopt the CDC public health information network (PHIN) implementation guide version 2.2 associated with HL7 2.3.1 for the transmission of immunization information and the CDC implementation guide as well as the implementation guide associated with HL7 2.5.1.

Response. In the Interim Final Rule, we expressed our interest in receiving public comment on whether there were additional implementation specifications that we should adopt. We also noted that we would consider adopting implementation specifications for any or all of the standards adopted in the Interim Final Rule. After further consideration of commenters' recommendations and consultation with the CDC, we agree with these commenters and believe that adopting implementation specifications for the transmission of immunization information would benefit EHR technology developers and users. Moreover, given commenters' general requests for greater specificity and our stated goal of greater interoperability, we believe that it would be appropriate to adopt the following implementation specifications for the submission of immunization data. For HL7 2.3.1 we have adopted the "Implementation Guide for Immunization Data Transactions using Version 2.3.1 of the Health Level Seven (HL7) Standard Protocol, Implementation Guide Version 2.2." We are aware that this implementation specification has been successfully adopted numerous times in various contexts since its publication four years ago and do not believe that it will be burdensome for Complete EHR and EHR Module developers to implement these specifications. For HL7 2.5.1, we have adopted the "Implementation Guide for Immunization Messaging Release 1.0." This implementation specification represents the collaborative effort of the American Immunization Registry Association (AIRA) and the CDC. We have also consulted with CDC, and the CDC confirms the appropriateness and supports the usage of these implementation specifications in this context. We encourage migration to this newer implementation specification and believe that it will likely advance interoperability across the country and improve query capabilities.

Comment. A commenter recommended that we clarify that the certification criterion should be limited to verifying the ability of the system to record, retrieve, and transmit immunization information.

Response. The purpose of testing and certifying a Complete EHR or EHR Module to this certification criterion is to verify that it can perform the capabilities included in the certification criterion.

Comment. A couple of commenters strongly supported the transmission of immunization data to state and local immunization registries but requested that the data requirements be expanded to include the transmission of information regarding diseases such as cystic fibrosis to pediatric registries.

Response. Presently, we do not believe that it is necessary or appropriate to expand this certification criterion in this manner. We emphasize, though, that this should not preclude eligible professionals or eligible hospitals from using Certified EHR Technology to submit other types of information as medically appropriate and if the recipient of the information is capable of receiving the data.

Comment. A commenter recommended including the term "modify" in the certification criterion.

Response. We agree, and consistent with our other certification criteria that include the term "modify," we have added this term.

Section 170.302(n)—Public Health Surveillance

Meaningful use Stage 1 objective	Meaningful use Stage 1 measure	Certification criterion
Capability to submit electronic syndromic surveillance data to public health agencies and actual submission in accordance with 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 and follow-up submission if the test is successful (unless none of the public health agencies to which an EP, eligible hospital or CAH submits such information have the capacity to receive the information electronically).	Interim Final Rule Text: *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). Final Rule Text: § 170.302(l). *Public health surveillance.* Electronically record, modify, retrieve, and submit syndrome-based public health surveillance information in accordance with the standard (and applicable implementation specifications) specified in § 170.205(d)(1) or § 170.205(d)(2).

Comments. A couple of commenters supported the adoption of certification criteria related to public health reporting. One commenter believed that this certification criterion should be implemented as adopted.

Response. We appreciate commenters' support of this certification criterion.

Comment. One commenter recommended that we defer any vocabulary standard for public health reporting and surveillance until a later date. Another commenter expressed

concern that we would adopt as a standard, "according to applicable public health agency requirements," because they thought it could be problematic for hospital systems with facilities in two or more states, as their EHR technology would have to meet whatever standards each state elected to use.

Response. We clarify for commenters that we adopted two content exchange standards for electronic submission to public health agencies for surveillance and reporting. We did not adopt a specific vocabulary standard, nor did we include the phrase one commenter stated that we included. However, we have, consistent with our rationale in the immunization submission certification criterion, removed our reference to "public health agencies" as the recipient of information. Also, consistent with the certification criterion above, we have replaced the term "transmit" with "submit."

Comments. A couple of commenters stated that compliance with HL7 2.5.1 not be included in this adopted set of standards. One commenter suggested HL7 2.5.1 should be adopted in a future rulemaking. Another commenter suggested that HL7 2.3.1 be required for the purposes of certification. Another commenter recommended that the standard be HL7 2.3.1, because in its opinion many public health agencies cannot comply with HL7 2.5.1 while another commenter took the opposite position and recommended HL7 2.5.1.

Response. Given the diversity in implementations and public health agencies' ability to receive information in a given standard, we believe that the flexibility included in this criterion is necessary for the foreseeable future. However, relative to the general comments we received regarding the adoption of implementation specifications for adopted standards, we have adopted the following implementation specifications for HL7 2.5.1: Public Health Information Network HL7 Version 2.5 Message Structure Specification for National Condition Reporting Final Version 1.0 and the Errata and Clarifications National Notification Message Structural Specification. We believe that these implementation specifications provide the additional clarity commenters were seeking and will enable Complete EHR and EHR Module developers to focus their efforts on a more specific implementation of the HL7 2.5.1 standard. We do not believe that a suitable implementation specification for HL7 2.3.1 exists for the purpose of public health surveillance and reporting.

Comments. Multiple commenters stated concerns that the Federal government and state governments, as well as other public health agencies, do not have the capability to receive information electronically in a standardized format. One commenter stated that while they supported using the HL7 standards, some agencies are only able to accept public health submissions if they have an HL7-based feed. Several commenters suggested that the public health reporting requirement be delayed until a single, national standard exists. One commenter stated that requiring EHRs to "electronically record, retrieve, and transmit syndrome-based public health surveillance information to public health agencies" is a worthwhile future goal, but they strongly questioned the likelihood that it could be accomplished within the 2011–2012 timeframe. The commenter also noted that the certification criterion did not specify which agencies (local, state, Federal) are included, and that most of those agencies are not prepared to receive biosurveillance data electronically in the format specified. The commenter concluded that it would be difficult for any EHR to prove compliance with the certification criterion as written and recommended the following alternative: "Electronically record, retrieve, and be capable of producing an electronic message containing syndrome-based public health surveillance information in accordance with one of the standards specified in § 170.205(g)."

Response. We recognize that some public health agencies do not yet have the capability of electronically receiving information. We do not believe that this should serve as a limiting factor, however, or preclude Certified EHR Technology from having the capability to transmit information in a standard format.

Comment. One commenter commented that if a public health agency is unable to accept the data, separate reports could be filed with the public health agency to ensure compliance with the standards.

Response. The commenter's point is unclear, as is its proposal. We therefore reiterate that Certified EHR Technology must be capable of transmitting health information in accordance with the standards adopted by the Secretary, regardless of whether a specific public health agency can accept or receive the information.

Comment. One commenter suggested that if current interfaces comply with public health surveillance data using older versions of HL7, the organizations should be allowed to keep these versions and not be required to upgrade to a newer version.

Response. We permit a Complete EHR or EHR Module to be tested and certified to either HL7 2.3.1 or HL7 2.5.1. No other versions will be considered compliant with the adopted standards or certification criterion.

Comment. One commenter recommended that we specify acceptable testing methods. The commenter also recommended that the testing methods should include an evaluation of HL7 conformance, completeness, and accuracy of test messages sent to a state public health agency with a demonstrated capability for electronic laboratory reporting.

Response. We do not specify the testing methods applicable to the certification criterion, because that information is outside the scope of this final rule.

Comment. One commenter suggested that adverse events be reported to public health agencies.

Response. Our certification criterion does not preclude other types of reportable events from occurring. Presently, we do not believe that it is appropriate to modify the certification criterion to explicitly refer to adverse events.

Comment. One commenter recommended that because some public health agencies do not have the ability to receive public health surveillance information in electronic format, we should clarify that this certification criterion is limited to verifying the ability of the system to record, modify, retrieve, and submit such information based on at least one test of these capabilities.

Response. We reiterate, that the purpose of certification is to verify that a Complete EHR or EHR Module can perform these capabilities. That should not be construed to mean that an eligible professional or eligible hospital is exempt from using Certified EHR Technology to meet the meaningful use objective and measure.

Comment. A commenter recommended including the word "modify" in the certification criterion.

Response. Consistent with our rationale above, we have added the word modify to the certification criterion.

Section 170.302(o)—Access Control

Meaningful use Stage 1 objective	Meaningful use Stage 1 measure	Certification criterion
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 and correct identified security deficiencies as part of its risk management process.	Interim Final Rule Text: *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. Final Rule Text: § 170.302(o). Unchanged.

Comment. One commenter explicitly noted its support for this certification criterion. We received other comments that included some mention of "access" but did not expressly focus on the certification criterion or provide any related suggestions or recommendations.

Response. We appreciate the comment supporting this certification criterion. This certification criterion remains unchanged from the certification criterion adopted in the Interim Final Rule.

Section 170.302(p)—Emergency Access

Meaningful use Stage 1 objective	Meaningful use Stage 1 measure	Certification criterion
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 and correct identified security deficiencies as part of its risk management process.	Interim Final Rule Text: *Emergency access.* Permit authorized users (who are authorized for emergency situations) to access electronic health information during an emergency. Final Rule Text: § 170.302(p). Unchanged.

Comment. One commenter asked that we clarify the circumstances that would qualify as an "emergency" and further clarify whether compliance with this certification criterion is intended to preempt conflicting or stricter state laws that may limit this type of access or require patient consent. Further, the commenter questioned whether we were implying that some authorized users of Certified EHR Technology would not be authorized for emergency situations or whether we intended for any authorized user to be entitled to access in an emergency situation. Finally, another commenter requested clarification as to whether emergency access is driven by organizational policies and whether capturing such access in an audit log is appropriate.

Response. We have adopted certification criteria to ensure that Certified EHR Technology includes certain capabilities, in this case that Certified EHR Technology be capable of permitting authorized users to access electronic health information during an emergency. The criterion is not intended to specify what constitutes an emergency or who would be authorized to access electronic health information in an emergency. In a medical emergency, those determinations would be made under specific factual circumstances and in accordance with applicable state and federal laws, organizational policies and procedures, and the relevant standard of care.

With respect to emergency access, we note that HHS stated in the HIPAA Security Final Rule (68 FR 8355):

> We believe that emergency access is a necessary part of access controls and, therefore, is properly a required implementation specification of the "Access controls" standard. Access controls will still be necessary under emergency conditions, although they may be very different from those used in normal operational circumstances. For example, in a situation when normal environmental systems, including electrical power, have been severely damaged or rendered inoperative due to a natural or manmade disaster, procedures should be established beforehand to provide guidance on possible ways to gain access to needed electronic protected health information.

We believe that this certification criterion is consistent with the HIPAA Security Rule.

Some commenters appeared to interpret our reference to "emergency" in "emergency access" as solely constituting a clinical or life threatening emergency related to a patient for which access would be required. We believe that emergency could encompass that scenario, as well as a broader range of possibilities, including normal patient care when timely access to electronic health information becomes critical. Therefore, we have not sought to limit the development of emergency access capabilities for Certified EHR Technology to a particular scenario.

Comment. One commenter suggested that we require automated notification of user activity to system administrators when emergency access is invoked.

Response. We appreciate this suggestion. However, at the present time, we do not believe that this requirement should be a condition of certification because a person or entity's organizational policies and procedures may ensure timely notification of appropriate personnel.

Section 170.302(q)—Automatic Log-Off

Meaningful use Stage 1 objective	Meaningful use Stage 1 measure	Certification criterion
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 and correct identified security deficiencies as part of its risk management process.	Interim Final Rule Text: *Automatic log-off.* Terminate an electronic session after a predetermined time of inactivity. Final Rule Text: § 170.302(q). Unchanged.

Comments. One commenter supported this requirement. Another commenter concurred with the purpose of the certification criterion, but noted that it may be difficult in some circumstances for eligible professionals or eligible hospitals to implement this capability if the Certified EHR Technology is offered as a service and multiple individuals are using the Certified EHR Technology at the same time.

Response. We appreciate the commenters' support for the adoption of this certification criterion. We believe that automatic logoff capabilities are commonplace and that this certification criterion can be met by any Complete EHR or EHR Module developer. We are aware that many Web services today logoff customers after a period of inactivity and do not believe this requirement is unduly burdensome for any Complete EHR or EHR Module developer.

Section 170.302(r)—Audit Log

Meaningful use Stage 1 objective	Meaningful use Stage 1 measure	Certification criterion
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 and correct identified security deficiencies as part of its risk management process.	Interim Final Rule Text: (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. Final Rule Text: § 170.302(r). (1) *Record actions.* Record actions related to electronic health information in accordance with the standard specified in § 170.210(b). (2) *Generate audit log.* Enable a user to generate an audit log for a specific time period and to sort entries in the audit log according to any of the elements specified in the standard at 170.210(b).

Comments. Several commenters recommended that we add to the standard specified at § 170.210(b) "access," "reading," or "viewing" as triggers for when actions needed to be recorded as part of an audit log. One commenter recommended expanding the audit content to include maintaining the before-access content of the information accessed as well as the after-access content. Some commenters requested clarification of the intended meaning of the reference to recording the action of "printing." Commenters recommended expanding or replacing "print" in the standard with other types of output methods such as extraction, copy, exchange, report, and export. Some commenter stated that the print function in many operating systems and software products is a multiple step process that is difficult for any system to audit. Other commenters expressed concerns that the requirement to audit all printing would be difficult because there were numerous ways to circumvent the specific action of printing, such as using the print screen function and printing out the image of the screen shot. One commenter stated that auditing of the print function would be possible, but complete auditing of all possible ways of printing would be impracticable.

Response. We appreciate the thoughtfulness and thoroughness of the comments provided on this standard. We agree with commenters that auditing the action of printing, as it was originally envisioned, could be circumvented in such ways as to make the burden of trying to accurately audit such occurrences outweigh the benefit. Accordingly, we have removed "printed" from the standard. We also agree with commenters that our omission of "access" should be corrected and we have added "accessed" to the standard. We view the action of "access" to encompass "reading" or "viewing" and consequently have not included those terms as well. Finally, we believe that the action of "accessed" is a superset of actions which may include "export" and for that reason have not included, per some commenters' suggestions, the word "exported" in the standard. Additionally, to provide greater clarity, we have added in "and by whom" toward the end of the standard in order to more clearly specify that the actions recorded should be associated with the user identification that is recorded.

The final standard will read as follows: "The date, time, patient identification, and user identification must be recorded when electronic health information is created, modified, accessed, or deleted; and an indication of which action(s) occurred and by whom must also be recorded."

Comments. Some commenters requested that we clarify the term "user identification" in the standard specified at § 170.210(b) and recommended the use of existing standards-based definitions, such as HL7's definition of *author* which includes person, organization, or device.

Response. We specified in the standard that the date, time, patient identification, and user identification must be recorded when certain actions take place. The HL7's definition of author is consistent with our expectation. While we believe that in most cases a user will be a health care professional performing an action using Certified EHR Technology, it is also possible that a device or another software process or program could perform any one of these actions. We do not intend to preclude Complete EHR and EHR Module developers from including these and other types of specific features.

Comment. One commenter stated that the audit alert criterion exceeds reasonable expectations for Certified EHR Technology to provide automatic alerts, and recommended that the audit criteria focus on record access rather than electronic alerts. Several commenters suggested that alerts are not well defined and should be removed from the criteria. Several commenters expressed concern that the audit alerting criterion goes beyond what is required by HITECH and HIPAA and exceeds the current capabilities of products in the market, and recommends that the alerting criterion be eliminated from the final rule. Some commenters recommended against the adoption of certification criterion that requires EHR systems to create an unlimited and open-ended series of rules to produce user-defined alerts, and suggested that we should clearly define

which actions should be recorded and what alerts should be defined and provided in an audit log. Several commenters stated that the use of the phrase "based on user-defined events" in the criterion could be easily misinterpreted or misunderstood to extend beyond "entity-defined" events to include individual patient preferences. Some of the commenters that expressed concerns also contended that it would be difficult to test and certify this portion of the certification criterion.

Response. Again, we appreciate the thoroughness of the commenters' suggestions. With respect to alerts based on user-defined events, we had intended for Complete EHRs or EHR Modules designed to provide this capability to be capable of being configured by a specific user of Certified EHR Technology or based on organizational policy to generate alerts when certain actions (defined in the standard) had taken place. For example, a user-defined event could be when a patient's health information is accessed outside of normal business hours. In this case, it was our expectation that Certified EHR Technology would alert a specific user of the Certified EHR Technology or the organization's information security staff. We understand the point that commenters raise, however, about the potential for misinterpretation of this certification criterion and the consequent potential burden.

Our overall intent for the third paragraph of this certification criterion was to ensure that Certified EHR Technology provided the capability for eligible professionals and eligible hospitals to gain access to a specified portion, or a complete representation, of the Certified EHR Technology's audit log. We believe that this capability is essential for eligible professionals and eligible hospitals for risk analysis and other purposes. Therefore, in concert with the feedback commenters provided on the second paragraph, we analyzed whether combining the third paragraph with the second paragraph into a single paragraph would express a clearer requirement. Accordingly, we have merged the two paragraphs and have adopted in the final rule a requirement that we believe more clearly expresses our intent for this certification criterion. We also note for clarification that the phrase "any of the elements specified by 170.210(b)" would also include, for example, "date" or that information has been "deleted."

Finally, we believe that it is important for our privacy and security certification criteria to remain consistent with the HIPAA Security Rule to the degree that Certified EHR Technology includes technical capabilities that are associated with assisting HIPAA covered entities comply with applicable legal requirements. We disagree, however, with those commenters who stated that we did not have a sufficient legal basis to adopt this certification criterion the way we did because it went beyond the HIPAA Security Rule. What a HIPAA covered entity must do to remain in compliance with the HIPAA Security Rule is separate and distinct from the capabilities that a Complete EHR or EHR Module must include in order to be certified. We do not believe that we are precluded by the HITECH Act from adopting certification criteria that go beyond the requirements specified by the HIPAA Security Rule. We believe that the HITECH Act, while directing that standards, implementation specifications, and certification criteria be consistent with the HIPAA standards, authorizes the Secretary to adopt certification criteria more broadly for the electronic use and exchange of health information. Section 3004(b)(1) of the PHSA, as added by the HITECH Act, requires the Secretary, for instance, to adopt an initial set of standards, implementation specifications, and certification criteria to enhance the interoperability, functionality, utility, and security of health information technology.

With respect to the concern expressed that this certification criterion requires capabilities that exceed the current capabilities of products in the market, we disagree. Based on our understanding of the current EHR technology in the market, we believe that the capabilities we have specified in the criterion and the embedded standard are already common industry practice, and further, that the industry has expanded the functionality available in audit logs.

Comment. One commenter suggested we defer our adoption of the standard until the next rulemaking related to meaningful use.

Response. We disagree. As stated above, we believe that audit log capabilities are an essential component of Certified EHR Technology. As we mentioned above, we believe that the actions we have specified in the standard, in response to public comment, are already common industry practice. Moreover, audit logs will provide valuable information to eligible professionals and eligible hospitals in the event of a security incident.

Comments. Several commenters acknowledged the importance of the audit log, but emphasized that the audit log requirements should address the availability of the audit log and its security. Several commenters recommended that additional requirements be added, including that the audit log always be on during normal production for the minimum elements specified in 170.210(b), be maintained in a secure manner, be produced in a human readable format, and be retained in conjunction with the retention period of the record.

Response. We agree with these commenters on the merits of their suggestions. In particular, we note that audit logs provide an important resource for eligible professionals and eligible hospitals. Audit logs can assist in the identification of security incidents, such as unauthorized access, as well as serve to deter users from conducting fraudulent or abusive activities and detect such activities. The purpose of adopted certification criteria is to specify the capabilities Complete EHRs and EHR Modules must include in order to be certified, not when such capabilities must be used. Accordingly, we do not believe that it would be appropriate to specify in this certification criterion the time period for which an audit log should be "on." We agree with commenters that audit logs should be maintained in a secure manner. For this reason, we have preserved the capability we adopted in the Interim Final Rule as part of the integrity certification criterion that specified that Certified EHR Technology must be capable of detecting alterations to audit logs. We encourage the HIT Standards Committee to consider additional capabilities that could be specified related to audit logs.

Comment. One commenter recommended that the IHE Audit Trail and Node Authentication (ATNA) Integration Profile be used, but that its use be constrained to the electronic transactions among organizations, rather than electronic transmissions within an organization.

Response. We decided to defer our adoption of the ATNA standard because it can be configured in multiple ways and we did not believe that it would be appropriate at this time to require a specific implementation as a condition of certification. Our deferral does not preclude Complete EHR and EHR Module developers from using the standard, however.

Comment. One commenter requested clarification between "read" audits and "write" audits, and how each is to be used. The commenter suggested that not requiring the capability of "read" audits will significantly reduce the ability of auditors to identify and investigate

inappropriate use of health information when records are accessed but not manipulated. The commenter noted that auditing all read operations for all data elements within an EHR is infeasible. The commenter further suggested that "read" operations should be audited only when certain demographic health information needed to identify a patient (*e.g.,* name, record number, date of birth, address) is presented to or can be known by the user.

Response. As discussed above, we have adopted in the standard the action of "accessed" which would encompass the action of "read." At the present time, we only identify certain data elements in the adopted standard that must be recorded and believe that this specificity will help reduce any potential burden associated with recording the action of "accessed."

Section 170.302(s)—Integrity

Meaningful use Stage 1 objective	Meaningful use Stage 1 measure	Certification criterion
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 and correct identified security deficiencies as part of its risk management process.	Interim Final Rule Text: (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). Final Rule Text: § 170.302(s). (1) Create a message digest in accordance with the standard specified in 170.210(c). (2) Verify in accordance with the standard specified in 170.210(c) upon receipt of electronically exchanged health information that such information has not been altered. (3) *Detection.* Detect the alteration of audit logs.

Comments. Several commenters requested a definition of "in transit." Other commenters suggested that hashing of messages in transit be limited to circumstances of transmission over public networks only. These commenters suggested that messages transmitted over private networks be exempt from complying with this standard. One commenter suggested that in addition to message hashing, digital signatures should be required on messages in transit. Another commenter stated that requiring hashing of messages in transit is overly burdensome. One commenter requested that we clarify whether we intended § 170.302(s)(1) to require that the receiver of a message always verify messages received rather than simply demonstrate the capability to use hashing.

Response. We intend for this certification criterion to support, at a minimum, the HIPAA Security Rule implementation specification provided at 45 CFR 164.312(e)(2)(i) "[i]mplement security measures to ensure that electronically transmitted electronic protected health information is not improperly modified without detection until disposed of." Because this certification criterion specifies a capability that Certified EHR Technology must include, we do not believe that it is necessary or appropriate for us to address whether hashing is applicable to public and private networks. Additionally, we clarify that Certified EHR Technology must include the capability to check the integrity of health information that has been received through electronic exchange. However, similar to our approach to many adopted certification criteria, we do not specify the instances in which this capability needs to be executed. Nevertheless, in response to public comments we have attempted to clarify this certification criterion. We clarify that we expect Certified EHR Technology to be capable of creating a message digest and when in receipt of a message digest, to use the message digest to verify that the contents of the message have not been altered. We have revised the certification criterion to clarify our intent.

Additionally, based on these revisions in the certification criterion, we wish to clarify the wording of the integrity standard specified at 170.210(c). The standard currently includes the words "or higher" at the end of the standard. To provide more certainty to the industry of our intended meaning, we are replacing those words with more accurate terminology. We have modified the standard to read as follows: "A hashing algorithm with a security strength equal to or greater than SHA–1 must be used to verify that electronic health information has not been altered." More information on SHA–1 and other secure hash algorithms can be found in FIPS 180–3 [5] while more information on the security strength of certain hashing algorithms can be found in NIST Special Publication 800–107.[6]

Comments. Some commenters noted that § 170.302(s)(2) refers to the use of the adopted standard which specifies the use of hashing to detect audit log alteration or deletion and that such a requirement is inappropriate. Other commenters recommended that hashing should not, at the present time, be used for detecting alterations to data at rest.

Response. We have considered these comments and agree with these commenters that this requirement requires further clarification. We note that part of this requirement as adopted in the Interim Final Rule ("detect * * * deletion of electronic health information") is redundant with the standard we specify for audit logs which requires that deletions of electronic health information be recorded. For this reason, we have removed the reference to the detection of deleted electronic health information and have opted for a more concise requirement that alterations to audit logs be detected. In response to public comment, we have chosen not to specify a standard for detecting alterations to audit logs at this time.

Comment. One commenter requested clarification as to how message hashing should work when messages are part of a multi-part transmission process, *e.g.,* through switches, clearinghouses, and other brokers.

Response. We expect Certified EHR Technology to be capable of generating a hash of electronic health information and upon receipt of such information, verifying that it has not been altered when it has been electronically exchanged. We recognize that certain situations may not be conducive to the

[5] *http://csrc.nist.gov/publications/fips/fips180-3/fips180-3_final.pdf.*

[6] *http://csrc.nist.gov/publications/nistpubs/800-107/NIST-SP-800-107.pdf.*

use of hashes, which is why, as we noted above, we do not specify the instances in which hashing must be used, just that Certified EHR Technology include these capabilities.

Comment. One commenter stated that secure transmission requirements are "inappropriate" because they do not support any meaningful use requirements.

Response. We disagree. Meaningful use requires the electronic exchange of health information and the protection of such information. We believe that the only practical and effective way that electronic health information can be exchanged in a meaningful manner is if the integrity of the information can be maintained. Information "integrity" is also one of the three pillars of securing or "protecting" electronic information.

Section 170.302(t)—Authentication

Meaningful use Stage 1 objective	Meaningful use Stage 1 measure	Certification criterion
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 and correct identified security deficiencies as part of its risk management process.	Interim Final Rule Text: (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). Final Rule Text: *§ 170.302(t).* *Authentication.* Verify that a person or entity seeking access to electronic health information is the one claimed and is authorized to access such information.

Comments. One commenter expressly supported this certification criterion. A majority of commenters expressed concerns related to § 170.302(t) and the cross-enterprise authentication standard specified at § 170.210(d). Some commenters misinterpreted our example and stated that Security Assertion Markup Language (SAML) should not be required or be a named standard. One commenter suggested expanding the set of examples we provided. Other commenters requested that the standard and the related portion of the certification criterion be removed because it was too burdensome to implement at the present time, was overly broad, and could be subject to multiple interpretations. Other commenters contended that there is an insufficient infrastructure to support cross-enterprise authentication. One commenter stated that cross-enterprise authentication would not reside in an EHR application, but rather in the network infrastructure.

Response. We have considered the concerns issued by commenters and agree that the burden associated with cross enterprise authentication is unnecessarily high and cross-network authentication should not be a condition of certification at the present time. As a result, we have removed this specific part of the certification criterion and the associated standard.

Comment. A commenter requested clarification as to whether "user name and password" would be sufficient to authorize a user or whether biometrics would be required.

Response. We do not believe that it is appropriate to specify, as a condition of certification, the types of factors that users could utilize to authenticate themselves.

Section 170.302(u)—Encryption

Meaningful use Stage 1 objective	Meaningful use Stage 1 measure	Certification criterion
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 and correct identified security deficiencies as part of its risk management process.	Interim Final Rule Text: (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). Final Rule Text: § 170.302(u). *General encryption.* Encrypt and decrypt electronic health information in accordance with the standard specified in § 170.210(a)(1), unless the Secretary determines that the use of such algorithm would pose a significant security risk for Certified EHR Technology. § 170.302(v). *Encryption when exchanging electronic health information.* Encrypt and decrypt electronic health information when exchanged in accordance with the standard specified in § 170.210(a)(2).

Comments. A number of commenters stated that transmissions of health information over leased or private network lines should not be subject to the encryption of data in transit requirement.

Response. Certified EHR Technology must include the capability to encrypt and decrypt information regardless of the transmission method used. This certification criterion and related standard do not specify the circumstances under which encryption and decryption must be performed; they simply require the capability. If an eligible professional or eligible hospital determines that encryption is an appropriate and necessary safeguard, we believe that Certified EHR Technology should provide the capability to

implement encryption. Overall, we want to ensure that Certified EHR Technology is capable of assisting eligible professionals and eligible hospitals to implement more secure technical solutions if they determine, based on their risk analysis, that technical safeguards such as encryption are reasonable and appropriate, or required.

Comment. One commenter requested further clarification of the phrase "encrypted and integrity protected link." Several commenters recommended that Transport Layer Security (TLS) ought to be specifically named as a required protocol. Other commenters also expressed concern that unless TLS is explicitly named, all example protocols would be required to be supported.

Response. The example list of protocols that would meet the certification criterion is not intended to be exhaustive or suggest that Complete EHRs or EHR Modules must be capable of using all of the listed protocols to be certified. The example list of protocols in the Interim Final Rule was included solely for illustrative purposes. We have, however, consistent with the way we have restructured the regulatory text for some standards (to better associate them with the adopted certification criterion that reference them), modified this standard to simply express that the standard is any encrypted and integrity protected link.

Comments. Several commenters suggested replacing the functional description of the encryption standard with a specific reference to FIPS 140–2. These commenters also noted that HHS had included such a reference in an update to its guidance specifying the technologies and methodologies that render protected health information unusable, unreadable, or indecipherable that was included in the Breach Notification for Unsecured Protected Health Information Interim Final Rule, published on August 24, 2009 (74 FR 42740), and further, requested that we make our standard consistent with this guidance. Some commenters explicitly recommended that AES be specified as the encryption algorithm standard.

Response. We have considered these commenters' points and have decided to revise our adopted standard to be more flexible regarding the encryption algorithms we permit EHR Technology to implement to be certified. We have also sought to clarify how our adopted standard relates to the guidance included in the breach notification interim final rule. We have revised the general encryption standard to read as follows: "Any encryption algorithm identified by the National Institute of Standards and Technology (NIST) as an approved security function in Annex A of the Federal Information Processing Standards (FIPS) Publication 140–2."

The National Institute of Standards and Technology (NIST) published Federal Information Processing Standards (FIPS) Publication 140–2 to specify the security requirements for cryptographic modules. As part of FIPS 140–X conformance, NIST publishes "annexes" of different "approved" security protocols. For purposes of encryption, NIST maintains "Annex A" which identifies "approved security functions." Annex A identifies both symmetric and asymmetric key encryption algorithms that NIST has identified for use in accordance with FIPS 140–2. In response to commenters' concerns, we believe that leveraging NIST's work in this area provides for a clearer requirement for compliance and provides Complete EHR and EHR Module developers with the ability to use one or more secure encryption algorithms for the purposes of demonstrating compliance with this certification criterion. We believe this flexibility will benefit eligible professionals and eligible hospitals because they may be able to leverage a broader suite of secure encryption algorithms. As noted in Special Publication 800–111, which is specified in the guidance included in the breach notification interim final rule for the encryption of data at rest, "[w]henever possible, AES should be used for the encryption algorithm because of its strength and speed."

We point out that the adopted certification criterion identifies certain discretionary authority that the Secretary is retaining with respect to acceptable encryption algorithms. We have adopted the list of approved encryption algorithms that NIST has identified and referenced in FIPS 140–2 Annex A, which is being incorporated by reference. While the list is intended to be current, we anticipate that NIST will on an as-needed basis revise and update the list, based on the development of new technologies or perhaps on identified vulnerabilities associated with a particular algorithm. Regardless of any revisions to this list by NIST, this version of Annex A that is incorporated by reference will remain effective for purposes of serving as the adopted encryption standard. With that said, if the Secretary determines that one of the listed encryption algorithms poses a significant security risk for Certified EHR Technology, the Secretary will notify the public on the Department's Web site (and perhaps with some time delay in the **Federal Register**), and will direct ONC–ATCBs or ONC–ACBs not to test and certify Complete EHRs and EHR Modules according to the specified compromised algorithm. The Department would then follow-up with rulemaking as necessary and appropriate to update the adopted list of acceptable encryption algorithms.

Comments. Many commenters expressed concerns that the rule would require the encryption of data at rest. One commenter recommended that encryption not be a required functionality of EHR systems, but defined as limited to devices. Some commenters stated that requiring EHR systems to be capable of encryption would hinder adoption.

Response. We require that Certified EHR Technology must be capable of encrypting electronic health information. We do not specify the policies surrounding the use of encryption by an eligible professional or eligible hospital nor do we specify that it should only apply to devices. Rather we intend for Certified EHR Technology to be technologically capable of encryption, thereby allowing, if desired or required, an eligible professional or eligible hospital who adopts Certified EHR Technology to use this capability. We disagree that requiring Certified EHR Technology be capable of encryption would hinder adoption. To the contrary, we believe that Certified EHR Technology capable of encrypting electronic health information will be desired, especially in light of the new breach notification requirements established by the HITECH Act and the Breach Notification for Unsecured Protected Health Information Interim Final Rule. We also take this opportunity to make a technical correction to this certification criterion. We inadvertently combined both encryption capabilities under the same paragraph and per our reaffirmed interpretation expressed in the Temporary Certification Program, we believe that the scope of one certification criterion starts at the first paragraph level and includes all subparagraphs. As a result, we view these as two distinct capabilities and have created a separate certification criterion for each.

Comments. One commenter stated that the security requirements, particularly for encryption, are lower than the security standards it already meets. This commenter consequently believes that our adoption of this standard would require it to reduce the security of its products. Another commenter stated that encryption technology should not be integrated into an EHR product, but should instead be implemented through other means as

part of the system on which an EHR may be installed.

Response. We believe that Certified EHR Technology must be capable of performing encryption. Because of the flexibility in the adopted standard, however, how encryption is technically implemented is up to the Complete EHR or EHR Module developer to determine within the parameters of Annex A of FIPS 140–2. Given the changes we have made to the general encryption standard, we believe that the full range of the most secure encryption algorithms are available for Complete EHR and EHR Module developers to implement.

Comments. A few commenters stated that the term "user-defined preferences" in the certification criteria was too vague and allowed too much latitude for divergent interpretations of the requirement. Other commenters noted that users do not always get to define such preferences as they would conflict with overarching organizational policies.

Response. We intended the phrase, "according to user-defined preferences" in the Interim Final Rule, to mean that users would have the ability to elect when they wanted encryption to occur, for example, at log-off. We recognize that organizational policies, software as service models and other architectures in which Certified EHR Technology may be implemented, could lead to encryption being instituted in significantly different ways and, as a result, we have removed the reference to "user-defined preferences."

Section 170.302(v)—Accounting of Disclosures

Meaningful use Stage 1 objective	Meaningful use Stage 1 measure	Certification criterion
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 and correct identified security deficiencies as part of its risk management process.	Interim Final Rule Text: Record disclosures made for treatment, payment, and health care operations in accordance with the standard specified in § 170.210(e). Final Rule Text: § 170.302(w). Certification criterion made optional, while the text of this certification criterion remains unchanged.

Comments. Many commenters asserted that the certification criterion and accompanying standard for accounting of disclosures for treatment, payment, and health care operations (as these terms are defined at 45 CFR 164.501) would be a resource intensive process and too administratively, technically, and financially burdensome. A large portion of commenters further conveyed specific challenges including: The ability to differentiate between a "use" and a "disclosure" (as these terms are defined at 45 CFR 160.103); storing three years worth of disclosures, which many noted could be voluminous; that health care providers, especially hospitals, have decentralized systems, which today are manually accessed to create an accounting of disclosures; the development time for such a capability would take more time than is available before the meaningful use Stage 1 effective date; that it would be difficult to account for these types of disclosures in real-time without a code set for disclosures; that this requirement could affect workflow; and the scope of electronic exchanges that the term "disclosure" would encompass is unclear. A majority of commenters also echoed that the Secretary should use discretion provided by the HITECH Act to delay the compliance date for accounting of disclosures for treatment, payment, and health care operations. Commenters supported this suggestion by pointing out that the Secretary has not yet formally established the policies for accounting of disclosures. They explained that the HITECH Act requires the Secretary to promulgate a rule no later than six months *after* the Secretary has adopted a standard for accounting of disclosures, which has not yet occurred. Many of these commenters suggested that the certification criterion and standard should be removed or their adoption delayed until after the technical specifications for accounting of disclosures can be harmonized with the Secretary's forthcoming promulgation of a regulation on this issue. Other commenters noted that the HIT Policy Committee included accounting of disclosures in its suggestions as a meaningful use Stage 3 objective. In response to the questions we posed, several commenters noted that to whom the disclosure was made (recipient) should be an important element included in an accounting of disclosures. One commenter noted that the standard should be the same as what is currently applicable to disclosures that are not for treatment, payment, and health care operations and cited the requirements at 45 CFR 164.528(b)(2). Other commenters stated that the adopted certification criterion should be an audit log.

Response. We appreciate the thoroughness, specificity, and detail provided by many of those who commented on this certification criterion. We recognize that significant technical and policy challenges remain unresolved. Accordingly, we do not believe that the capability to account for disclosures should be a condition of certification at the present time. As discussed in the beginning of the preamble of this final rule, we have decided to make this certification criterion "optional" instead of removing it. Additionally, the standard will remain unchanged as currently worded and as applicable to the certification criterion to provide guidance to Complete EHR and EHR Module developers that choose to adopt this capability at this time. As an optional certification criterion, though, Complete EHR or EHR Module will not be required to possess the capability for certification. As we stated previously in the Interim Final Rule, we plan to work collaboratively with the Office for Civil Rights (OCR) as it develops the regulatory policy related to this requirement. We anticipate updating this certification criterion and the related standard in a future rulemaking to reflect OCR's final policies regarding accounting of disclosures.

Comment. Several commenters requested that we clarify what is meant by a "description of the disclosure." Some commenters noted that it would not be possible to include these descriptions in an accounting without code sets for the various types of disclosures. These commenters also indicated that this requirement could have serious workflow implications unless it can be fully automated.

Response. We recognize the technological challenges associated with effectively and efficiently addressing this aspect of the standard which some commenters mentioned. We also recognize that the regulated community is awaiting the proposed rule and subsequent final rule that will implement important privacy provisions

of the HITECH Act. As we discussed in the Interim Final Rule, we intended to leave Complete EHR and EHR Module developers with the flexibility to innovate in this area and to develop new solutions to address the needs of their customers. We anticipated that a "description of the disclosure" would, at the present time, be a free text field that would have included any information that could be readily and electronically associated with the disclosure. For example, we envisioned that some descriptive information could be included such as the words "treatment," "payment," or "health care operations" separately or together as a general category. We also assumed that Complete EHR and EHR Module developers could find innovative ways to associate certain electronically available information with the disclosures, such as, to whom the disclosure was made. Again, for the time being, we have made this certification criterion optional, and will wait for OCR to promulgate final regulations for accounting of disclosures, before revisiting whether this certification criterion should be required.

b. Specific Certification for Complete EHRs or EHR Modules Designed for an Ambulatory Setting—§ 170.304

Section 170.304(a)—Computerized Provider Order Entry

Meaningful use Stage 1 objective	Meaningful use Stage 1 measure	Certification criterion
Use CPOE for medication orders directly entered by any licensed healthcare professional who can enter orders into the medical record per state, local and professional guidelines.	More than 30% of unique patients with at least one medication in their medication list seen by the EP or admitted to the eligible hospital's or CAH's inpatient or emergency department (POS 21 or 23) have at least one medication order entered using CPOE.	Interim Final Rule Text: 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. Final Rule Text: § 170.304(a). *Computerized provider order entry.* Enable a user to electronically record, store, retrieve, and modify, at a minimum, the following order types: (1) Medications; (2) Laboratory; and (3) Radiology/imaging.

Comments. A couple of commenters noted that within the confines of many hospitals, just about any "order" can be entered, so the process of order entry is defined. For providers, the commenter noted that the ability to perform orders varies. The commenter inquired whether a specific meaning for order entry was intended for this certification criterion. A few commenters supported the certification criterion. One commenter recommended that referrals to dieticians, speech therapists, child life and social services be added to the order types, as well as durable medical equipment, orthotics, and prosthetics. Another commenter recommended that CPOE include a Patient Plan of Care (PPOC) because, according to the commenter, PPOC requires the content necessary for electronic data interoperability. The commenter felt that PPOC within an EHR would help to achieve the integration goals that promote the appropriate exchange of medical information for the optimal coordination of patient care in different healthcare settings. Another commenter suggested that we narrow the CPOE requirements to focus on medications, laboratory tests, and imaging tests. One commenter stated that based on the discussions of CPOE in the Interim Final Rule and the Medicare and Medicaid EHR Incentive Programs proposed rule, we should consider a request for a consultation or a provider referral made by an eligible professional in a private practice to constitute an order that should be handled functionally through CPOE.

Response. We agree with the commenter that suggested that we narrow our focus, in order to reduce the burden associated with this certification criterion. Accordingly, we have removed "provider referrals" from the certification criterion. Complete EHR and EHR Module developers may include additional orders as they see fit and as recommended by some commenters, however in order to be certified they must include at a minimum the three order types (medications, laboratory, and radiology/imaging) specified in the certification criterion. Many commenters generally supported these three specified order types and we note that while the final meaningful use Stage 1 objective focuses on medication orders, we believe that for the purposes of certification and to equip eligible professionals with a basic set of ordering capabilities, it is appropriate to continue to maintain these three order types. (This response also applies to the change we made in the CPOE certification criterion for Complete EHRs or EHR Modules designed for an inpatient setting). Finally, in further reviewing this certification criterion in light of comments received, we have also determined that it would be appropriate and clearer to replace the term "manage" with "modify" to be more consistent with the terminology used in other certification criteria. We have also made this change in the CPOE certification criterion for Complete EHRs and EHR Modules designed for an inpatient setting.

Comment. A commenter stated that the lab industry does not have any standards for order entry, and even among lab providers, their operating units utilize different standards. The commenter contended that this lack of consistency in order entry would require EHRs to build custom interfaces to every lab. They recommended that we require that Certified EHR Technology provide the ability to link the results to the original order. Another commenter recommended that the certification criterion include the requirement for standardized bi-directional laboratory interfaces, including functionality pertinent to all the laboratory order data needed for the laboratory to conduct proper testing, patient matching and billing (including limited coverage rules and printing of Advance Beneficiary Notices (ABNs)).

Response. In the certification criterion discussed above regarding incorporating laboratory test results, we have required that Certified EHR Technology be capable of electronically attributing, associating, or linking a laboratory test result to a laboratory order or patient record. Bidirectional exchange (including electronic transmission of

laboratory orders) is not a requirement of meaningful use Stage 1 and is beyond the scope of this rule.

Comments. Several commenters recommended we clarify that the user of CPOE includes the eligible professional and any authorized user in the office of the eligible professional (EP). They also recommended that CPOE be deemed to include the scenario in which only the actual orders are entered by the EP, with the additional billing and demographic information entered by authorized users in the EP's office or even by third parties (*e.g.* laboratory personnel in the patient service center of a laboratory that collects specimens from the patient).

Response. As we stated in an earlier response, the standards, implementation specifications, and certification criteria adopted in this final rule apply to Complete EHRs and EHR Modules. We have focused on whether Certified EHR Technology must include a capability and how it must perform the capability. As a result, it is not within the scope of this rulemaking to specify the persons who would need to use CPOE.

Comment. A commenter suggested that we not create controlled vocabularies or value sets in the regulation but rather refer to and adopt existing controlled vocabularies or subsets. The commenter also stated that the regulation introduces a requirement to record, store, retrieve and manage orders, though no vocabularies are specified and further pointed out that there are no vocabularies or standards for orders, images, or referrals in any part of the Interim Final Rule. The commenter recommended that the Department focus its efforts on identifying and adopting standards for computable and interoperable representations of these elements and processes before directing eligible professionals to implement "CPOE."

Response. We appreciate the commenter's concern. This is an initial set of standards, implementation specifications, and certification criteria and we expect to adopt more standards, implementation specifications, and certification criteria in the future as necessary to improve the comprehensiveness of certain capabilities.

Comment. A commenter requested that we clarify whether only imaging and radiology reports were intended to be included in this capability, or, if we intended to include the images themselves in addition to the imaging reports as part of the certification criteria. The commenter recommended that we further clarify the criterion and moreover, adopt the DICOM standard in the initial set of standards, as an essential step in meeting the CPOE capability.

Response. We clarify that the adopted certification criteria related to CPOE pertain only to the ordering, and not to the delivery of results (reports or images). As a result, we do not believe that this commenter's recommendation is applicable to this certification criterion.

Comment. A commenter recommended that the CPOE certification criterion should include a prompt for an authorized user of the CPOE to include diagnosis codes at order entry.

Response. We do not believe that it would be appropriate to specify this type of capability as a condition of certification because it is not central to the meaningful use objective and measure this certification criterion is intended to support.

Section 170.304(b)—Electronically Exchange Prescription Information

Meaningful use Stage 1 objective	Meaningful use Stage 1 measure	Certification criterion
Generate and transmit permissible prescriptions electronically (eRx).	More than 40% of all permissible prescriptions written by the EP are transmitted electronically using certified EHR technology.	Interim Final Rule Text: Enable a user to electronically transmit medication orders (prescriptions) for patients in accordance with the standards specified in § 170.205(c). Final Rule Text: § 170.304(b). *Electronic prescribing.* Enable a user to electronically generate and transmit prescriptions and prescription-related information in accordance with: (1) The standard specified in § 170.205(b)(1) or § 170.205(b)(2); and (2) The standard specified in 170.207(d).

Comments. Many commenters supported the adoption of NCPDP SCRIPT 8.1 and the inclusion of NCPDP SCRIPT 10.6. These commenters also encouraged the exclusive adoption of NCPDP 10.6 for meaningful use Stage 2. One commenter stated that more clarification was needed as to which NCPDP SCRIPT standard was required for certification.

Response. In the Interim Final Rule, we stated that we expected that CMS would identify as a backwards compatible standard NCPDP SCRIPT 10.6 and permit its use as an alternative to NCPDP SCRIPT 8.1 for the electronic transmission of prescription and certain other prescription-related information for Medicare Part D covered drugs prescribed for Part D eligible individuals (75 FR 38026). Further, we stated that "if SCRIPT 10.6 is permitted, prior to any modification of the provisions of this interim final rule in response to public comment, we would expect to change our requirement to simply permit either SCRIPT 8.1 or SCRIPT 10.6." Accordingly, we have modified this certification criterion to specify that Complete EHR and EHR Module developers may seek to have their Complete EHR or EHR Module tested and certified to either solely NCPDP SCRIPT 8.1 or 10.6. Additionally, we have also replaced the standard adopted in the Interim Final Rule and have adopted both NCPDP SCRIPT 8.1 and NCPDP SCRIPT 10.6. As discussed in the beginning of the preamble, we have revised our approach to specifying the certification criteria to more clearly focus on the capabilities with which they must be associated. Therefore, we have modified this certification criterion to specify that a Complete EHR or EHR Module would be compliant with this certification criterion if it has the capability of generating and transmitting prescription and prescription-related information according to NCPDP SCRIPT 8.1 while also using the adopted vocabulary standard, or if it is capable of generating and transmitting prescriptions and prescription-related information according to NCPDP SCRIPT 10.6 while also using the adopted vocabulary standard.

Comments. Several commenters supported the adoption of RxNorm and the use of RxNorm code sets as a vocabulary standard. One commenter recommended that RxNorm be adopted

in Stage 1 while one commenter stated that Stage 2 is likely the earliest timeframe practicable for implementation. Others suggested that more testing was needed before RxNorm could be adopted in full. Some commenters stated that RxNorm is not complete and requested guidance on how gaps in RxNorm will be addressed. A couple commenters stated a concern that current drug databases do not map to RxNorm and that in order to develop interfaces for electronic prescribing services, pharmacies and developers will need to expend significant effort. Other commenters stated that more clarification was needed with respect to the description of the adopted standard and one of those commenters recommended that the description be changed to "a drug data source provider that demonstrates group domain comprehensiveness."

Response. We have consolidated and addressed our adopted vocabulary standard for medications under this certification criterion. However, our response and subsequent clarifications are applicable to all certification criteria that reference this vocabulary standard.

As we explained in the Interim Final Rule, we determined that the HIT industry would benefit from a certain degree of flexibility with respect to the coding of medications. To provide this flexibility while also establishing a glide path to full adoption of RxNorm, we adopted a standard that permits the use of one of many different vocabulary standards. We specified that a Complete EHR or EHR Module would be compliant with the adopted vocabulary standard if it utilized "[a]ny 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." We specified the standard this way in order to establish what we believe is an important bridge to full RxNorm adoption and will help facilitate this transition over time. Our adoption of this standard stems from our belief that Complete EHRs and EHR Modules should be capable of classifying and categorizing medications for the purpose of clinical quality measurement and clinical decision support. The National Library of Medicine (NLM) maintains the Unified Medical Language System® (UMLS®), which contains the mapping between RxNorm and commonly utilized drug vocabularies.

At the time we published the Interim Final Rule, we noted that NLM, according to the most recent RxNorm release, listed a number of RxNorm drug data source providers with complete data sets integrated within RxNorm. After the Interim Final Rule was published, NLM subsequently released several more RxNorm versions. NLM has also reorganized the RxNorm documentation in a way that we believe more clearly specifies the intent of our standard. Accordingly, we believe that this standard, particularly in response to public comments, can be further clarified. In addition, to permit the development or mapping and use of other vocabularies independent of NLM, we have dropped the requirement that NLM explicitly identify the acceptable data sources. Instead, the standard now permits the use of codes from any drug vocabulary successfully included in RxNorm. To provide guidance and clarification to the industry, we will recognize any source vocabulary that is identified by NLM's RxNorm Documentation as a source vocabulary included in RxNorm. We are therefore revising the standard to state: "Any source vocabulary that is included in RxNorm, a standardized nomenclature for clinical drugs produced by the United States National Library of Medicine." We note that in section 3.1, of the most recent release of the "RxNorm Documentation (06/07/10, Version 2010–3) [7]," NLM has identified the following source vocabularies as being included in RxNorm.

- GS—Gold Standard Alchemy.
- MDDB—Medi-Span Master Drug Data Base.
- MMSL—Multum MediSource Lexicon.
- MMX—Micromedex DRUGDEX.
- MSH—Medical Subject Headings (MeSH).
- MTHFDA—FDA National Drug Code Directory.
- MTHSPL—FDA Structured Product Labels.
- NDDF—First DataBank NDDF Plus Source Vocabulary.
- NDFRT—Veterans Health Administration National Drug File—Reference Terminology.
- SNOMED CT—SNOMED Clinical Terms (drug information).
- VANDF—Veterans Health Administration National Drug File.

We clarify for commenters that the standard we have adopted is a functional standard that enables the use of any source vocabulary that is included within RxNorm. Consequently, any one of these "source vocabularies" identified by NLM may be used, or any other source vocabulary successfully included within RxNorm.

Comments. A few commenters stated concerns about this certification criterion causing two different workflows because of the restrictions placed on the electronic prescribing of controlled substances.

Response. The Drug Enforcement Agency has since published an interim final rule (75 FR 16236) on the requirements related to the electronic prescribing of controlled substances. At the present time, we do not require as a condition of certification for Complete EHRs and EHR Modules that they be capable of enabling compliance with the current DEA provisions for the electronic prescribing of controlled substances.

Comments. A couple of commenters stated that the prescribing capabilities must allow for weight-based dosing calculation with intelligent rounding and that without this, e-prescribing will not be helpful to pediatricians.

Response. We recognize that this is an important capability for pediatricians; however, we do not believe that it necessary to require it as a condition of certification at the present time. Again, this does not preclude Complete EHR and EHR Module developers from including this capability.

Comments. A few commenters expressed concerns about some pharmacies not being capable of receiving electronic prescriptions which they stated could cause a negative impact on the workflow. One commenter suggested that we add a "where possible" to the certification criterion.

Response. While we recognize that some pharmacies may be unable to receive electronic prescriptions at the present time, we do not believe this limitation should affect the capability that Certified EHR Technology must provide. Further, we do not believe that inserting "where applicable" would be beneficial because it would make the criterion unnecessarily ambiguous. This phrase would relate to when electronic prescribing should be conducted, not how it should be done, which is the focus of this certification criterion.

Comment. A commenter stated that the electronic prescribing process should be linked to the contraindication and formulary conflict process and should provide automatic alerts. Another commenter recommended that information relating to the language the patient speaks should be required as part of the electronic prescribing process, so that pharmacy is notified of a patient's need for language assistance.

Response. We do not believe that it would be appropriate to expand the certification criterion as suggested at this time. This does not preclude a Complete EHR or EHR Module

[7] *http://www.nlm.nih.gov/research/umls/rxnorm/docs/2010/rxnorm_doco_full_2010–3.html.*

developer from pursuing other ways to optimize how a Complete EHR or EHR Module may function.

Section 170.304(c)—Record Demographics

Meaningful use Stage 1 objective	Meaningful use Stage 1 measure	Certification criterion
Record demographics: • preferred language • gender • race • ethnicity • date of birth	More than 50% of all unique patients seen by the EP or admitted to the eligible hospital's or CAH's inpatient or emergency department (POS 21 or 23) have demographics recorded as structured data	Interim Final Rule Text: Enable a user to electronically record, modify, and retrieve patient demographic data including preferred language, insurance type, gender, race, ethnicity, and date of birth. Final Rule Text: § 170.304(c). *Record demographics.* Enable a user to electronically record, modify, and retrieve patient demographic data including preferred language, gender, race, ethnicity, and date of birth. Enable race and ethnicity to be recorded in accordance with the standard specified at 170.207(f).

Comments. Several commenters recommended that we adopt the OMB race and ethnicity codes.

Response. We agree with these commenters and have adopted the OMB race and ethnicity codes. In the Medicare and Medicaid EHR Incentive Programs proposed rule (75 FR 1855), CMS stated that race and ethnicity codes should follow current Federal standards. We note that the OMB race and ethnicity codes constitute a government-unique standard for the purposes of the National Technology Transfer and Advancement Act of 1995 (NTTAA). We have adopted this standard because it provides an easily understood structure and format for electronically transmitting the data elements identified in the meaningful use Stage 1 objective, the standard is readily available, in general it provides the best standard to use to support our policies goals. Moreover, we are unaware of any alternative voluntary consensus standard that accomplishes the same purpose.

Comments. Several commenters recommended additional elements for the certification criterion for us to consider adding. One commenter recommended that we include more demographic data items to allow successful matching with prior admissions and further that we consider requiring the inclusion of social security number, birthplace, and years of education, if available. A couple commenters requested that we add occupation and industry status as well because they are already required for cancer registries. Another commenter suggested that we add family history to demographics that should be captured and reported. One commenter suggested that we also include a patient's functional status. Many commenters suggested that we encourage self-reporting of demographics and indicate whether information was self-reported. Finally, one commenter stated that EHRs are not appropriate source of legal documentation for births and deaths.

Response. While we understand commenters' intentions, we do not believe that it would be appropriate to expand this certification criterion beyond what is required to support meaningful use. Again, as we have previously stated, this does not preclude a Complete EHR or EHR Module developer from including the capability to record additional demographic information. Finally, consistent with the Medicare and Medicaid EHR Incentive Programs final rule, we have removed the capability to record insurance type from the certification criterion.

Section 170.304(d)—Generate Patient Reminder List

Meaningful use Stage 1 objective	Meaningful use Stage 1 measure	Certification criterion
Send reminders to patients per patient preference for preventive/follow up care	More than 20% of all unique patients 65 years or older or 5 years old or younger were sent an appropriate reminder during the EHR reporting period	Interim Final Rule Text: 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. Final Rule Text: § 170.304(d). *Patient reminders.* Enable a user to electronically generate a patient reminder list for preventive or follow-up care according to patient preferences based on, at a minimum, the data elements included in: (1) Problem list; (2) Medication list; (3) Medication allergy list; (4) Demographics; and (5) Laboratory test results.

Comments. Several commenters stated that they support this certification criterion. Other commenters requested further definition of the term "specific conditions," particularly whether this term refers to data as contained in the problem list. One commenter suggested that the criterion text be modified to read: "Electronically generate, upon request, a patient reminder list for preventive or follow-up care according to patient or physician preferences based on demographic data, specific conditions, and/or medication list." Several commenters requested further definition of the term "patient preferences." Clarification was requested about the meaning of the term, how these preferences would be recorded, how the preferences would be used, and whether the preferences should be automated. A question was raised by two commenters about how many choices should be allowed for the preferred reminder delivery method due to additional EHR system programming that may be

needed to support the set of choices. One commenter was concerned about whether there would be a cost to physician practices to implement this requirement and whether the practices will have the capacity to accommodate this requirement. Another commenter suggested that this requirement be moved to meaningful use stage 2 to allow more time for EHRs to be enhanced. Several commenters requested clarification of the term "upon request." One commenter wanted to know which persons would be authorized to request the patient reminder list and how often. Another commenter suggested that the phrase "upon request" be removed, as it believed that outpatient physicians could make significant advances in the health of their patients by generating and delivering reminders at every encounter.

Response. In response to comments, we have revised this certification criterion to more clearly articulate the capability we expect Certified EHR Technology to include. CMS discusses and clarifies the intended meaning of "patient preferences" in the Medicare and Medicaid EHR Incentive Programs final rule and because this term is derived from the meaningful use objective, we encourage commenters to review CMS's responses to their requests for clarification. Consistent with the revisions we made to the "generate patient lists" certification criterion, we believe that Certified EHR Technology should be able to leverage the information, specifically the structured data it had available to it, to assist eligible professionals and eligible hospitals generate a patient reminder list. We have removed "upon request" from the certification criterion, because, after further review, we believe that the action of requesting a list is implied by the certification criterion and the meaningful use measure, and therefore, unnecessary to further specify.

Comments. Two commenters stated that specialists will use patient reminders differently than primary care providers. These commenters worried that some patients' preferences may exceed a system's current capabilities and one commenter requested that the phrase "with respect to system capability" be added after "patient preferences."

Response. We understand these commenters' points of view, however, we do not believe that this addition is necessary given the references in the certification criterion to specified data elements and CMS's express desire to consider patient preferences as described in the Medicare and Medicaid EHR Incentive Programs final rule.

Comments. Two commenters asked whether this requirement refers to the creation of a list for the internal purposes of the eligible professional and his/her staff only and does not refer to or require electronic communication to a patient.

Response. Yes, we expect Certified EHR Technology to be capable of generating a patient reminder list for an eligible professional and his/her staff. The meaningful use measure establishes the requirement for an eligible professional to take action once the reminder list has been generated.

Comments. Two commenters suggested that the set of variables contained in the demographic information for the patient lists note the preferred language of the patient.

Response. Preferred language is included in demographics and we do not believe that it is necessary to expressly call it out as part of this certification criterion.

Section 170.304(e)—Clinical Decision Support

Meaningful use Stage 1 objective	Meaningful use Stage 1 measure	Certification criterion
Implement one clinical decision support rule relevant to specialty or high clinical priority along with the ability to track compliance that rule.	Implement one clinical decision support rule.	Interim Final Rule Text: *(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. Final Rule Text: § 170.304(e). *(1) Implement rules.* Implement automated, electronic clinical decision support rules (in addition to drug-drug and drug-allergy contraindication checking) based on the data elements included in: problem list; medication list; demographics; and laboratory test results. *(2) Notifications.* Automatically and electronically generate and indicate in real-time, notifications and care suggestions based upon clinical decision support rules.

Comments. Several commenters were explicitly supportive of this certification criterion, while others offered specific suggestions and requests for clarification. Several commenters requested that we specify the decisions support rules that should be included. One commenter asked if we could clarify whether a Complete EHR or EHR Module developer would have to include specific rules that individual eligible professionals would want or whether those rules could be added later. Another commenter asked for clarification regarding several terms including "diagnostic test results," whether a "condition" was equivalent to "problem," as well as whether the rules would be associated with quality measures.

Response. In consideration of commenters' request for clarification and to more closely align this certification criterion with the meaningful use measure, we have revised this certification criterion. We have removed the terms that caused some confusion with commenters and believe that these revisions will provide more specificity and will make

compliance with the certification criterion easier. Moreover, we clarify that with respect to notifications, that "real-time" means at the point of clinical decision making (*i.e.,* notifications must be provided when an eligible professional is using Certified EHR Technology and not run overnight and provided in the morning, for instance).

Comments. A number of commenters asked questions and requested clarifications regarding "alerts." One commenter requested whether it is the number of alerts that is important or the type of alerts that is important and how we expect an eligible professional to respond to an alert. The commenter also asked if we could clarify what would qualify as a "response." One commenter stated that whether we intended for the examples (pop-up or sound) to be inclusive of the types of alerts we expected Certified EHR Technology would include and whether this was deemed more valuable than a more passive notification. The commenter suggested that the word "alert" be replaced with "notification" while another suggested the word "advisory." Some commenters requested clarification regarding "alerts responded to by a user" and whether there was an expectation that alerts communicate structured reasons. These commenters also asked whether users would enter a reason for any overrides or, in the case of notifications, the user would simply acknowledge the alert by clicking "OK." The commenters also questioned whether ignored alerts should be tracked? Many of these commenters recommended removing § 170.304(e)(3). Alternatively, one commenter recommended that we not only consider the number of alerts "responded to" but also the action prompted and whether or not that action was taken.

Response. We thank commenters for the thorough feedback on this certification criterion. We have already addressed in our responses above the concerns raised by commenters and will not repeat them here. With respect to the third part of this certification criterion, we have considered public comment and have decided to remove the requirement from the certification criterion. We also removed this requirement to be more consistent with CMS's expectations for meaningful use, which do not include requiring the tracking of alerts at this time.

Comments. A few commenters asked for clarification on what we meant by "evidence grade" and what standard for evidence grading will be applied in order to determine compliance with this objective. Other commenters noted that "evidence grade" as a part of the rules to trigger alerts is not widely available in the marketplace and that using evidence grade in this manner could be burdensome and present a significant maintenance issue.

Response. We have considered public comment, and agree that evidence grade is not as widely available in the marketplace as we had anticipated. We therefore remove our reference to "evidence grade" in the certification criterion.

Section 170.304(f)—Electronic Copy of Health Information

Meaningful use Stage 1 objective	Meaningful use Stage 1 measure	Certification criterion
Provide patients with an electronic copy of their health information (including diagnostic test results, problem list, medication lists, medication allergies), upon request.	More than 50% of all patients of the EP or the inpatient or emergency departments of the eligible hospital or CAH (POS 21 or 23) who request an electronic copy of their health information are provided it within 3 business days.	Interim Final Rule Text: 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). Final Rule Text: § 170.304(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, and medication allergy list in: (1) Human readable format; and (2) On electronic media or through some other electronic means in accordance with: (i) The standard (and applicable implementation specifications) specified in § 170.205(a)(1) or § 170.205(a)(2); and (ii) For the following data elements the applicable standard must be used: (A) *Problems.* The standard specified in § 170.207(a)(1) or, at a minimum, the version of the standard specified in § 170.207(a)(2); (B) *Laboratory test results.* At a minimum, the version of the standard specified in § 170.207(c); and (C) *Medications.* The standard specified in § 170.207(d).

Comment. A commenter recommended that durable medical equipment and supplies be added to the minimum list.

Response. In the context of the Meaningful Use Stage 1 objective and measure, we do not believe that it is appropriate, at the present time, to add durable medical equipment in the certification criterion. However, that does not preclude Complete EHRs and

EHR Modules from having that additional capability.

Comments. A few commenters requested clarification as to the underlying intent of the certification criterion and whether it was intended that a patient be provided with a complete medical record or simply a "snapshot." Commenters also asked how longitudinal the copy must be and requested that we specify a time period that the electronic copy must cover. A commenter stated that eligible professionals should be able to limit the applicable time period by episode of care or other parameters. The commenter noted that state law also specifies the information that can be provided to a patient without the provider serving as an intermediary. A few commenters requested clarification that the medication list is limited to the current medication list. A commenter recommended that the certification criterion be limited only to information readily available to the provider at the conclusion of a patient encounter.

Response. We expect Certified EHR Technology to be capable of generating an electronic copy of health information that includes the minimum elements required as a condition of certification. We do not believe that it is appropriate to dictate the timeframe such information must encompass, but we would expect that it would include, at a minimum, the most current information that is available and accessible within the Certified EHR Technology. We do not believe that limiting this certification criterion to specify that just the information available at the end of an encounter is consistent with our policy objectives.

Comments. Many commenters requested a definition of "diagnostic test results." One commenter suggested that for Stage 1, the definition of diagnostic test result be made clear and be limited to, at a minimum, lab results.

Response. This term is derived from the Medicare and Medicaid EHR Incentive Programs final rule, and its meaning is described there. We encourage commenters to review the Medicare and Medicaid EHR Incentive Programs final rule.

Comments. Several commenters requested that ONC define how relevant procedures are determined for the certification criterion. The commenters suggested that a subset of procedures (*e.g.,* surgeries, catheterizations) be defined to avoid generating huge lists of "small" procedures (*e.g.,* venipunctures). These commenters expressed that it was critical for the rule to provide a clear, clinically-relevant definition of which types of procedures are to be included.

Response. We appreciate the comment and have revised this certification criterion to remove "procedures" as well as "immunizations," to be more consistent with the final meaningful use objective and measure and for greater clarity.

Comment. A commenter requested clarification on how an electronic copy will be disseminated, and provided examples such as a web-portal, e-mail, and compact disc.

Response. We do not specify the method by which an individual must receive an electronic copy of the specified health information, only that Certified EHR Technology be capable of electronically generating an electronic copy in human readable format and in accordance with one of the adopted summary record standards. While Certified EHR Technology must be capable of creating an electronic copy of a patient's health information as specified in this certification criterion, we encourage Complete EHR and EHR Module developers to also include the capability to generate an electronic copy in a manner that allows eligible professionals (and eligible hospitals as this capability relates to Complete EHRs and EHR Modules designed for an inpatient setting) to comply with applicable provisions of the HIPAA Privacy and Security Rules.

Comment. A commenter requested that we add a requirement for alerts to prompt users to ask patients if they want a copy of their health information and include the ability to record whether the information was actually provided and the patient's preference on the format of the information. The commenter believed that this requirement is necessary because many patients are not aware that they can make such a request.

Response. While potentially useful as a reminder, we do not believe that this capability should be a condition of certification. This capability would exceed the scope of the relevant meaningful use Stage 1 objective and measure. We also note that Complete EHR and EHR Module developers are not precluded from including this capability in their EHR technology.

Comment. A commenter noted that with our emphasis on the representation of clinical information in the format of a CCD or CCR, it is unclear whether the certification criterion is enough to meet patients' expectations.

Response. We recognize that this minimum information may not satisfy every patient's interests, however, we believe that the information specified represents a core set of information that most patients will appreciate is more readily accessible to them.

Comment. A commenter requested clarification on the use of the word "and" in the certification criterion and questioned whether it suggested that the Certified EHR Technology must generate two outputs to produce an electronic copy (*i.e.,* a copy in human readable format and a copy as a CCD or CCR). The commenter made this inquiry because it believed that the certification criterion could be met through the production of a CCD or CCR with an appropriate style sheet. Additionally, a commenter stated that it is unclear whether the electronic copy of the health information provided to patients must be in a CCD or CCR format for Stage 1 or if alternative formats are allowed. This commenter recommended that we clarify and distinguish between the electronic medium carrying the information and the content enclosed.

Response. Yes, in order to meet this certification criterion, Certified EHR Technology must be able to generate an electronic copy that is in human readable format and as a CCD or CCR. If Certified EHR Technology is capable of generating one copy that could meet both of these requirements, we would consider that to be a compliant implementation of this capability.

Section 170.304(g)—Timely Access

Meaningful use Stage 1 objective	Meaningful use Stage 1 measure	Certification criterion
Provide patients with timely electronic access to their health information (including lab results, problem list, medication lists, medication allergies) within four business days of the information being available to the EP.	More than 10% of all unique patients seen by the EP are provided timely (available to the patient within four business days of being updated in the certified EHR technology) electronic access to their health information subject to the EP's discretion to withhold certain information.	Interim Final Rule Text: 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. Final Rule Text: § 170.304(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, and medication allergy list.

Comments. Many commenters suggested that we should replace the word "online" with "electronic" to be more clearly aligned with meaningful use and to not preclude other forms of legitimate electronic access.

Response. We disagree. The purpose and intent of this certification criterion and its associated meaningful use objective and measure (as clarified in the Medicare and Medicaid EHR Incentive Programs final rule) is to ensure that patients have the ability to access their health information when they see fit to do so. Accordingly, referring to "electronic" in this certification criterion would not ensure that Certified EHR Technology provides the desired capability.

Comments. A few commenters asked for clarification on the meaning of "procedures" and type of results to be listed in the electronic copy, for example, lab test results, problem list, medication lists, or others specified by the eligible professional.

Response. As discussed above, we have revised this certification criterion to remove "procedures" as well as "immunizations," to be more consistent with the final meaningful use objective and measure.

Section 170.304(h)—Clinical Summaries

Meaningful use Stage 1 objective	Meaningful use Stage 1 measure	Certification criterion
Provide clinical summaries for patients for each office visit.	Clinical summaries provided to patients for more than 50% of all office visits within 3 business days.	Interim Final Rule Text: (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). Final Rule Text: § 170.304(h). *Clinical summaries.* 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, and medication allergy list. If the clinical summary is provided electronically it must be: (1) Provided in human readable format; and (2) Provided on electronic media or through some other electronic means in accordance with: (i) The standard (and applicable implementation specifications) specified in § 170.205(a)(1) or § 170.205(a)(2); and (ii) For the following data elements the applicable standard must be used: (A) *Problems.* The standard specified in § 170.207(a)(1) or, at a minimum, the version of the standard specified in § 170.207(a)(2); (B)*Laboratory test results.* At a minimum, the version of the standard specified in § 170.207(c); and (C) *Medications.* The standard specified in § 170.207(d).

Comments. Several commenters requested that "diagnostic test results" be further defined, with one commenter suggesting that lab results be the minimum and other commenters suggesting a more comprehensive list, including diagnostic imaging results. Many commenters requested clarification on the list of procedures and asked whether this would include only procedures in a recent hospitalization or historically all procedures performed on the patient. One commenter questioned why immunization data appeared in the list

and believed its inclusion was inconsistency with the other items.

Response. We have made revisions to this certification criterion consistent with the changes that we have already discussed above, including the removal of certain terms.

Comment. One commenter expressed concern that patient summaries are most useful when the patient/family literacy and the context of the health and follow-up care are taken into consideration. The commenter noted further that as written there is little flexibility in this certification criterion and that many patients will be overwhelmed with technical data that comes with little context for understanding it.

Response. We understand the commenter's point; however, we do not believe that certification (which will validate whether a Complete EHR or EHR Module can perform this capability in a manner compliant with the standards adopted by the Secretary) is the appropriate mechanism to address this commenter's concerns.

Comment. One commenter urged that patient summaries be affirmatively offered to the patient, without their requesting them, and that the offer be provided in their native language with the offer documented in the EHR.

Response. We do not believe that it is within the scope of this final rule to require eligible professionals to offer patient summaries to patients.

Comments. Several commenters requested that this rule clarify that providers would only be responsible for the completeness and accuracy of the clinical summary to the extent they provided or did not provide the relevant data (*e.g.* if another provider has not forwarded data, they are not responsible).

Response. We do not believe that this behavior can be addressed by the certification criterion, nor do we believe that it is within the scope of this final rule.

Section 170.304(i)—Exchange Clinical Information and Patient Summary Record

Meaningful use Stage 1 objectives	Meaningful use Stage 1 measures	Certification criterion
Capability to exchange key clinical information (for example, problem list, medication list, medication 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.	Interim Final Rule Text: (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:
The EP, eligible hospital or CAH who transitions their patient to another setting of care or provider of care or refers their patient to another provider of care should provide summary of care record for each transition of care or referral.	The EP, eligible hospital or CAH who transitions or refers their patient to another setting of care or provider of care provides a summary of care record for more than 50% of transitions of care and referrals.	(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). Final Rule Text: § 170.304(i) (1) *Electronically receive and display.* Electronically receive and display a patient's summary record, from other providers and organizations including, at a minimum, diagnostic tests results, problem list, medication list, and medication allergy list in accordance with the standard (and applicable implementation specifications) specified in § 170.205(a)(1) or § 170.205(a)(2). Upon receipt of a patient summary record formatted according to the alternative standard, 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, and medication allergy list in accordance with: (i) The standard (and applicable implementation specifications) specified in § 170.205(a)(1) or § 170.205(a)(2); and (ii) For the following data elements the applicable standard must be used: (A) *Problems.* The standard specified in § 170.207(a)(1) or, at a minimum, the version of the standard specified in § 170.207(a)(2); (B) *Laboratory test results.* At a minimum, the version of the standard specified in § 170.207(c); and

Meaningful use Stage 1 objectives	Meaningful use Stage 1 measures	Certification criterion
		(C) *Medications.* The standard specified in § 170.207(d).

Comments. A few commenters supported our adoption of the Continuity of Care Record (CCR) standard for patient summary records; a couple commenters expressed no preference; while many commenters were opposed to our adoption of CCR as an alternate standard and did not believe that it was an appropriate selection. Several commenters did not comment on the merits of adopting CCD and CCR but rather expressed general concern that adopting two standards would be wasteful, counter-productive, confusing, time-consuming, and reduce interoperability. Of the commenters that supported the adoption of CCR, most expressed their appreciation for the flexibility we had provided. These commenters contended that CCR was easier to implement and would make it easier for smaller Complete EHR and EHR Module developers to enter the market and get certified. One commenter suggested that if we intended to keep both CCD and CCR as adopted standards that we specify the transactions for which each standard should apply. This commenter recommended that CCD be used for exchanging summary records between health care providers and that CCR be used for exchanging summary records to PHRs. Of the commenters that opposed our selection of CCR, many of them recommended that we adopt the CCD standard as the sole standard for summary records. These commenters principally referenced that the CCD was a harmonization of CDA and CCR. Some commenters stated that we did not provide sufficient rationale for adopting CCR and we had reopened a debate over the two standards that was purportedly previously settled. Some commenters were concerned that CCR could not support certain information, particularly, in the hospital setting. These commenters contended that CCR could not support discharge information and that CCR cannot provide input into clinical decision support due to the lack of a common definition of how data is structured. Other commenters referenced that CCR is not extensible and questioned its ability to be used for quality reporting. Several commenters recommended that, short of adopting solely CCD, we provide clearer guidance to the industry regarding what standard we expect to adopt for future stages of meaningful use because CCD and CCR are not based on a common information model.

Response. We appreciate the constructive comments and recommendations provided by commenters. We address our adoption of the patient summary record standards in this certification criterion because we believe that it is the most applicable place to do so. Section 3004(b)(1) of the PHSA requires the Secretary to adopt an initial set of standards, implementation specifications, and certification criteria. Section 3004(b)(2) of the PHSA provided the Secretary with additional flexibility in considering what standards, implementation specifications, and certification criteria to adopt in the initial set. Section 3004(b)(2) states that "[t]he standards, implementation specifications, and certification criteria adopted before the date of the enactment of this title through the process existing through the Office of the National Coordinator for Health Information Technology may be applied towards meeting the requirement of paragraph (1)." Accordingly, we looked at all of the standards, implementation specifications, and certification criteria recognized by the Secretary at any point in time prior to the enactment of the HITECH Act to determine whether they should be included in this initial set. Contrary to some commenters statements, the CCR patient summary record standard was in fact recognized by the Secretary in 2008 (73 FR 3976) as part of the HITSP Consumer Empowerment Interoperability Specification (HITSP V2.1 2007 IS03). We understand that in January, 2009, the Secretary recognized (74 FR 3604) an updated HITSP IS03 which removed the CCR standard. We do not believe that section 3004(b)(2) precludes the Secretary from considering all possible standards that were part of the "prior process." To the contrary, we believe the HITECH Act provided the Secretary with the authority and flexibility to determine which standards would be best to include in this initial set. Accordingly, we adopted both the CCR and CCD as patient summary record standards.

We adopted both standards for a few reasons. First, we are aware, contrary to some commenters' statements, that a significant segment of the HIT industry still uses the CCR patient summary record standard and that some health care providers prefer the CCR over the CCD. For this reason, we did not want to mandate, at such an early stage, that all of these early adopters adopt a different summary record standard for the purposes of meaningful use Stage 1, given that electronic health information exchange is not required. Second, we understand that in some circumstances the CCR is easier, faster, and requires fewer resources to implement than the CCD. We have therefore concluded that it was appropriate to adopt the CCR standard for patient summary records in this initial set of standards. Finally, we believe that at the present time, each standard could equally be used to satisfy the requirements of meaningful use Stage 1.

Comments. Numerous commenters questioned why we did not adopt the HITSP C32 implementation specification for the CCD. These commenters requested that we adopt the C32 implementation specification. They noted that it had been accepted by the industry, tested and implemented in several operating environments, and was supported by multiple EHR technology developers. A few commenters requested additional clarification regarding our adoption of a "level 2" CCD as part of this standard and stated that use of a level 2 CCD was inconsistent with our adoption of several adopted vocabulary standards. These commenters questioned whether we intended to adopt a level 3 CCD. At least one commenter recommended the removal of our reference to levels. Another commenter stated that problem list, medication list, medication allergy list, procedures, etc. are commonly referred to as "sections" of the CDA or CCD document, not "fields." They stated that sections may contain narrative text using the CDA XML format for text, and need not contain level 3 entries; however, they believed that in order to use the specified clinical vocabularies found in the Interim Final Rule in an interoperable fashion, the codes from these selected vocabularies must appear in level 3 entries. Some commenters also noted this and recommended that we adopt CCD and specify that the standard must be implemented in accordance with the HITSP C32 implementation specification, using the vocabulary standards we had adopted in the Interim Final Rule. One commenter noted that units of measure are components of structured entries (CDA

level 3) in these sections. The commenter supported specified clinical vocabularies and level 3 CCD because the commenter felt that level 3 would be necessary to properly communicate the information.

Response. We have considered public comments and, in response, have made two changes. Both are related to our adoption of the CCD standard. In the Interim Final Rule we explicitly included a reference to "level 2" to indicate that we expected a Complete EHR or EHR Module would be capable of generating a level 2 CCD. After further consideration, we agree that removing "level 2" from the adopted standard will help clarify the requirements regarding the implementation of CCD. As some commenters pointed out, the coded data elements we expect to populate the fields of the CCD would necessitate "level 3" entries. Thus, we have removed the reference to "level 2." We also agree, that the HITSP C32 (version 2.5) implementation specification for CCD would be appropriate to adopt. We understand that a majority of Complete EHR and EHR Module developers who have implemented the CCD standard do so according to the HITSP C32 implementation specification, and consequently we do not believe that this would be a significant burden. We further clarify that, for the purposes of testing and certification, a compliant CCD implemented according to the HITSP C32 must include the information for those entries "required" by the HITSP C32. Additionally, we note that as specified by this certification criterion, we expect that certain health information for which other certification criteria require to be recorded will be used to populate certain "optional" entries specified by the HITSP C32 implementation specification (*e.g.,* problems from a problem list should in most cases be available to populate the "condition content module" section of the HITSP C32). Accordingly, we expect that the test data used to evaluate whether a Complete EHR or EHR Module can successfully generate a CCD according to the HITSP C32 will include the data specified in the certification criterion to populate the "optional" entries for which we have adopted vocabulary standards (*e.g.,* problems). Moreover, from a consistency perspective, we expect that the same test data referenced above, which would be used to test and certify a CCD implemented according to the HITSP C32 would also be used to test and certify a Complete EHR or EHR Module's ability to populate a CCR. This principle is also applicable to Complete EHRs and EHR Modules designed for an inpatient setting.

Comment. One commenter noted that although CVX is identified as the required standard for interaction with state immunization registries, no standard for "immunizations" is outlined for the clinical summary. They presumed that CVX could be used for this purpose, but stated that CVX does not include a dose or date or reaction.

Response. Consistent with the changes we have made elsewhere in the final rule, we have removed "immunizations" from this certification criterion.

Comment. A commenter suggested that ONC strike the following from the certification criteria "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." Another commenter stated that data transport is not addressed in the standards, and the criterion instead refers to "transmit." The commenter suggested changing the first part of the criterion to "display" instead of "receive," and the second part of the criterion to "export" instead of "transmit."

Response. We disagree and have not made these changes. We believe that this certification criterion expresses the capabilities we expect Certified EHR Technology will include. Furthermore, the action of "exporting" a patient summary record does not indicate or require that Certified EHR Technology is actually capable of transmitting a patient summary record to Certified EHR Technology implemented by a different eligible professional or eligible hospital.

Comment. A commenter requested clarification on how historical data from paper records should be treated for the purpose of certification. If historical data is on paper, the standards for display are inapplicable.

Response. Data from paper records would not be a relevant factor for the purposes of testing and certification. We are concerned with whether Complete EHRs and EHR Modules have implemented specific capabilities in compliance with the certification criteria adopted by the Secretary.

Comments. A couple of commenters requested definition of "diagnostic test result" and "procedures" in the context of this criterion.

Response. Again, we do not believe that it is appropriate to define "diagnostic test result" in this final rule since the term is derived from the Medicare and Medicaid EHR Incentive Programs final rule. Consistent with other revisions we have made in the final rule, we have removed "procedures" from the certification criterion.

Comment. At least one commenter requested that we clarify what Certified EHR Technology needs to be capable of meeting this certification criterion. The commenter asked whether the generation of a CCD or CCR would constitute compliance with this criterion or would the import and human readable display of both document types be required.

Response. We clarify that compliance with this certification criterion can be achieved by demonstrating that the Complete EHR or EHR Module is capable of receiving and displaying patient summary records that comply with either patient summary record standard (and if the alternative standard is used, displaying the non-natively implemented patient summary record standard in human readable format) and generating and transmitting a patient summary record according to one of the patient summary record standards populated with the specified data types and their applicable standard(s). For example, a Complete EHR designed to generate patient summary records in the CCD standard would need to be capable of generating and transmitting patient summary records in accordance with CCD. Upon receipt of a patient summary record formatted according to the CCR standard, the Complete EHR must also be capable of displaying the CCR-formatted patient summary record in human readable format. We clarify that we also expect that the Complete EHR designed to natively generate a CCD would be tested and certified as being capable of properly displaying any CCD that it receives and have added the term "display" in the beginning of the certification criterion. This change is also applicable to the certification criterion for Complete EHRs and EHR Modules designed for an inpatient setting.

Comment. A commenter requested that we clarify how we intended adopted vocabularies to be used. The commenter queried whether vocabulary standards that we had adopted apply to EHRs or to transactions that EHRs conduct. The commenter further requested that we clarify whether a local/proprietary medication vocabulary could be mapped to RxNorm, and whether a local/proprietary problem list vocabulary could be mapped to SNOMED–CT®. Finally, the commenter asked if mapping is permitted, and if so, requested that we identify the subsets of these vocabularies that should be used.

Response. For purposes of electronically exchanging a patient summary record, we expect the patient summary record to include health information that is coded, where applicable, in accordance with adopted vocabulary standards. Therefore, unless otherwise required in the context of a meaningful use objective and measure, an eligible professional (or eligible hospital) would be permitted to map or crosswalk local/proprietary codes to the adopted vocabulary standards prior to transmitting a patient summary record. We do not believe that it would be appropriate to specify subsets of adopted vocabularies at this time and would seek additional input from the HIT Standards Committee or public comment prior to specifying vocabulary subsets.

Comment. A commenter stated that the adopted data exchange standards do not provide for the inclusion of narrative text results, such as a radiology report, or images of scanned paper documents. The commenter questions how meaningful use objectives will be achieved without these and recommends that implementation guidance be issued that includes specific references to content or vocabulary standards.

Response. We have not adopted standards for radiology reports or images; however, both the CCR and CCD can be used to convey narrative text and objects such as scanned documents.

Comments. A couple of commenters requested clarification as to the testing we expected to occur related to a Complete EHR or EHR Module's compliance with this certification criterion. These commenters questioned whether the generation of a CCD and XDS (HITSP/TP13)/FTP/e-mail of a document would meet the certification criterion requirements.

Response. We clarify that because we have removed the adopted transport standards, we do not require as a condition of certification that a specific transport standard be used to transmit a generated CCD.

Comments. One commenter expressly agreed with the expectations of the certification criterion. Another commenter stated that this functionality is crucial to support the patient/family-centered medical home. One commenter recommended that the Certified EHR Technology be designed so that the amount of data transmitted could be adjusted by physicians so they do not violate the HIPAA Privacy Rule's "minimum necessary" requirements.

Response. We appreciate commenters' support for this certification criterion and agree that patient summary records serve a valuable purpose. Presently, we do not believe that it is appropriate to require as a condition of certification a capability associated with the HIPAA Privacy Rule's minimum necessary requirements because such requirements are generally context specific and determined when a HIPAA covered entity uses or discloses protected health information or when a HIPAA covered entity requests protected health information from another HIPAA covered entity. We do not preclude, however, Complete EHR and EHR Module developers from including additional features to assist HIPAA covered entities comply with these and other HIPAA Privacy Rule requirements.

Comment. A commenter recommended that the summary care record should include the durable medical equipment and supplies used by the patient.

Response. Presently, the correlated meaningful use objective and measure do not specify that a patient summary record must contain information regarding durable medical equipment. Accordingly, we do not believe that it would be appropriate to require this as a condition of certification.

c. Specific Certification for Complete EHRs or EHR Modules Designed for an Inpatient Setting—§ 170.306

Section 170.306(a)—Computerized Provider Order Entry

Meaningful use Stage 1 objective	Meaningful use Stage 1 measure	Certification criterion
Use CPOE for medication orders directly entered by any licensed healthcare professional who can enter orders into the medical record per state, local and professional guidelines.	More than 30% of unique patients with at least one medication in their medication list seen by the EP or admitted to the eligible hospital's or CAH's inpatient or emergency department (POS 21 or 23) have at least one medication order entered using CPOE.	Interim Final Rule Text: 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. Final Rule Text: § 170.306(a). *Computerized provider order entry.* Enable a user to electronically record, store, retrieve, and modify, at a minimum, the following order types: (1) Medications; (2) Laboratory; and (3) Radiology/imaging.

A commenter recommended that we clarify what is meant by order entry because the commenter believes that within the confines of many hospitals, just about any "order" can be performed. A few commenters requested that "diet orders" be added to the list of CPOE order types in order to prevent inconsistent patient care. Another commenter recommended that speech-language pathology and audiology also be added. Two commenters noted that the certification criterion specifies a long list of order types. The commenters recommended that we not attempt to create an exhaustive list. One of the commenters also noted that no information is given as to what constitutes adequate functionality for any of the orders after the first three order types and that some, such as "dialysis" may not be appropriate order functionality for a general EHR system for hospitals. Both commenters

recommended that we remove all orders from four through 10 and replace them with a single provision "other order types."

Response. Consistent with the revisions we made to the CPOE certification criterion associated with Complete EHRs and EHR Modules designed for an ambulatory setting, we agree with those commenters who recommended that we specify a minimum core set of orders as a condition of certification. Accordingly, we identify medication, laboratory, and radiology/imaging as the minimum types of orders a Complete EHR or EHR Module designed for inpatient settings must include in order to be certified.

While this certification criterion is now the same as the certification criterion for Complete EHRs and EHR Modules designed for an ambulatory setting, we have not combined and moved the CPOE certification criteria to the general certification criteria section. Rather, we have kept the certification criteria for CPOE separate because we anticipate that these certification criteria could in the future include different requirements, specific to the settings for which Complete EHRs and EHR Modules are developed.

Comment. A commenter repeated a question it raised with respect to CPOE for eligible professionals. The commenter requested that we clarify whether only imaging and radiology reports were intended to be included in this capability, or, if we intended to include the images themselves in addition to the imaging reports as part of the certification criteria. The commenter recommended that we further clarify the criterion and requested that the DICOM standard be adopted in the initial set of standards, as an essential step in meeting the CPOE capability.

Response. We refer this commenter to our previous response above regarding this issue.

Section 170.306(b)—Record Demographics

Meaningful use Stage 1 objective	Meaningful use Stage 1 measure	Certification criterion
Record demographics ..... • preferred language • gender • race • ethnicity • date of birth • date and preliminary cause of death in the event of mortality in the eligible hospital or CAH	More than 50% of all unique patients seen by the EP or admitted to the eligible hospital's or CAH's inpatient or emergency department (POS 21 or 23) have demographics recorded as structured data.	Interim Final Rule Text: 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. Final Rule Text: § 170.306(b). *Record demographics.* Enable a user to electronically record, modify, and retrieve patient demographic data including preferred language, gender, race, ethnicity, date of birth, and date and preliminary cause of death in the event of mortality. Enable race and ethnicity to be recorded in accordance with the standard specified at § 170.207(f).

Many commenters expressed the same comments with respect to this certification criterion as they did for the record demographics certification criterion for Complete EHRs and EHR Modules designed for ambulatory setting. These commenters recommended the addition of other demographic information for additional clarity, as discussed above.

Comment. A commenter stated that an EHR is not an appropriate source of legal documentation for births and deaths because they indicated that it is not possible to obtain official birth and death certificates from a provider or hospital.

Response. In concert with and following the changes made to this meaningful use objective which are explained in more detail in the Medicare and Medicaid EHR Incentive Programs final rule, we believe that the changes we have made to this specific part of the certification criterion address this commenter's concern.

Section 170.306(c)—Clinical Decision Support

Meaningful use Stage 1 objective	Meaningful use Stage 1 measure	Certification criterion
Implement one clinical decision support rule related to a high priority hospital condition along with the ability to track compliance with that rule.	Implement one clinical decision support rule.	Interim Final Rule Text: (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. Final Rule Text: § 170.306(c). (1) *Implement rules.* Implement automated, electronic clinical decision support rules (in addition to drug-drug and drug-allergy contraindication checking) based on the data elements included in: problem list; medication list; demographics; and laboratory test results. (2) *Notifications.* Automatically and electronically generate and indicate in real-time, notifications and care suggestions based upon clinical decision support rules.

This certification criterion is now exactly the same as the certification criterion applicable to Complete EHRs and EHR Modules designed for an ambulatory setting. As a result, our responses and subsequent changes to the certification criterion above are also applicable to this certification criterion. While this certification criterion is now the same as the certification criterion for Complete EHRs and EHR Modules designed for an ambulatory setting, we have not combined and moved the clinical decision support certification criteria to the general certification criteria section because the focus of the meaningful use objective is different and specific to eligible hospitals. We also believe that it is useful to keep these certification criteria separate because we anticipate that these certification criteria could in the future include different requirements, specific to the settings for which Complete EHRs and EHR Modules are developed.

Comments. Some commenters requested that we clarify the meaning of high priority hospital condition.

Response. We have removed this term, consistent with the other revisions we made to this certification criterion.

Section 170.306(d)—Electronic Copy of Health Information

Meaningful use Stage 1 objective	Meaningful use Stage 1 measure	Certification criterion
Provide patients with an electronic copy of their health information (including diagnostic test results, problem list, medication lists, medication allergies, discharge summary, procedures), upon request.	More than 50% of all patients of the EP or the inpatient or emergency departments of the eligible hospital or CAH (POS 21 or 23) who request an electronic copy of their health information are provided it within 3 business days.	Interim Final Rule Text: 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). Final Rule Text: § 170.306(d). (1) 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, and procedures: (i) In human readable format; and (ii) On electronic media or through some other electronic means in accordance with: (A) The standard (and applicable implementation specifications) specified in § 170.205(a)(1) or § 170.205(a)(2); and (B) For the following data elements the applicable standard must be used: (*1*) *Problems.* The standard specified in § 170.207(a)(1) or, at a minimum, the version of the standard specified in § 170.207(a)(2); (*2*) *Procedures.* The standard specified in § 170.207(b)(1) or § 170.207(b)(2); (*3*) *Laboratory test results.* At a minimum, the version of the standard specified in § 170.207(c); and (*4*) *Medications.* The standard specified in § 170.207(d). (2) Enable a user to create an electronic copy of a patient's discharge summary in human readable format and on electronic media or through some other electronic means.

Comment. A commenter expressed concern that requiring organizations to provide anything on electronic media was dangerous and counterproductive to the HITECH Act's HIPAA Privacy and Security Rule changes. This commenter also stated that thumb drives and CD/DVD burners are not available to staff. The commenter recommended that we remove this certification criterion and adopt a patient portal requirement in the next round of rulemaking.

Response. While we understand that in certain locations (*e.g.,* areas that are readily accessible to patients) health care professionals do not normally have access to use certain ancillary features at their workstations, we disagree that requiring organizations to provide patients with an electronic copy presents problems related to HITECH modifications to the HIPAA privacy and security requirements. We do not specify that electronic media such as thumb drives or CDs must be used. An eligible hospital will be able to determine, consistent with its security posture, if certain electronic media is permissible and if so, what types. It will also be able to determine the means and location through which an electronic copy may be provided, *e.g.,* at the records management department or office. As the commenter suggested, a patient portal would be an acceptable mechanism to provide an electronic copy.

Comment. A commenter stated the certification criterion for eligible hospitals should be limited to information or tests performed during the course of a patient visit or hospital stay and include only summary information of diagnostic test results or of information that is clinically significant and discovered during the encounter or admission. Other commenters requested that we clarify

the reference to procedures. The commenters asked that the regulations specify whether the EHR technology must enable the user to create an electronic copy of procedures associated with the most recent hospitalization, or any historical procedures, or the procedures that the patient should follow-up to do after discharge.

Response. At a minimum, Certified EHR Technology must be capable of generating an electronic copy of health information that includes the elements specified by the certification criterion in an electronic copy. We do not specify the time period for which the electronic copy must cover as a condition of certification.

Comment. A commenter requested that we consider eliminating the reference to standards in this certification criterion for Stage 1 and focusing on human readable formats.

Response. We disagree, as doing so would run counter to our long term goals and would not help build the foundation necessary for more comprehensive capabilities to be added in the future.

Comments. A few commenters noted that neither the CCD nor CCR contain an applicable section for discharge summary. One commenter recommended that because the provision of an electronic copy of discharge instructions was required by another certification criterion, that discharge instructions should be removed as an element in this electronic copy.

Response. We reviewed commenters' concerns and agree that there is no applicable section for a discharge summary. Therefore, we have revised this certification criterion to reflect that while the other data elements can be conveyed using the patient summary record standards (CCR or CCD), we are not requiring the use of any standards for the discharge summary section. In order to support the meaningful use objective and measure, however, we note that we do expect Certified EHR Technology to be capable of providing a electronic copy of a discharge summary like a patient summary record, in human readable format and on electronic media or through some other electronic means. Other electronic means could include, for example, the discharge summary represented as a CCD plus the "Hospital Course" CDA section or provided as a PDF. We have revised the certification criterion accordingly.

We note that our responses to the following comments also apply to other certification criteria that reference procedures.

Comments. A commenter requested clarification as to what we meant by "procedures" for hospitals, because coding for medical procedures typically occurs after the patient has been discharged. Another commenter requested that we further clarify the subset of relevant procedures that should be included. The commenter explained that it believed including CPT–4 or ICD–9 codes seemed inappropriate for clinical summaries since these codes are used for "procedures as billed," and the commenter further asked whether we intended to include only major procedures.

Response. We clarify that the adopted standard pertains to the vocabulary that would be used to express procedures, regardless of how they are selected, or included.

Comments. A commenter stated that with an X12 837 standard transaction, ICD–9–CM is accompanied by a flag that indicates whether this code is being used to bill for services meant to eliminate a diagnosis. The commenter stated that neither the CCR nor the CCD support such a flag, and concluded that there was no way to know whether ICD–9–CM codes used in either CCD or CCR could accurately convey a patient's problems. The commenter also recommended SNOMED–CT® should be used with a CCD, because ICD–9 codes have too little clinical detail. Another commenter favored the use of SNOMED–CT® as well and stated that SNOMED–CT® would be more clinically accurate and better suited for our purposes. Another commenter encouraged us to adopt the Current Dental Terminology.

Response. The diagnoses included within the patient summary record are meant to convey clinically relevant conditions as recorded in Certified EHR Technology's problem list, rather than billing diagnoses. While we agree that SNOMED–CT® provides additional clinical detail, this is often not available in current practice. Furthermore, while its use is not precluded, we do not believe that it is necessary to adopt the Current Dental Terminology as a condition of certification for all Complete EHRs and EHR Modules.

Comments. A commenter recommended against the adoption of the alternative standard (CPT–4), unless we subsidized the cost of licensing CPT–4 as has been done for certain other code sets. Some commenters expressed concerns about the license requirements and one commenter stated that the license cost will likely be passed down from the EHR developer to the eligible professional or eligible hospital. Some commenters believed that if we intended to keep this alternative standard, we should make it freely available.

Response. We understand that most current EHR technology already includes the CPT–4 code sets, and we believe that this indicates that the licensing costs are not prohibitive. Regardless, we have adopted an alternative standard to CPT–4, SNOMED–CT®, which is freely available.

Comment. A commenter noted that the certification criterion references immunizations but the Medicare and Medicaid EHR Incentive Programs proposed rule did not include immunizations in the objective. The commenter suggested that we modify our certification criterion to match the proposed rule.

Response. We have removed this term, consistent with the previous revisions we have made to other certification criteria above.

Section 170.306(e)—Electronic Copy of Discharge Information

Meaningful use Stage 1 objective	Meaningful use Stage 1 measure	Certification criterion
Provide patients with an electronic copy of their discharge instructions at time of discharge, upon request.	More than 50% of all patients who are discharged from an eligible hospital or CAH's inpatient department or emergency department (POS 21 or 23) and who request an electronic copy of their discharge instructions are provided it.	Interim Final Rule Text: 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. Final Rule Text: § 170.306(e). *Electronic copy of discharge instructions.* Enable a user to create an electronic copy of the discharge instructions for a patient, in human readable format, at the time of discharge on electronic media or through some other electronic means.

Comment. A few commenters expressed support for this certification criterion. Some commenters requested that we clarify the meaning of "procedures" in the context of this certification criterion.

Response. We have revised this certification criterion to be consistent with the changes to the meaningful use objective and measure in the Medicare and Medicaid EHR Incentive Programs final rule, which removes the word "procedures" from the meaningful use objective.

Comment. A commenter requested that we clarify the meaning of the phrase "at time of discharge" and specifically, whether it means literally at the time when a patient is discharged or more broadly, soon after the discharge occurs, in which case the instructions could be made available to the patient, for example, through a web portal.

Response. This phrase is derived from the Medicare and Medicaid EHR Incentive Programs final rule, and CMS has provided clarifying remarks related to this comment.

Comment. One commenter recommended that the certification criterion include consideration of the patient's preferred language.

Response. Like our prior responses, we do not believe that requiring this information is appropriate or necessary to include as a condition of certification. However, we do not preclude Complete EHRs and EHR Modules from being designed to reference a patient's preferred language.

Section 170.306(f)—Exchange Clinical Information and Summary Record

Meaningful use Stage 1 objectives	Meaningful use Stage 1 measures	Certification criterion
Capability to exchange key clinical information (for example, discharge summary, procedures, problem list, medication list, medication 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.	Interim Final Rule Text: (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);
The EP, eligible hospital or CAH who transitions their patient to another setting of care or provider of care or refers their patient to another provider of care should provide summary of care record for each transition of care or referral.	The EP, eligible hospital or CAH who transitions or refers their patient to another setting of care or provider of care provides a summary of care record for more than 50% of transitions of care and referrals .	(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). Final Rule Text: § 170.306(f). (1) *Electronically receive and display.* Electronically receive and display a patient's summary record from other providers and organizations including, at a minimum, diagnostic test results, problem list, medication list, medication allergy list, and procedures in accordance with the standard (and applicable implementation specifications) specified in § 170.205(a)(1) or § 170.205(a)(2). Upon receipt of a patient summary record formatted according to the alternative standard, 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, and procedures in accordance with: (i) The standard (and applicable implementation specifications) specified in § 170.205(a)(1) or § 170.205(a)(2); and (ii) For the following data elements the applicable standard must be used: (A) *Problems.* The standard specified in § 170.207(a)(1) or, at a minimum, the version of the standard specified in § 170.207(a)(2); (B) *Procedures.* The standard specified in § 170.207(b)(1) or § 170.207(b)(2); (C) *Laboratory test results.* At a minimum, the version of the standard specified in § 170.207(c); and (D) *Medications.* The standard specified in § 170.207(d).

Overall this certification criterion is very similar to the certification criterion applicable to Complete EHRs and EHR Modules designed for an ambulatory setting. As a result, our responses and subsequent changes to the certification criterion above are also applicable to this certification criterion. Below are the comments that are unique to this certification criterion.

Comment. A few commenters requested clarification on what is meant by the term "discharge summary." The commenter stated that neither the CCD nor the CCR has a document section or module for a "discharge summary." One commenter suggested that we either define the term or remove it. At least one commenter suggested that discharge summary be initially permitted to be an unstructured CDA instead of requiring the use of a CCD. As an alternative, it was suggested that the CCD combined with the "Hospital Course" CDA section be allowed to qualify as the discharge summary.

Response. As noted in one of our responses above, we recognize that neither CCD nor CCR specifically supports the inclusion of discharge summary. In the Medicare and Medicaid EHR Incentive Program final rule, CMS references discharge summary in the meaningful use objective as an example of "key clinical information" but further clarifies within the preamble of that rule that it is up to an eligible professional or eligible hospital to determine what constitutes key clinical information. In that regard, CMS notes that we specify the minimum set of information that Certified EHR Technology must be capable of electronically transmitting. Given our prior statements regarding the ability of CCD and CCR to support the inclusion of the discharge summary and the principle expressed by CMS that we specify a minimum set of information in the adopted certification criterion, we believe that in this instance it is appropriate to exclude discharge summary from the certification criterion.

Section 170.306(g)—Reportable Lab Results

Meaningful use Stage 1 objective	Meaningful use Stage 1 measure	Certification criterion
Capability to submit electronic data on reportable (as required by state or local law) lab results to public health agencies and actual submission in accordance with applicable law and practice.	Performed at least one test of certified EHR technology's capacity to provide electronic submission of reportable lab results to public health agencies and follow-up submission if the test is successful (unless none of the public health agencies to which eligible hospital or CAH submits such information have the capacity to receive the information electronically).	Interim Final Rule Text: 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). Final Rule Text: § 170.306(g). *Reportable lab results.* Electronically record, modify, retrieve, and submit reportable clinical lab results in accordance with the standard (and applicable implementation specifications) specified in § 170.205(c) and, at a minimum, the version of the standard specified in § 170.207(c).

Comment. One commenter requested that we clarify the meaning of "LOINC when LOINC codes have been received from a laboratory." The commenter questioned whether the information exchange for which this criterion would apply is solely exchange within an organization or only between organizations.

Response. For a more detailed response to this request for clarification, we refer to the relevant comments and responses relating to the "incorporate laboratory test results" certification criterion, where we discuss this issue at length.

Comment. One commenter stated that it believed the standards we have adopted are too general or at too high a level for vendors to be able to implement them uniformly. This commenter suggested that we clarify when lab results should be transmitted, for instance upon the occurrence of particular trigger events, or in response to specific messages, and in accordance with a reporting time table. The commenter queries, for example, if EHR systems should use discharge as a trigger for the transmission of a reportable condition using encounter level demographic segments, or whether EHR systems should provide a periodic batch reporting of reportable conditions (*e.g.* daily or weekly).

Response. We clarify that the certification criterion does not specify, and is not intended to specify, the requirements for how the reports are to be triggered nor the periodicity of the reporting requirements. As a certification criterion, it only specifies capabilities necessary for certification.

Comment. A commenter recommended that we clarify the meaning of "reportable" in the certification criterion.

Response. Each public health jurisdiction maintains its list of diseases or conditions that require notification of public health authorities by law. The CDC and the Council of State and Territorial Epidemiologists also maintain a list of nationally notifiable conditions (*http://www.cdc.gov/ncphi/disss/nndss/phs/infdis.htm*). We reiterate, the adoption of this certification criterion is not intended to affect applicable Federal or state law concerning public health authority notification requirements.

Comments. Many commenters requested further specification of the data format for transmitting information to public health agencies. Most of these comments recommended HL7 2.5.1 version, although at least one commenter noted that HL7 2.3.1 was still being used by some public health agencies. Another commenter suggested that either standard be allowed to accommodate for the variation in public health departments' ability to receive these reports. Many commenters raised the concern that the criterion appears to place the burden of compliance on the sender. This problem could be compounded if states and localities adopt multiple standards, which would make both compliance and certification testing difficult and burdensome. Several commenters raised the concern that some public health agencies are not capable of receiving electronic data. One commenter suggested removing the language "or applicable state-designated standard format" and directly specifying the format in the final rule. One commenter suggested having the states agree upon a standard format. At least one commenter requested additional clarity, suggesting that the HL7 message profile types be specified: ORU message for public health reporting, ADT for syndromic surveillance, and VXU for immunizations. One commenter also requested that we clarify whether HL7 V3 constructs would be allowable.

Response. We agree with the majority of commenters, who requested greater specificity for this certification criterion.

Many of these commenters suggested adopting implementation specifications for the adopted standard (HL7 2.5.1). In response to those comments, and to more fully support this meaningful use objective and measure which specify the submission of laboratory results to public health, we have decided to adopt the HL7 Version 2.5.1 Implementation Guide: Electronic Laboratory Reporting to Public Health, Release 1 (US Realm) to further constrain how HL7 2.5.1 is formatted for the purposes of submitting laboratory test results to public health. With respect to the comment regarding HL7 V3, we do not believe that the industry and public health departments are currently able to support the HL7 V3 constructs on a widespread basis and are therefore not adopting them.

Comment. One commenter suggested adding the term "modify" to the certification criterion, while one commenter requested clarification on the term "retrieve."

Response. Consistent with the changes we have made to the other certification criterion, we have included the word "modify."

Comments. A few commenters suggested the use of SNOMED–CT® and UCUM for reporting.

Response. We do not believe that the industry and public health departments are currently able to support the use of SNOMED–CT® and UCUM for reporting on a widespread basis.

d. Adoption and Realignment of Certification Criteria To Support the Final Requirements for Meaningful Use Stage 1.

In the Interim Final Rule, we noted that the Secretary was adopting an initial set of standards, implementation specifications, and certification criteria to "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." We also noted that the reason we routinely referred to eligible professionals and eligible hospitals in the Interim Final Rule was "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." In this regard, and as many commenters acknowledged and expressed in their comments, this final rule and the Medicare and Medicaid EHR Incentive Program final rule are closely and inextricably linked. Recognizing the unique connection between these two rules, some commenters went so far as to issue CMS and ONC a single set of comments recommending changes to both rules in context. Many other commenters treated both rules as almost being one in the same, acknowledging that a change in Medicare and Medicaid EHR Incentive Programs final rule would need to be reflected in this final rule. Other commenters submitted comments to ONC on the Medicare and Medicaid EHR Incentive Programs proposed rule, and to CMS on the Interim Final Rule. As we discussed previously, CMS and ONC shared these comments between the offices and we included within our review all comments that could be reasonably identified as comments on the Interim Final Rule.

The following three certification criteria have been adopted as part of the initial set of certification criteria, implementation specifications, and standards in order to realign the adopted certification criteria with the final meaningful use Stage 1 requirements and to ensure that Certified EHR Technology will provide such capabilities.

Record Advance Directives

In the Medicare and Medicaid EHR Incentive Programs proposed rule, the Department explained that the HIT Policy Committee had recommended that eligible hospitals "record advance directives." Due in part to the ambiguity of the recommendation, the Department discussed but did not include the objective "Record Advance Directives" for the reasons explained by CMS. In its final rule, however, the Department stated that based on comments received as well as resolution of some of the ambiguity associated with the measure, CMS was including this objective among its meaningful use Stage 1 objectives. The Department noted that some commenters reported that having this information available would allow eligible hospitals to make decisions that were better aligned with the patient's express wishes. The "record advance directives" certification criterion would ensure that Certified EHR Technology enables users to electronically record whether a patient has an advance directive, which in turn will help ensure that a patient's wishes are known and can be followed.

Meaningful use Stage 1 objective	Meaningful use Stage 1 measure	Certification criterion
Record advance directives for patients 65 years old or older.	More than 50% of all unique patients 65 years old or older admitted to the eligible hospital's or CAH's inpatient department (POS 21) have an indication of an advance directive status recorded.	Final Rule Text: § 170.306(h). *Advance directives.* Enable a user to electronically record whether a patient has an advance directive.

Comments. The Department received several comments that we should include the capability to record advance directives as part of meaningful use of Certified EHR Technology and, specifically, that it should be a requirement that pertains to eligible hospitals. Other commenters reported that having this information available for the patient would allow eligible hospitals to make decisions that were better aligned with the patient's express wishes. The HIT Policy Committee clarified that the purpose of the meaningful use Stage 1 measure would be to indicate whether a patient has an advanced directive. Furthermore, the committee recommended limiting this measure to patients 65 and older.

Response. We agree that the capability for a Complete EHR or EHR Module designed for an inpatient setting should be included as a condition of certification. Including this certification criterion in this final rule will enable eligible hospitals to meet a meaningful use objective they would otherwise not have been able to meet. We do not believe that the capability we have required will be a significant burden for Complete EHR and EHR Module developers and assume that some already have this or a similar type of capability already built in.

Patient-Specific Education Resources

The Medicare and Medicaid EHR Incentive Programs proposed rule discussed but did not include the objective of providing "access to patient specific education resources upon request," primarily because of the belief that there was a paucity of knowledge resources integrated within EHRs that are also widely available. CMS also noted that the ability to provide patient education resources in multiple languages might be limited. In response to comments, the Medicare and Medicaid EHR Incentive Programs final rule included this objective and a related measure, finding that the availability of education resources linked to EHRs is in fact more widely available than the Department had previously indicated in the proposed rule. The Medicare and Medicaid EHR Incentive Programs final rule expressly requires that more than 10 percent of all unique patients seen by the EP or admitted to the eligible hospital's or CAH's inpatient or emergency department (POS 21 or 23) during the EHR reporting period must be provided patient-specific education resources in order to meet the related meaningful use stage 1 objective. To support the achievement of this objective and measure, we are therefore adopting as a certification criterion the capability of enabling a user to electronically identify and provide patient-specific education resources that include particular types of data elements.

Meaningful use Stage 1 objective	Meaningful use Stage 1 measure	Certification criterion
Use certified EHR technology to identify patient-specific education resources and provide those resources to the patient if appropriate.	More than 10% of all unique patients seen by the EP or admitted to the eligible hospital's or CAH's inpatient or emergency department (POS 21 or 23) are provided patient-specific education resources.	Final Rule Text: § 170.302(m). *Patient-specific education resources.* Enable a user to electronically identify and provide patient-specific education resources according to, at a minimum, the data elements included in the patient's: problem list; medication list; and laboratory test results; as well as provide such resources to the patient.

Comments. The Department received many comments, including comments from both the HIT Policy Committee and MedPAC, that this capability should be included among the certification criteria for Certified EHR Technology, to enable eligible professionals and eligible hospitals to achieve meaningful use. Commenters indicated that the availability of education resources that could be linked to EHR technology is widely available.

Response. We agree that this capability should be included as a certification criterion for a Complete EHR or EHR Module designed for an ambulatory or inpatient setting. Accordingly, we have included this certification criterion in the general certification section. We clarify that we do not specify how Certified EHR Technology must be used to provide such resources to a patient. That is, such resources could be printed out, faxed, or e-mailed.

Automated Calculation of Percentage-Based Meaningful Use Measures

While the Interim Final Rule only expressly provided for the calculation of BMI and the calculation and electronic display of certain quality measures, the Department's operating assumption in the Interim Final Rule was that Certified EHR Technology would provide for the automated calculation of meaningful use Stage 1 measures. The Medicare and Medicaid EHR Incentive Programs proposed rule for instance stated that CMS and ONC had worked together to define certain terms, such as numerator and denominator, for the calculation of percentages to demonstrate the successful attainment of the meaningful use objectives. The Medicare and Medicaid EHR Incentive Programs final rule confirmed that "the ability to calculate the measure is included in certified EHR technology." To make explicit the Department's operating assumption, to confirm some commenters' original understanding, and to respond to other commenters' points, we are adopting the following certification criterion regarding the automated calculation of percentage-based meaningful use measures.

Meaningful use Stage 1 objective	Meaningful use Stage 1 measure	Certification criterion
N/A	N/A	Final Rule Text: § 170.302(n). *Automated measure calculation.* For each meaningful use objective with a percentage-based measure, electronically record the numerator and denominator and generate a report including the numerator, denominator, and resulting percentage associated with each applicable meaningful use measure.

Comments. The Department received several comments noting that Certified EHR Technology should be expressly required, as a condition of certification, to automatically calculate the meaningful use measures for which eligible professionals and eligible hospitals would need to report percentages to CMS or States at the end of an EHR reporting period. Some commenters explicitly noted that ONC should require the automated calculation of certain measures as a condition of certification. Commenters pointed out that this was already a certification requirement for clinical quality measures and it would be inconsistent not to require automated calculation for the functionality measures as part of certification. Many commenters expressed concerns about the difficulties of capturing the denominators for the meaningful use measures that required percentage calculations. They pointed out that the formulas CMS identified for many objectives would require providers to conduct labor-intensive counts of paper documents such as prescriptions or laboratory results in order to compute the denominators of the percentage based measures. Commenters also indicated that if Certified EHR Technology did not include this capability that it would dramatically increase the burden on potential meaningful users to demonstrate meaningful use and could potentially serve as a factor in their decision to participate in the Medicare and Medicaid EHR incentive programs.

Response. We agree with commenters that unless we expressly adopt a certification criterion to specify that Certified EHR Technology must be capable of performing percentage-based calculations for meaningful use measures that it would present a significant burden to eligible professionals and eligible hospitals and could deter them from participating in the Medicare and Medicaid EHR incentives programs. Accordingly, we believe that it is critical to adopt the certification criterion specified above. We clarify that Certified EHR Technology must be capable of calculating all denominators for those meaningful use measures which are percentage-based and for which CMS requires an eligible professional or eligible hospital to submit the results at the end of an EHR reporting period. (CMS provides a detailed discussion in the Medicare and Medicaid EHR Incentive Programs final rule on denominators.) We note that as discussed in the Medicare and Medicaid EHR Incentive Programs final rule under the heading "Discussion of the Burden Created by the Measures associated with the Stage 1 Meaningful Use Objectives," an eligible professional or eligible hospital is responsible for verifying that the denominator produced by Certified EHR Technology is complete. The eligible professional or eligible hospital would be expected to know whether data had been incorrectly entered into Certified EHR Technology or whether all patient records were included in Certified EHR Technology. For Stage 1 meaningful use criteria, CMS identifies these measures in the table in its final rule with the headings: "Measures with a Denominator of Unique Patients Regardless of Whether the Patient's Records Are Maintained Using Certified EHR Technology" and "Measures with a Denominator of Based on Counting Actions for Patients whose Records are Maintained Using Certified EHR Technology." We do not require, as a condition of certification, that a Complete EHR or EHR Module provide results for the meaningful use measures that only require a "yes/no" attestation since these results should be readily apparent. These measures are also identified by CMS in the table in its final rule with the heading "Measures Requiring Only a Yes/No Attestation." We do not believe that adoption of this certification criterion poses a significant technical challenge. Rather, we believe that this capability will provide Complete EHR and EHR Modules developers with a platform from which to innovate and compete regarding, for example, the EHR products' ease of use.

E. Additional Comments

Comments. In response to our request for public comment, several commenters recommended that we adopt certification criteria requiring technical capabilities to provide greater access for people with disabilities. These commenters also pointed to a few standards currently being used to assure accessibility, including the Web Content Accessibility Guidelines (WCAG 2.0) and the Electronic and Information Technology Accessibility Standards. The commenters requested that we coordinate more with the disability communities on accessibility and usability and how HIT will impact members of this community. The commenters requested that we clarify the applicability of accessibility standards and that we add technological non-discrimination as a goal to guide future standards work.

Response. We appreciate the thorough and thoughtful comments provided related to accessibility. We believe that HIT has the potential to provide all persons with more efficient access to their health information. In that regard, we solicited public comment on the issue of accessibility and certification to garner more information about available standards and to begin a path forward that included these standards as part of the overall standards adoption process. We reiterate what we discussed in the interim final rule when we provided the context for our solicitation of public comment on accessibility.

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 * * *. 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.

While we have not yet adopted specific accessibility standards as a condition of certification, we believe that the adoption of such standards in a future rulemaking would prove beneficial, to enable all persons (including health care providers with disabilities) to have equitable access to EHR technology and the electronic information it generates. In the interim, we encourage Complete EHR and EHR Module developers to design their EHR technology with the needs of users of assistive technology in mind, and remind eligible professionals and eligible hospitals who seek to adopt Certified EHR Technology to review and comply with applicable legal obligations regarding accessibility. Among the ways of designing certain capabilities with accessibility in mind, we would encourage Complete EHR and EHR Module developers to consider implementing, for example, the WCAG 2.0 [8] when providing web-oriented content so that it is more accessible to persons with disabilities. We expect the HIT Standards Committee to identify accessibility-oriented standards [9] when it issues recommendations regarding the standards that the Secretary should adopt in future years.

Comments. Several commenters made recommendations related to standards that we could adopt to support future stages of meaningful use. Other commenters expressed concerns related to the "candidate Stage 2 standards" that we referenced in the Interim Final Rule. Finally, commenters requested that Certified EHR Technology include specific capabilities that had no relationship to meaningful use.

Response. We have reviewed these comments and appreciate the forethought provided by commenters. Given that these suggestions were not germane to the policies associated with the Interim Final Rule we have not considered them for the purposes of promulgating this final rule.

F. Comments Beyond the Scope of This Final Rule

In response to the Interim Final Rule, some commenters chose to raise issues that are beyond the scope of our

[8] *http://www.w3.org/TR/WCAG20/.*

[9] As previously mentioned, there are several accessibility standards for electronic and information technology currently in use. For example, Section 508 of the Rehabilitation Act requires Federal agencies to ensure that electronic and information technology that they develop, procure, maintain, or use is accessible to persons with disabilities and authorizes the Architectural and Transportation Barriers Compliance Board (Access Board) to promulgate standards setting forth the technical and functional performance criteria necessary to implement the requirements of Section 508. Information regarding the Electronic and Information Technology Standards can be found on the Access Board's Web site at *http://www.access-board.gov/508.htm.*

proposals. We do not summarize or respond to those comments in this final rule.

IV. Collection of Information Requirements

This final rule contains no new information collection requirements subject to review by the OMB under the Paperwork Reduction Act (PRA).

V. Regulatory Impact Analysis

A. Introduction

We have examined the impacts of this final 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 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 final rule, we have prepared an RIA that to the best of our ability presents the costs and benefits of the final rule.

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.[10] We examine the burden of the 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 2010, that threshold is approximately $135 million. This rule will not impose an unfunded mandate on States, tribal government or the private sector of more than $135 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 the 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. On January 13, 2010, the Secretary published in the **Federal Register** an interim final rule to adopt the initial set of standards, implementation specifications, and certification criteria. This final rule has been published to amend previously adopted standards, implementation specifications, and certification criteria in order to realign such standards, implementation specifications, and certification criteria with final meaningful use Stage 1 objectives and measures, and to respond to public comments received. 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. Executive Order 12866—Regulatory Planning and Review Analysis

1. Comment and Response

Comments. A few commenters offered opinions related to the cost estimates included in the Interim Final Rule. One commenter disagreed with our approach. This commenter contended that our analysis followed a simplistic, linear model that did not account for the other potential costs that Complete EHR and EHR Module developers and health care providers would bear. The commenter suggested that we address other costs in our calculations including: whether a Complete EHR or EHR Module developer has adequate resources available to modify its HIT in order to prepare for certification; the loss of a Complete EHR or EHR Module developer's net worth and dislocation of jobs if it fails and goes out of business; and the resulting impacts that would occur if a Complete EHR and EHR Module developer went out of business and left behind customers (some or many of which could then be ineligible for Medicare and Medicaid EHR Incentive Programs) with unsupported HIT. Another commenter questioned the cost estimates in the Interim Final Rule, but acknowledged that it was not prepared to offer alternative cost estimates. The commenter did state that it believed our dollar values seemed low and that the gap of 25%, representing previously CCHIT-certified-EHRs that will need additional preparation to be tested and certified to the certification criteria adopted by the Secretary, also seemed low. The commenter suggested a 40–50% gap. The commenter also recommended that we revise our cost estimates based on the certification criteria in the final rule to: consider costs associated with workflow redesign within an eligible professional or eligible hospitals environment; factor in the costs for "interoperability implementation" (no further explanation was provided); account for the costs associated with implementing the clinical quality measures certification criterion; account for the costs for hardware capable of supporting the adopted security requirements; and factor in the costs for internal resources and customer resources. One commenter noted that the cost related to dentistry EHR technology may be higher due to what it perceived as a lack of commercially available EHR technology and that additional costs may be incurred by dentistry EHR developers that are not as familiar as EHR developers for other health providers with the certification criteria adopted by the Secretary. One commenter agreed with the $10,000 to $250,000 cost range we estimated for the per-certification-criterion preparation, while another commenter seemed to misinterpret this estimate as being the total cost to prepare a Complete EHR or EHR Module. This commenter offered that it could take over 2,500 hours to prepare a Complete EHR for certification. One commenter appeared to associate the costs related to the preparation of a Complete EHR to be tested and certified with the actual cost to be tested and certified, but nonetheless expressed concern that we had estimated that it would cost a Complete EHR developer whose EHR technology had not previously been certified no less than

[10] *http://sba.gov/idc/groups/public/documents/sba_homepage/serv_sstd_tablepdf.pdf.*

$1.2 million to become compliant with the Interim Final Rule's requirements. The commenter requested that HHS provide assistance to EHR vendors with revenues of less than $1 million in order to help offset the costs of the certification process.

Response. We appreciate commenters' recommendations and suggestions related to our cost analysis. While we understand why some commenters recommended additional factors for us to consider as part of our analysis, we do not believe many of those factors are relevant for two primary reasons: (1) We believe that it is improbable that this rule will result in the outcomes speculated and their associated costs; and (2) the factors contributing to or causing the increased costs are outside the scope of this rule (*e.g.,* hypothetical business failure and job loss, workflow redesign) and could not be reasonably or accurately estimated. In this regard, we reiterate what we stated in the Interim Final Rule related to how costs would be estimated. "This interim final rule estimates the costs commercial vendors, open source developers, and relevant Federal agencies 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." Accordingly, we disagree with the commenter who contended that our estimates were too simplistic and linear. We believe that in the absence of any additional data or an alternative model (which no commenter provided), our assumptions are sound and our analysis is reasonable for estimating the costs associated with complying with this final rule.

We believe that it is important to note to commenters that compliance with this final rule is voluntary and as such, seeking to have a Complete EHR or EHR Module certified is voluntary. A Complete EHR or EHR Module developer is not required to comply with this final rule in order to operate its business. Rather, a Complete EHR or EHR Module developer will need to rely upon this final rule only if it ultimately seeks to have its EHR technology tested and certified as being compliant with the certification criteria adopted by the Secretary. Consequently, if a Complete EHR or EHR Module developer does not have the resources available to redesign its Complete EHR or EHR Module to incorporate the standards and implementation specifications or meet the certification criteria adopted in this rule, this rule does not create any new expenses for its business. Given this clarification, we believe that our estimates represent a higher than likely number of Complete EHR and EHR Module developers that will prepare their HIT to be tested and certified to the certification criteria adopted by the Secretary, and thus, the highest potential cost.

We considered whether an hourly preparation cost should replace the assumptions we made in the Interim Final Rule, but found it difficult to determine what reasonable low and high hour ranges would be even if we were to assume 2500 hours to be the average. Further, for the purposes of testing this alternative approach, we assumed that it would be reasonable for the employees of a Complete EHR or EHR Module developer responsible for preparing a Complete EHR or EHR Module for testing and certification to be paid equivalent to a Federal employee with a Federal Salary Classification of GS–15 Step 1 ($59.30/hr plus 21.35/hr for benefits) given the educational and professional experience we believe would be necessary to lead this type of activity. Multiplying the total hourly rate by the 2500 hours yields a total preparation cost of approximately $201,000. Thus, even if we were to assume that a high average for preparation of a Complete EHR or EHR Module would be double what the commenter stated, it would only represent close to $400,000 in preparation costs. Accordingly, we believe that our estimates are in fact comparatively high and the estimate range covers a wide range of possibilities.

In the absence of additional data or any evidence to the contrary from public comment to guide revisions to our estimates, we are finalizing them according to the data and assumptions we identified in the Interim Final Rule. We believe that our estimates are sound, based on reasonable assumptions and data, and sufficiently accommodate varying costs for different types of Complete EHR and EHR Module developers. We believe that the additional clarity and specificity we have provided for some certification criteria and the removal of some required capabilities would further contribute to lowering the cost estimates for complying with this final rule. Consequently, we anticipate actual costs will fall somewhere between the low and mid-point ranges of our estimates rather than between the mid-point and high ranges of our estimates.

Finally, with respect to the commenter who expressed concern regarding the total costs associated with developing a Complete EHR which had never been certified, we note that our estimates should not be construed to imply that a Complete EHR developer would have to spend over $1 million in order to prepare a Complete EHR. To the contrary, had we calculated our low range for preparing a Complete EHR based on the absolute low we estimated for a per certification cost ($10,000), the total cost would have only been $240,000, or one-fifth the cost we estimated in the Interim Final Rule. The approach we took in the Interim Final Rule was designed to be inclusive of a middle range of possibilities, but was never meant to preclude the possibility that a Complete EHR developer could design a Complete EHR that was compliant with the certification criteria adopted by the Secretary for less than we estimated. Also in response to the commenter's request, we do not believe that it would be appropriate, nor are we authorized, to provide subsidies to Complete EHR or EHR Module developers for the costs of the preparing a Complete EHR or EHR module for testing and certification.

2. Executive Order 12866 Final Analysis

a. Costs

This 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. Our analysis focuses on the direct effects of the provisions of this final rule—the costs incurred by Complete EHR and EHR Module developers to prepare Complete EHRs and EHR Modules to be tested and certified in accordance with the certification criteria adopted by the Secretary. That is, we focus on the technological development costs necessary to include the capabilities in a Complete EHR or EHR Module that will be compliant with the certification criteria adopted by the Secretary. Again, as noted above, the actual cost a Complete EHR or EHR Module developer will incur to be tested and certified is accounted for in our certification programs final rules.

As we noted in the Interim Final Rule, we analyzed previously developed CCHIT ambulatory and inpatient

certification criteria and believe that many of those criteria, but not all, require the exact same capabilities as the 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, we believe that a significant number of previously CCHIT-certified-EHRs will only incur moderate costs to prepare for certification. For the purpose of estimating costs, we presume that previously CCHIT-certified-EHRs include the functionality to meet the definition of a Complete EHR. As a result, for our estimates in Table 1, we anticipate that these previously CCHIT-certified-EHRs will again be prepared for certification as Complete EHRs. We estimated in the Interim Final Rule that there were 74 CCHIT-certified-EHRs certified to its 2008 ambulatory certification criteria and 17 CCHIT-certified-EHRs certified to its 2007 or 2008 inpatient certification criteria.[11, 12, 13] Of these 74 and 17 previously CCHIT-certified-EHRs, we expect that 90% will be prepared and submitted for certification according 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 EHRs that were previously CCHIT-certified will include more capabilities than what they had when CCHIT originally tested and certified them, and they may consequently be able to more easily meet the certification criteria adopted by the Secretary). Based on this assumption, we have created low and high ranges for the costs 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) will have been widely implemented and deployed in HIT so that there will be little or no need to modify Complete EHRs or EHR Modules for certification. 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 for testing and certification taking into account the factors identified directly above. We have used this per certification criterion range as the basis for our low and high cost range estimates. For the ease of our calculations, we have rounded to "40" the number of certification criteria that the Secretary is adopting.

For Table 1 we have made the following assumptions based on our understanding of the capabilities present in previously CCHIT-certified-EHRs: (1) In general, Complete EHR developers who previously obtained a CCHIT certification for their EHR technology will possess a Complete EHR that will meet approximately 75% of the adopted certification criteria and, as a result, these Complete EHR developers may need to make more comprehensive adjustments to their Complete EHRs in order to prepare the Complete EHRs to be tested and certified to the remaining 25% of the certification criteria adopted by the Secretary; (2) the average low and high per certification criterion cost for ambulatory EHRs previously certified by CCHIT which need to be prepared for testing and certification 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 for testing and certification will be $75,000 and $200,000, respectively.

TABLE 1—ESTIMATED ONE-TIME COSTS FOR COMPLETE EHR DEVELOPERS TO PREPARE PREVIOUSLY CCHIT–CERTIFIED-EHRS TO BE TESTED AND CERTIFIED (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
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

[11] 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 discernible effect on our estimates.

[12] *http://www.cchit.org/products/Ambulatory*—when certification years 2006 and 2007 are unchecked. While 78 EHRs are now listed, we do not believe that changing our estimate would have a measureable effect on the overall costs.

[13] *http://www.cchit.org/products/Inpatient.*

prepared to be tested and certified as Complete EHRs rather than as EHR Modules.[14] We assume the EHR technology that falls into this category may require more extensive changes than previously CCHIT-certified-EHRs identified in Table 1. 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 [15] represented by the previously CCHIT-certified-EHRs included in Table 1 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.[16]

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 additional assumptions in our Table 2 calculations based on our understanding of the capabilities currently present in these EHR technologies: (1) In general, Complete EHR developers who have out-of-date CCHIT-Certified-EHRs or who never previously had their Complete EHRs certified by CCHIT will possess Complete EHRs that will meet approximately 40% of the adopted certification criteria and, as a result, these Complete EHR developers may need to make more comprehensive adjustments to their Complete EHRs in order to prepare the Complete EHRs to be tested and certified to the remaining 60% of the certification criteria adopted by the Secretary; (2) the average low and high per certification criterion costs 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 costs for Complete EHRs for eligible hospitals to be prepared to be tested and certified will be $75,000 and $200,000, respectively.

TABLE 2—ESTIMATED ONE-TIME COSTS FOR COMPLETE EHR DEVELOPERS TO PREPARE NEVER CCHIT-CERTIFIED-EHRS AND OUT-OF-DATE CCHIT-CERTIFIED-EHRS TO BE TESTED AND CERTIFIED (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. We clarify as noted in the Temporary Certification Program final rule that these EHR Modules are not "self-developed," and we assume that an EHR Module developer interested in commercially marketing its EHR Module to eligible professionals and eligible hospitals would develop them. We assumed in the Interim Final Rule that certain types of EHR Modules (*e.g.,* computerized provider order entry; quality reporting; online patient portals) would be more likely than others to be prepared to be tested and certified, and we estimated based on our assumption that there would be 7 EHR Modules prepared to be tested and certified for each of the 7 types of EHR Modules we identified. This estimate (number of modules X types of modules) resulted in an approximate number of 50 EHR Modules that would be prepared to be tested and certified. Again, we have provided low and high preparation cost estimates in Table 3 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 will 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 of costs for preparing these types of EHR Modules for testing and certification. We estimated in the Interim Final Rule and reiterate below a low average one-time cost of $100,000 to prepare an EHR Module, based on the assumption that some of the less sophisticated EHR Modules would only be prepared to be tested and certified to 1 or 2 certification criteria. We estimated in the Interim Final Rule and reiterate below, a high average cost one-time cost of $500,000 to prepare an EHR Module, based on the assumption that some of the more sophisticated EHR Modules would only be prepared to be tested and certified to 1 or 2 of the more complicated certification criteria or would be prepared to be tested and certified to multiple certification criteria.

TABLE 3—ESTIMATED ONE-TIME COSTS TO EHR MODULE DEVELOPERS TO PREPARE EHR MODULES TO BE TESTED AND CERTIFIED (3-YEAR PERIOD)—TOTALS ROUNDED

Type	Number prepared	One-time cost per EHR module ($M)			Total cost all EHR modules over 3-year period ($M)		
		Low	High	Mid-point	Low	High	Mid-point
EHR Modules	50	$0.1	$0.5	$0.3	$5.0	$25.0	$15.0

[14] CCHIT began testing and certifying inpatient EHRs in 2007 and we assume that all of those EHRs are included in Table 1 which is why they are not included in this discussion.

[15] *http://www.cchit.org/about*—"* * * EHR products certified by mid-2009, representing over 75% of the marketplace."

[16] This estimate is premised in part on 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 3—ESTIMATED ONE-TIME COSTS TO EHR MODULE DEVELOPERS TO PREPARE EHR MODULES TO BE TESTED AND CERTIFIED (3-YEAR PERIOD)—TOTALS ROUNDED—Continued

Type	Number prepared	One-time cost per EHR module ($M)			Total cost all EHR modules over 3-year period ($M)		
		Low	High	Mid-point	Low	High	Mid-point
Total	50				5.0	25.0	15.0

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 $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. As a result, we believe as represented in Table 4 that the costs attributable to this final rule will be distributed as follows: 45% for 2010, 40% for 2011 and 15% for 2012.

TABLE 6—DISTRIBUTED TOTAL PREPARATION COSTS FOR COMPLETE EHR AND EHR MODULE DEVELOPERS (3-YEAR PERIOD)—TOTALS ROUNDED

Year	Ratio (percent)	Total low cost estimate ($M)	Total high cost estimate ($M)	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	205.30	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.

b. Benefits

We believe that there will be several benefits arising from this final rule. By adopting the revisions to 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 the meaningful use of Certified EHR Technology. The capabilities specified in the adopted certification criteria will help ensure that health care providers have the necessary information technology 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 final rule will serve as a catalyst for a more competitive and innovative marketplace. Finally, adopted certification criteria can be used by Complete EHR and EHR Module developers as technical requirements to ensure that their HIT can be tested and certified and subsequently adopted and implemented as Certified EHR Technology. Adopting these certification criteria will also ultimately help enable eligible professionals and eligible hospitals to qualify for incentive payments under Medicare and Medicaid EHR Incentive Programs.

D. Regulatory Flexibility Act Analysis

1. Comment and Response

Comment. Some commenters noted that we incorrectly referenced the proportion of businesses in the marketplace that would qualify as small businesses under the SBA's size standard. The commenters cited a presentation by CCHIT which indicated that potentially up to 75% of Complete EHR developers who design Complete EHRs for ambulatory settings would qualify as small businesses.

Response. We appreciate commenters pointing out this additional information. We have revised the discussion accordingly in the final RFA analysis. However, we do not believe that this additional information substantially changes our analysis. We do not believe that any relief can be provided to small businesses under the SBA size standard that would not undercut our programmatic goals and objectives. A Complete EHR or EHR Module developer will need to design a Complete EHR or EHR Module that can be tested and successfully certified to all applicable certification criteria adopted by the Secretary in order for the Complete EHR or EHR Module to attain certification. Accordingly, we see no viable alternatives to reducing the requirements in the final rule or providing for alternatives to adopted certification criteria. Additionally, we believe that the regulation builds in a certain amount of flexibility already in that a small business without the resources available to develop a Complete EHR has the option to develop an EHR Module which will presumably require less of an investment (time and money) to develop.

2. Final RFA 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.

While Complete EHRs and EHR Module developers represent a small segment of the overall information technology industry, we believe that the entities impacted by this final rule most likely fall under the North American Industry Classification System (NAICS) code 541511 "Custom Computer

Programming Services" specified at 13 CFR 121.201 where the SBA publishes "Small Business Size Standards by NAICS Industry." The size standard associated with this NAICS code is set at $25 million in annual receipts [17] which "indicates the maximum allowed for a concern and its affiliates to be considered small entities."

Based on our analysis, we believe that there is enough data generally available to establish that between 75% and 90% of entities that are categorized under the NAICS code 541511 are under the SBA size standard, but note that the available data does not show how many of these entities will develop a Complete EHR or EHR Module. We also note that with the exception of aggregate business information available through the U.S. Census Bureau and the SBA related to NAICS code 541511, it appears that many Complete EHR and EHR Module developers are privately held or owned and do not regularly, if at all, make their specific annual receipts publicly available. As a result, it is difficult to locate empirical data related to many of the Complete EHR and EHR Module developers to correlate to the SBA size standard.

We estimate that this final rule could have effects on Complete EHR and EHR Module developers, some of which may be small entities. However, we believe that we have established the minimum amount of requirements necessary to accomplish our policy goals and that no appropriate regulatory alternatives could be developed to lessen the compliance burden associated with this final rule. In order for a Complete EHR or EHR Module to provide the capabilities an eligible professional or eligible hospital will be required to use under the Medicare and Medicaid EHR Incentive Programs final rule, it will need to comply with the applicable certification criteria adopted by the Secretary. Moreover, we note that this final rule does not impose the costs cited in the regulatory impact analysis as compliance costs, but rather as investments which Complete EHR and EHR Module developers voluntarily take on and expect to recover with an appropriate rate of return. Accordingly, we do not believe that the final rule will create a significant impact on a substantial number of small entities. The Secretary certifies that this final rule will not have a significant impact on a substantial number of small entities.

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 final rule imposes substantial direct compliance costs on State and local governments, preempts State law or otherwise has federalism implications. We are not aware of any State laws or regulations that are contradicted or impeded by any of the standards, implementation specifications, or certification criteria that have been adopted.

The Office of Management and Budget reviewed this final rule.

List of Subjects in 45 CFR Part 170

Computer technology, Electronic health record, Electronic information system, Electronic transactions, Health, Health care, Health information technology, Health insurance, Health records, Hospitals, Incorporation by reference, Laboratories, Medicaid, Medicare, Privacy, Reporting and recordkeeping requirements, Public health, Security.

■ For the reasons set forth in the preamble, 45 CFR subtitle A, subchapter D, part 170, is amended as follows:

PART 170–HEALTH INFORMATION TECHNOLOGY STANDARDS IMPLEMENTATION SPECIFICATIONS, AND CERTIFICATION CRITERIA AND CERTIFICATION PROGRAMS FOR HEALTH INFORMATION TECHNOLOGY

■ 1. The authority citation for part 170 continues to read as follows:

Authority: 42 U.S.C. 300jj–11; 42 U.S.C. 300jj–14; 5 U.S.C. 552.

■ 2. Amend § 170.102 by revising the definitions of "Complete EHR," "Certified EHR Technology," and "Disclosure" and adding the definition of "Human readable format" to read as follows:

§ 170.102 Definitions.

* * * * *

Certified EHR Technology means:

(1) A Complete EHR that meets the requirements included in the definition of a Qualified EHR and has been tested and certified in accordance with the certification program established by the National Coordinator as having met all applicable certification criteria adopted by the Secretary; or

(2) A combination of EHR Modules in which each constituent EHR Module of the combination has been tested and certified in accordance with the certification program established by the National Coordinator as having met all applicable certification criteria adopted by the Secretary, and the resultant combination also meets the requirements included in the definition of a Qualified EHR.

Complete EHR means EHR technology that has been developed to meet, at a minimum, all applicable certification criteria adopted by the Secretary.

Disclosure is defined as it is in 45 CFR 160.103.

* * * * *

Human readable format means a format that enables a human to read and easily comprehend the information presented to him or her regardless of the method of presentation.

* * * * *

■ 3. Revise subpart B to read as follows:

Subpart B—Standards and Implementation Specifications for Health Information Technology

Sec.
170.200 Applicability.
170.202 [Reserved]
170.205 Content exchange standards and implementation specifications for exchanging electronic health information.
170.207 Vocabulary standards for representing electronic health information.
170.210 Standards for health information technology to protect electronic health information created, maintained, and exchanged.
170.299 Incorporation by reference.

§ 170.200 Applicability.

The standards and implementation specifications adopted in this part apply with respect to Complete EHRs and EHR Modules.

§ 170.202 [Reserved]

§ 170.205 Content exchange standards and implementation specifications for exchanging electronic health information.

The Secretary adopts the following content exchange standards and associated implementation specifications:

(a) *Patient summary record—(1) Standard.* Health Level Seven Clinical Document Architecture (CDA) Release 2, Continuity of Care Document (CCD) (incorporated by reference in § 170.299). *Implementation specifications.* The Healthcare Information Technology Standards Panel (HITSP) Summary

[17] 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.*

Documents Using HL7 CCD Component HITSP/C32 (incorporated by reference in § 170.299).

(2) Standard. ASTM E2369 Standard Specification for Continuity of Care Record and Adjunct to ASTM E2369 (incorporated by reference in § 170.299).

(b) *Electronic prescribing. (1) Standard.* The National Council for the Prescription Drug Programs (NCPDP) Prescriber/Pharmacist Interface SCRIPT standard, Implementation Guide, Version 8, Release 1 (Version 8.1) October 2005 (incorporated by reference in § 170.299)

(2) Standard. NCPDP SCRIPT Standard, Implementation Guide, Version 10.6 (incorporated by reference in § 170.299).

(c) *Electronic submission of lab results to public health agencies. Standard.* HL7 2.5.1 (incorporated by reference in § 170.299). *Implementation specifications.* HL7 Version 2.5.1 Implementation Guide: Electronic Laboratory Reporting to Public Health, Release 1 (US Realm) (incorporated by reference in § 170.299).

(d) *Electronic submission to public health agencies for surveillance or reporting. (1) Standard.* HL7 2.3.1 (incorporated by reference in § 170.299).

(2) Standard. HL7 2.5.1 (incorporated by reference in § 170.299). *Implementation specifications.* Public Health Information Network HL7 Version 2.5 Message Structure Specification for National Condition Reporting Final Version 1.0 and Errata and Clarifications National Notification Message Structural Specification (incorporated by reference in § 170.299).

(e) *Electronic submission to immunization registries. (1) Standard.* HL7 2.3.1 (incorporated by reference in § 170.299). *Implementation specifications.* Implementation Guide for Immunization Data Transactions using Version 2.3.1 of the Health Level Seven (HL7) Standard Protocol Implementation Guide Version 2.2 (incorporated by reference in § 170.299).

(2) Standard. HL7 2.5.1 (incorporated by reference in § 170.299). *Implementation specifications.* HL7 2.5.1 Implementation Guide for Immunization Messaging Release 1.0 (incorporated by reference in § 170.299).

(f) *Quality reporting. Standard.* The CMS Physician Quality Reporting Initiative (PQRI) 2009 Registry XML Specification (incorporated by reference in § 170.299). *Implementation specifications.* Physician Quality Reporting Initiative Measure Specifications Manual for Claims and Registry (incorporated by reference in § 170.299).

§ 170.207 Vocabulary standards for representing electronic health information.

The Secretary adopts the following code sets, terminology, and nomenclature as the vocabulary standards for the purpose of representing electronic health information:

(a) *Problems*—(1) *Standard.* The code set specified at 45 CFR 162.1002(a)(1) for the indicated conditions.

(2) *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).

(b) *Procedures*—(1) *Standard.* The code set specified at 45 CFR 162.1002(a)(2).

(2) *Standard.* The code set specified at 45 CFR 162.1002(a)(5).

(c) *Laboratory test results. 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).

(d) *Medications. Standard.* Any source vocabulary that is included in RxNorm, a standardized nomenclature for clinical drugs produced by the United States National Library of Medicine.

(e) *Immunizations. Standard.* HL7 Standard Code Set CVX—Vaccines Administered, July 30, 2009 version (incorporated by reference in § 170.299).

(f) *Race and Ethnicity. Standard.* The Office of Management and Budget Standards for Maintaining, Collecting, and Presenting Federal Data on Race and Ethnicity, Statistical Policy Directive No. 15, October 30, 1997 (available at *http://www.whitehouse.gov/omb/rewrite/fedreg/ombdir15.html*).

§ 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. Any encryption algorithm identified by the National Institute of Standards and Technology (NIST) as an approved security function in Annex A of the Federal Information Processing Standards (FIPS) Publication 140–2 (incorporated by reference in § 170.299).

(2) Exchange. Any encrypted and integrity protected link.

(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, accessed, or deleted; and an indication of which action(s) occurred and by whom must also be recorded.

(c) Verification that electronic health information has not been altered in transit. Standard. A hashing algorithm with a security strength equal to or greater than SHA–1 (Secure Hash Algorithm (SHA–1) as specified by the National Institute of Standards and Technology (NIST) in FIPS PUB 180–3 (October, 2008)) must be used to verify that electronic health information has not been altered.

(d) 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 subpart 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) Health Level Seven, 3300 Washtenaw Avenue, Suite 227, Ann Arbor, MI 48104; Telephone (734) 677–7777 or *http://www.hl7.org/.*

(1) Health Level Seven Standard Version 2.3.1 (HL7 2.3.1), An Application Protocol for Electronic Data Exchange in Healthcare Environments, April 14, 1999, IBR approved for § 170.205.

(2) Health Level Seven Messaging Standard Version 2.5.1 (HL7 2.5.1), An Application Protocol for Electronic Data Exchange in Healthcare Environments,

February 21, 2007, IBR approved for § 170.205.

(3) Health Level Seven Implementation Guide: Clinical Document Architecture (CDA) Release 2—Continuity of Care Document (CCD), April 01, 2007, IBR approved for § 170.205.

(4) HL7 Version 2.5.1 Implementation Guide: Electronic Laboratory Reporting to Public Health, Release 1 (US Realm) HL7 Version 2.5.1: ORU^R01, HL7 Informative Document, February, 2010, IBR approved for § 170.205.

(5) [Reserved]

(c) ASTM International, 100 Barr Harbor Drive, PO Box C700, West Conshohocken, PA, 19428–2959 USA; Telephone (610) 832–9585 or *http://www.astm.org/*.

(1) ASTM 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.

(d) National Council for Prescription Drug Programs, Incorporated, 9240 E. Raintree Drive, Scottsdale, AZ 85260–7518; Telephone (480) 477–1000; and Facsimile (480) 767–1042 or *http://www.ncpdp.org*.

(1) National Council for Prescription Drug Programs Prescriber/Pharmacist Interface SCRIPT Standard, Implementation Guide, Version 8, Release 1, October 2005, IBR approved for § 170.205.

(2) SCRIPT Standard, Implementation Guide, Version 10.6, October, 2008, (Approval date for ANSI: November 12, 2008), IBR approved for § 170.205.

(3) [Reserved]

(e) 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 § 170.207.

(2) [Reserved]

(f) U.S. National Library of Medicine, 8600 Rockville Pike, Bethesda, MD 20894; Telephone (301) 594–5983 or *http://www.nlm.nih.gov/*.

(1) International Health Terminology Standards Development Organization Systematized Nomenclature of Medicine Clinical Terms (SNOMED CT®), International Release, July 2009, IBR approved for § 170.207.

(2) [Reserved]

(g) 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 § 170.207.

(2) Implementation Guide for Immunization Data Transactions using Version 2.3.1 of the Health Level Seven (HL7) Standard Protocol Implementation Guide Version 2.2, June 2006, IBR approved for § 170.205.

(3) HL7 2.5.1 Implementation Guide for Immunization Messaging Release 1.0, May 1, 2010, IBR approved for § 170.205.

(4) Public Health Information Network HL7 Version 2.5 Message Structure Specification for National Condition Reporting Final Version 1.0, including Errata and Clarifications, National Notification Message Structural Specification, 8/18/2007, August 18, 2007, IBR approved for § 170.205.

(5) [Reserved]

(h) Centers for Medicare & Medicaid Services, Office of Clinical Standards and Quality, 7500 Security Boulevard, Baltimore, Maryland 21244; Telephone (410) 786–3000

(1) CMS PQRI 2009 Registry XML Specifications, IBR approved for § 170.205.

(2) 2009 Physician Quality Reporting Initiative Measure Specifications Manual for Claims and Registry, Version 3.0, December 8, 2008 IBR approved for § 170.205.

(i) National Institute of Standards and Technology, Information Technology Laboratory, National Institute of Standards and Technology, 100 Bureau Drive, Gaithersburg, MD 20899–8930, *http://csrc.nist.gov/groups/STM/cmvp/standards.html*.

(1) Annex A: Approved Security Functions for FIPS PUB 140–2, Security Requirements for Cryptographic Modules, Draft, January 27, 2010, IBR approved for § 170.210.

(2) [Reserved]

(j) American National Standards Institute, Health Information Technology Standards Panel (HITSP) Secretariat, 25 West 43rd Street—Fourth Floor, New York, NY 10036, *http://www.hitsp.org*

(1) HITSP Summary Documents Using HL7 Continuity of Care Document (CCD) Component, HITSP/C32, July 8, 2009, Version 2.5, IBR approved for § 170.205.

■ 4. Revise subpart C to read as follows:

Subpart C—Certification Criteria for Health Information Technology

Sec.
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.

§ 170.300 Applicability.

(a) The certification criteria adopted in this subpart apply to the testing and certification of Complete EHRs and EHR Modules.

(b) When a certification criterion refers to two or more standards as alternatives, use of at least one of the alternative standards will be considered compliant.

(c) Complete EHRs and EHR Modules are not required to be compliant with certification criteria that are designated as optional.

§ 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, unless designated as optional, and in accordance with all applicable standards and implementation specifications adopted in this part:

(a) *Drug-drug, drug-allergy interaction checks—(1) Notifications.* Automatically and electronically generate and indicate in real-time, notifications at the point of care for drug-drug and drug-allergy contraindications based on medication list, medication allergy list, and computerized provider order entry (CPOE).

(2) Adjustments. Provide certain users with the ability to adjust notifications provided for drug-drug and drug-allergy interaction checks.

(b) *Drug-formulary checks.* Enable a user to electronically check if drugs are in a formulary or preferred drug list.

(c) *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 § 170.207(a)(1); or

(2) At a minimum, the version of the standard specified in § 170.207(a)(2).

(d) *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.

(e) *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.

(f) *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, height, weight, and blood pressure.

(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.

(g) *Smoking status.* Enable a user to electronically record, modify, and retrieve the smoking status of a patient. Smoking status types must include: current every day smoker; current some day smoker; former smoker; never smoker; smoker, current status unknown; and unknown if ever smoked.

(h) *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 test report information. Electronically display all the information for a test report specified at 42 CFR 493.1291(c)(1) through (7).

(3) Incorporate results. Electronically attribute, associate, or link a laboratory test result to a laboratory order or patient record.

(i) *Generate patient lists.* Enable a user to electronically select, sort, retrieve, and generate lists of patients according to, at a minimum, the data elements included in:

(1) Problem list;

(2) Medication list;

(3) Demographics; and

(4) Laboratory test results.

(j) *Medication reconciliation.* Enable a user to electronically compare two or more medication lists.

(k) *Submission to immunization registries.* Electronically record, modify, retrieve, and submit immunization information in accordance with:

(1) The standard (and applicable implementation specifications) specified in § 170.205(e)(1) or § 170.205(e)(2); and

(2) At a minimum, the version of the standard specified in § 170.207(e).

(l) *Public health surveillance.* Electronically record, modify, retrieve, and submit syndrome-based public health surveillance information in accordance with the standard (and applicable implementation specifications) specified in § 170.205(d)(1) or § 170.205(d)(2).

(m) *Patient-specific education resources.* Enable a user to electronically identify and provide patient-specific education resources according to, at a minimum, the data elements included in the patient's: problem list; medication list; and laboratory test results; as well as provide such resources to the patient.

(n) *Automated measure calculation.* For each meaningful use objective with a percentage-based measure, electronically record the numerator and denominator and generate a report including the numerator, denominator, and resulting percentage associated with each applicable meaningful use measure.

(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) Generate audit log. Enable a user to generate an audit log for a specific time period and to sort entries in the audit log according to any of the elements specified in the standard at § 170.210(b).

(s) *Integrity.* (1) Create a message digest in accordance with the standard specified in § 170.210(c).

(2) Verify in accordance with the standard specified in § 170.210(c) upon receipt of electronically exchanged health information that such information has not been altered.

(3) *Detection.* Detect the alteration of audit logs.

(t) *Authentication.* Verify that a person or entity seeking access to electronic health information is the one claimed and is authorized to access such information.

(u) *General encryption.* Encrypt and decrypt electronic health information in accordance with the standard specified in § 170.210(a)(1), unless the Secretary determines that the use of such algorithm would pose a significant security risk for Certified EHR Technology.

(v) *Encryption when exchanging electronic health information.* Encrypt and decrypt electronic health information when exchanged in accordance with the standard specified in § 170.210(a)(2).

(w) *Optional. Accounting of disclosures.* Record disclosures made for treatment, payment, and health care operations in accordance with the standard specified in § 170.210(d).

§ 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 modify, at a minimum, the following order types:

(1) Medications;

(2) Laboratory; and

(3) Radiology/imaging.

(b) *Electronic prescribing.* Enable a user to electronically generate and transmit prescriptions and prescription-related information in accordance with:

(1) The standard specified in § 170.205(b)(1) or § 170.205(b)(2); and

(2) The standard specified in § 170.207(d).

(c) *Record demographics.* Enable a user to electronically record, modify, and retrieve patient demographic data including preferred language, gender, race, ethnicity, and date of birth. Enable race and ethnicity to be recorded in accordance with the standard specified at § 170.207(f).

(d) *Patient reminders.* Enable a user to electronically generate a patient reminder list for preventive or follow-up care according to patient preferences based on, at a minimum, the data elements included in:

(1) Problem list;

(2) Medication list;

(3) Medication allergy list;

(4) Demographics; and

(5) Laboratory test results.

(e) *Clinical decision support—(1) Implement rules.* Implement automated, electronic clinical decision support rules (in addition to drug-drug and drug-allergy contraindication checking) based on the data elements included in: problem list; medication list; demographics; and laboratory test results.

(2) Notifications. Automatically and electronically generate and indicate in

real-time, notifications and care suggestions based upon clinical decision support rules.

(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, and medication allergy list in:

(1) Human readable format; and

(2) On electronic media or through some other electronic means in accordance with:

(i) The standard (and applicable implementation specifications) specified in § 170.205(a)(1) or § 170.205(a)(2); and

(ii) For the following data elements the applicable standard must be used:

(A) *Problems.* The standard specified in § 170.207(a)(1) or, at a minimum, the version of the standard specified in § 170.207(a)(2);

(B) *Laboratory test results.* At a minimum, the version of the standard specified in § 170.207(c); and

(C) *Medications.* The standard specified in § 170.207(d).

(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, and medication allergy list.

(h) *Clinical summaries.* 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, and medication allergy list. If the clinical summary is provided electronically it must be:

(1) Provided in human readable format; and

(2) Provided on electronic media or through some other electronic means in accordance with:

(i) The standard (and applicable implementation specifications) specified in § 170.205(a)(1) or § 170.205(a)(2); and

(ii) For the following data elements the applicable standard must be used:

(A) *Problems.* The standard specified in § 170.207(a)(1) or, at a minimum, the version of the standard specified in § 170.207(a)(2);

(B) *Laboratory test results.* At a minimum, the version of the standard specified in § 170.207(c); and

(C) *Medications.* The standard specified in § 170.207(d).

(i) *Exchange clinical information and patient summary record—(1) Electronically receive and display.* Electronically receive and display a patient's summary record, from other providers and organizations including, at a minimum, diagnostic tests results, problem list, medication list, and medication allergy list in accordance with the standard (and applicable implementation specifications) specified in § 170.205(a)(1) or § 170.205(a)(2). Upon receipt of a patient summary record formatted according to the alternative standard, 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, and medication allergy list in accordance with:

(i) The standard (and applicable implementation specifications) specified in § 170.205(a)(1) or § 170.205(a)(2); and

(ii) For the following data elements the applicable standard must be used:

(A) *Problems.* The standard specified in § 170.207(a)(1) or, at a minimum, the version of the standard specified in § 170.207(a)(2);

(B) *Laboratory test results.* At a minimum, the version of the standard specified in § 170.207(c); and

(C) *Medications.* The standard specified in § 170.207(d).

(j) *Calculate and submit clinical quality measures—(1) Calculate* (i) Electronically calculate all of the core clinical measures specified by CMS for eligible professionals.

(ii) Electronically calculate, at a minimum, three clinical quality measures specified by CMS for eligible professionals, in addition to those clinical quality measures specified in paragraph (1)(i).

(2) Submission. Enable a user to electronically submit calculated clinical quality measures in accordance with the standard and implementation specifications specified in § 170.205(f).

§ 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 modify, at a minimum, the following order types:

(1) Medications;

(2) Laboratory; and

(3) Radiology/imaging.

(b) *Record demographics.* Enable a user to electronically record, modify, and retrieve patient demographic data including preferred language, gender, race, ethnicity, date of birth, and date and preliminary cause of death in the event of mortality. Enable race and ethnicity to be recorded in accordance with the standard specified at § 170.207(f).

(c) *Clinical decision support—(1) Implement rules.* Implement automated, electronic clinical decision support rules (in addition to drug-drug and drug-allergy contraindication checking) based on the data elements included in: problem list; medication list; demographics; and laboratory test results.

(2) Notifications. Automatically and electronically generate and indicate in real-time, notifications and care suggestions based upon clinical decision support rules.

(d) *Electronic copy of health information.* (1) 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, and procedures:

(i) In human readable format; and

(ii) On electronic media or through some other electronic means in accordance with:

(A) The standard (and applicable implementation specifications) specified in § 170.205(a)(1) or § 170.205(a)(2); and

(B) For the following data elements the applicable standard must be used:

(1) Problems. The standard specified in § 170.207(a)(1) or, at a minimum, the version of the standard specified in § 170.207(a)(2);

(2) Procedures. The standard specified in § 170.207(b)(1) or § 170.207(b)(2);

(3) Laboratory test results. At a minimum, the version of the standard specified in § 170.207(c); and

(4) Medications. The standard specified in § 170.207(d).

(2) Enable a user to create an electronic copy of a patient's discharge summary in human readable format and on electronic media or through some other electronic means.

(e) *Electronic copy of discharge instructions.* Enable a user to create an electronic copy of the discharge instructions 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 patient summary record—(1) Electronically receive and display.* Electronically receive and display a patient's summary record from other

providers and organizations including, at a minimum, diagnostic test results, problem list, medication list, medication allergy list, and procedures in accordance with the standard (and applicable implementation specifications) specified in § 170.205(a)(1) or § 170.205(a)(2). Upon receipt of a patient summary record formatted according to the alternative standard, 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, and procedures in accordance with:

(i) The standard (and applicable implementation specifications) specified in § 170.205(a)(1) or § 170.205(a)(2); and

(ii) For the following data elements the applicable standard must be used:

(A) *Problems.* The standard specified in § 170.207(a)(1) or, at a minimum, the version of the standard specified in § 170.207(a)(2);

(B) *Procedures.* The standard specified in § 170.207(b)(1) or § 170.207(b)(2);

(C) *Laboratory test results.* At a minimum, the version of the standard specified in § 170.207(c); and

(D) *Medications.* The standard specified in § 170.207(d).

(g) *Reportable lab results.* Electronically record, modify, retrieve, and submit reportable clinical lab results in accordance with the standard (and applicable implementation specifications) specified in § 170.205(c) and, at a minimum, the version of the standard specified in § 170.207(c).

(h) *Advance directives.* Enable a user to electronically record whether a patient has an advance directive.

(i) *Calculate and submit clinical quality measures—(1) Calculate.* Electronically calculate all of the clinical quality measures specified by CMS for eligible hospitals and critical access hospitals.

(2) Submission. Enable a user to electronically submit calculated clinical quality measures in accordance with the standard and implementation specifications specified in § 170.205(f).

Dated: July 9, 2010.

Kathleen Sebelius,

Secretary.

[FR Doc. 2010–17210 Filed 7–12–10; 8:45 am]

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Federal Register

Wednesday,
July 28, 2010

Part IV

Department of the Treasury
Office of the Comptroller of the Currency

Federal Reserve System

Federal Deposit Insurance Corporation

Department of the Treasury
Office of Thrift Supervision

Farm Credit Administration

National Credit Union Administration

12 CFR Part 34, 208, 211, et al.

Registration of Mortgage Loan Originators; Final Rule

DEPARTMENT OF THE TREASURY

Office of the Comptroller of the Currency

12 CFR Part 34

[Docket ID OCC–2010–0007]

RIN 1557–AD23

FEDERAL RESERVE SYSTEM

12 CFR Parts 208 and 211

[Docket No. R–1357]

FEDERAL DEPOSIT INSURANCE CORPORATION

12 CFR Part 365

RIN 3064–AD43

DEPARTMENT OF THE TREASURY

Office of Thrift Supervision

12 CFR Part 563

[Docket No. 2010—0021]

RIN 1550–AC33

FARM CREDIT ADMINISTRATION

12 CFR Part 610

RIN 3052–AC52

NATIONAL CREDIT UNION ADMINISTRATION

12 CFR Parts 741 and 761

RIN 3133–AD59

Registration of Mortgage Loan Originators

AGENCY: Office of the Comptroller of the Currency, Treasury (OCC); Board of Governors of the Federal Reserve System (Board); Federal Deposit Insurance Corporation (FDIC); Office of Thrift Supervision, Treasury (OTS); Farm Credit Administration (FCA); and National Credit Union Administration (NCUA).

ACTION: Final rule.

SUMMARY: The OCC, Board, FDIC, OTS, FCA, and NCUA (collectively, the Agencies) are adopting final rules to implement the Secure and Fair Enforcement for Mortgage Licensing Act (the S.A.F.E. Act). The S.A.F.E. Act requires an employee of a bank, savings association, credit union or Farm Credit System (FCS) institution and certain of their subsidiaries that are regulated by a Federal banking agency or the FCA (collectively, Agency-regulated institutions) who acts as a residential mortgage loan originator to register with the Nationwide Mortgage Licensing System and Registry, obtain a unique identifier, and maintain this registration. The final rule further provides that Agency-regulated institutions must: require their employees who act as residential mortgage loan originators to comply with the S.A.F.E. Act's requirements to register and obtain a unique identifier, and adopt and follow written policies and procedures designed to assure compliance with these requirements.

DATES: This final rule is effective on October 1, 2010. Compliance with § __.103 (registration requirement) of the final rule is required by the end of the 180-day period for initial registrations beginning on the date the Agencies provide in a public notice that the Registry is accepting initial registrations.

FOR FURTHER INFORMATION CONTACT:

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Board: Anne Zorc, Counsel, Legal Division, (202) 452–3876, Virginia Gibbs, Senior Supervisory Analyst, (202) 452–2521, and Stanley Rediger, Supervisory Financial Analyst, (202) 452–2629, Division of Banking Supervision and Regulation, Board of Governors of the Federal Reserve System, 20th and C Streets, NW., Washington, DC 20551.

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OTS: Charlotte M. Bahin, Special Counsel (Special Projects), (202) 906–6452, Vicki Hawkins-Jones, Special Counsel, Regulations and Legislation Division, (202) 906–7034, Debbie Merkle, Project Manager, Credit Risk, (202) 906–5688, and Rhonda Daniels, Senior Compliance Program Analyst, Consumer Regulations, (202) 906–7158, Office of Thrift Supervision, 1700 G Street, NW., Washington, DC 20552.

FCA: Gary K. Van Meter, Deputy Director, Office of Regulatory Policy, (703) 883–4414, TTY (703) 883–4434, or Richard A. Katz, Senior Counsel, or Jennifer Cohn, Senior Counsel, Office of General Counsel, (703) 883–4020, TTY (703) 883–4020, Farm Credit Administration, 1501 Farm Credit Drive, McLean, VA 22102–5090.

NCUA: Regina Metz, Staff Attorney, Office of General Counsel, 703–518–6561, or Lisa Dolin, Program Officer, Division of Supervision, Office of Examination and Insurance, 703–518–6360, National Credit Union Administration, 1775 Duke Street, Alexandria, VA 22314–3428.

SUPPLEMENTARY INFORMATION:

I. Background

A. Statutory Requirements

The S.A.F.E. Act,[1] enacted on July 30, 2008, mandates a nationwide licensing and registration system for mortgage loan originators. Specifically, the Act requires all States to provide for a licensing and registration regime for mortgage loan originators who are not employed by Agency-regulated institutions within one year of enactment (or two years for States whose legislatures meet biennially). In addition, the S.A.F.E. Act requires the OCC, Board, FDIC, OTS and NCUA,[2] through the Federal Financial Institutions Examination Council (FFIEC), and the FCA to develop and maintain a system for registering mortgage loan originators employed by Agency-regulated institutions. The S.A.F.E. Act specifically prohibits an individual from engaging in the business of residential mortgage loan origination without first obtaining and maintaining annually: (1) A registration as a registered mortgage loan originator and a unique identifier if employed by an Agency-regulated institution (Federal registration), or (2) a license and registration as a State-licensed mortgage loan originator and a unique identifier.[3]

[1] The S.A.F.E. Act was enacted as part of the Housing and Economic Recovery Act of 2008, Public Law 110–289, Division A, Title V, sections 1501–1517, 122 Stat. 2654, 2810–2824 (July 30, 2008), *codified at* 12 U.S.C. 5101–5116. Citations in this Supplementary Information section are to the "S.A.F.E. Act" by section number in the public law.

[2] The OCC, Board, FDIC, OTS, and NCUA are referred to both in the S.A.F.E. Act and in this rulemaking as the "Federal banking agencies."

[3] If the Secretary of Housing and Urban Development (HUD) determines that any State fails, within the statutorily prescribed timeframe, to establish a licensing regime that meets the requirements of the S.A.F.E. Act, the Secretary is required to establish a system for the licensing and registration of mortgage loan originators in that State. S.A.F.E. Act at section 1508. *See* HUD proposed rule implementing this requirement at 75 FR 66548 (Dec. 15, 2009). HUD has reviewed the model legislation developed by the Conference of State Bank Supervisors and the American Association of Residential Mortgage Regulators to

The S.A.F.E. Act requires that Federal registration and State licensing and registration must be accomplished through the same online registration system, the Nationwide Mortgage Licensing System and Registry (Registry).

In connection with the Federal registration, the Agencies at a minimum must ensure that the Registry is furnished with information concerning the mortgage loan originator's identity, including: (1) Fingerprints for submission to the Federal Bureau of Investigation (FBI) and any other relevant governmental agency for a State and national criminal history background check; and (2) personal history and experience, including authorization for the Registry to obtain information related to any administrative, civil, or criminal findings by any governmental jurisdiction.[1] On June 9, 2009, the Agencies issued a notice of proposed rulemaking to implement these requirements for Agency-regulated institutions.[2]

B. Implementing the Requirements for Federal Registration

The Conference of State Bank Supervisors (CSBS) and the American Association of Residential Mortgage Regulators (AARMR) have developed and maintain a Web-based system, the Nationwide Mortgage Licensing System (NMLS), for the State licensing of mortgage loan originators in participating States.[3] Mortgage loan originators in these States electronically complete a single uniform form (the MU4 form). The data provided on the form is stored electronically in a centralized repository available to State regulators of mortgage companies, who use it to process license applications and to authorize individuals to engage in mortgage loan origination, as well as for other supervisory purposes.

The Federal banking agencies, through the FFIEC, and the FCA are working with CSBS to modify the NMLS so that it can accept registrations from mortgage loan originators employed by Agency-regulated institutions. This modified registry will be renamed the Nationwide Mortgage Licensing System and Registry. The existing NMLS was not designed to support the Federal registration of Agency-regulated institution employees, who are not required to obtain additional authorization from the appropriate Federal agency to engage in mortgage loan origination activities that are permissible for an Agency-regulated institution. Accordingly, the system must be modified to accommodate the differences between the requirements for State licensing/registration and Federal registration. It also must be modified to accommodate the migration of an individual between the State licensing/registration and the Federal registration regimes or the dual employment of an individual by both an Agency-regulated institution and a non-Agency-regulated institution.[1] Furthermore, the S.A.F.E. Act requires new enhancements to the current system, such as the processing of fingerprints and public access to certain mortgage loan originator data. These modifications and enhancements require careful analysis and raise complex legal and system development issues that the Agencies are addressing both through this rulemaking and through consultation with the CSBS and the SRR. The OCC, on behalf of the Agencies, has entered into an agreement with the SRR that will provide for appropriate consultation between the Agencies and the Registry concerning Federal registrant information requirements and fees, system functionality and security, and other operational matters. The issuance of this final rule establishing the requirements for Federal registrants will enable the Agencies and SRR to complete modifications that will enable the system to accept Federal registrations. As described in the **SUPPLEMENTARY INFORMATION** section of the proposed rule, the Agencies will publicly announce the date on which the Registry will begin accepting Federal registrations, which will mark the beginning of the period during which employees of Agency-regulated institutions must complete the initial registration process. When fully operational, mortgage loan originators and their Agency-regulated institution employers are expected to have access to the Registry, seven days a week, to establish and maintain their registrations.[1]

II. Overview of the Proposal and Public Comments

The proposed rule required individuals employed by Agency-regulated institutions who act as mortgage loan originators and who do not qualify for the *de minimis* exception set forth in the proposal to register with the Registry, obtain unique identifiers, and maintain their registrations through updates and renewals. The proposal also directed Agency-regulated institutions to require compliance with these requirements, and to adopt and follow written policies and procedures to assure such compliance. The S.A.F.E. Act does not require the Registry to screen or approve registrations received from employees of Agency-regulated institutions and the Registry will not do so. Instead, the Registry will be the repository of, and conduit for, information on those employees who are mortgage loan originators at Agency-regulated institutions. Pursuant to §§ __.104(d) and (h) of the proposed rule, it would be the responsibility of each Agency-regulated institution to establish reasonable procedures for confirming the adequacy and accuracy of employee registrations as well as to establish a process for reviewing any criminal history background reports received from the Registry.

The proposal provided for a 180-day period within which to complete initial registrations after the Registry is capable of accepting registrations from employees of Agency-regulated institutions. During this period, employees of Agency-regulated institutions would not be subject to sanctions if they originate residential mortgage loans without having completed their registration.

The Agencies received over 140 different comment letters from financial institutions and holding companies, trade associations, Federal government agencies, a training company, and individuals. A number of Agency-regulated institutions objected to the registration requirement in general, suggesting that the registration

assist States in meeting the minimum requirements of the S.A.F.E. Act and found it to meet these requirements. *See* 74 FR 312 (Jan. 5, 2009) and *http://www.hud.gov/offices/hsg/ramh/safe/cmsl.cfm.*

[1] S.A.F.E. Act at section 1507(a) (12 U.S.C. 5106(a)).

[2] 74 FR 27386 (June 9, 2009).

[3] The NMLS system is owned and operated by the State Regulatory Registry LLC (SRR), which is a limited-liability company established by CSBS and the American Association of Residential Mortgage Regulators as a subsidiary of CSBS to develop and operate nationwide systems for State regulators in the financial services industry. SRR has contracted with the Financial Industry Regulatory Authority (FINRA) to build and maintain the system. FINRA operates similar systems in the securities industry. More information about this system is available at *http://www.stateregulatoryregistry.org.*

[1] The Agencies note that some employees of Agency-regulated institutions also may be subject to the State licensing and registration regime. For example, employees who act as mortgage loan originators for a bank and a nondepository subsidiary of a bank holding company that is not a subsidiary of a depository institution would be subject to both the Federal and State regimes.

[1] Pursuant to section 1503(11) of the S.A.F.E. Act (12 U.S.C. 5102(11)), Agency-regulated institutions and their employees who are acting within the scope of their employment with the Agency-regulated institutions are not subject to State licensing or registration requirements for mortgage loan originators.

requirement should not be applied to them because they were not involved in the abuses that led to the enactment of the S.A.F.E. Act. In addition, many of these commenters found the registration requirement overly burdensome, especially as they are subject to regular examinations by the Agencies and they already closely supervise the activities of their employees.

Many commenters raised concerns related to the proposed *de minimis* exception from the registration requirement. Under the proposed *de minimis* exception, a mortgage loan originator would not have to register if he or she acted as a mortgage loan originator for five or fewer loans and the Agency-regulated institution employs mortgage loan originators who, while excepted from registration pursuant to the individual exception, in the aggregate acted as mortgage loan originators in connection with 25 or fewer residential mortgage loans. Commenters suggested raising the mortgage loan originator and institution loan limits or eliminating one of the limits. Community bank trade associations were particularly concerned that the narrowness of the exception would exclude most community banks. Some commenters suggested that the exception should be tied to an asset-based threshold in the range of $250 million to $1 billion.

Most commenters objected to having employees who engage in loan modifications or assumptions register under the rule, noting that these activities are fundamentally different than the mortgage loan origination process in that loan modifications and assumptions: (1) Are loss mitigation activities, not loan originations; (2) provide loan modification or assumption personnel little to no discretion in negotiating the terms and conditions of any changes; and (3) are outside of the Congressional intent and the plain language of the S.A.F.E. Act.

While some commenters found the 180-day initial registration period adequate, a number of commenters suggested alternative periods ranging up to one year. Some trade associations and institutions supported staggering registration periods in order to reduce system demands and to tailor an implementation schedule to the particular capacities of an institution or group of institutions, as long as the implementation period would still be 180 days for each institution.

A number of commenters also raised issues related to the provision of fingerprints to the Registry. Commenters asserted that it was not appropriate to have an age limit on fingerprints as they tend not to change; that the Registry should be able to accept fingerprints in a variety of formats, such as paper and scanned digital prints; and that Agency-regulated institutions should be permitted to use existing channels to process fingerprints.

Many commenters expressed privacy and security concerns regarding the types of personal information that mortgage loan originators would have to provide to the Registry and the ability of the public to have Internet access to such information.

Trade associations and large Agency-regulated institutions overwhelmingly requested that the Registry accommodate batch processing of registrations in order to reduce the costs and burden of data input, reduce errors, and efficiently register bank employees.

The Agencies have modified the proposal to take into account many of these comments. A detailed discussion of these comment letters and the Agencies' responses to them appears in the section-by-section description of the final rule that follows.[1]

III. Section-By-Section Description of the Final Rule

Section __.101—Authority, Purpose, and Scope

The Agencies adopt paragraphs (a) and (b) of § __.101 as proposed.[2] Paragraph (a) identifies the authority for this rule as the S.A.F.E. Act.[3] Paragraph (b) states that this rule implements the S.A.F.E. Act's Federal registration requirements, which apply to individuals who originate residential mortgage loans. This provision also describes the objectives of the S.A.F.E. Act, which are derived from section 1502 of the Act (12 U.S.C. 5101).

As in the proposal, paragraph (c)(1) of § __.101 of the final rule identifies the specific entities that employ individual mortgage loan originators—entities referred to in this **SUPPLEMENTARY INFORMATION** section as Agency-regulated institutions—and that also are covered by this rule. Under the S.A.F.E. Act, a mortgage loan originator must be Federally-registered if that individual is an employee of a depository institution, an employee of any subsidiary owned and controlled by a depository institution and regulated by a Federal banking agency, or an employee of an institution regulated by the FCA.[1] Section 1503(2) of the S.A.F.E. Act (12 U.S.C. 5102(2)) provides that "depository institution" has the same meaning as in section 3 of the Federal Deposit Insurance Act (FDI Act),[2] and includes any credit union. As we noted in the proposal, the definition of "depository institution" in the FDI Act and in the S.A.F.E. Act does not include bank or savings association holding companies or their non-depository subsidiaries. Employees of these entities who act as mortgage loan originators are not covered by the Federal registration requirement and, therefore, must comply with State licensing and registration requirements.

With respect to the OCC, this rule applies to national banks, Federal branches and agencies of foreign banks, their operating subsidiaries, and their employees who are mortgage loan originators.[3] For the Board, this rule applies to member banks of the Federal Reserve System (other than national banks); their respective subsidiaries that

[1] In addition to the changes described in this Supplementary Information section, the Agencies have replaced the cites in the proposed rule to sections of the S.A.F.E. Act with cites to the relevant provisions in the U.S. Code.

[2] Because each Agency's proposed rule will amend a different part of the Code of Federal Regulations, but will have similar numbering, relevant sections are cited as "§ __." followed by a number, unless otherwise noted.

[3] The Board and the OCC note that the authority in paragraph (a) of their respective rules supplements their authority to implement the S.A.F.E. Act, for example, Section 11 of the Federal Reserve Act (12 U.S.C. 248(a)) for the Board and section 5239A of the Revised Statutes (12 U.S.C. 93a) for the OCC.

[1] Agency-regulated institutions and their employees acting within the scope of their employment are subject only to the Federal registration requirements of the S.A.F.E. Act as implemented by the Agencies through this rulemaking, even if registration in the State system is available before Federal Registration. In consultation with the Agencies, CSBS/SRR are modifying the Registry so that it can accept registrations from employees of Agency-regulated institutions. An employee of an Agency-regulated institution may be engaged in activities outside the scope of his or her employment at an Agency-regulated institution that subject that employee to State licensing and registration requirements, such as dual employment at a non-Agency-regulated institution.

[2] Section 3 of the FDI Act defines "depository institution" as any bank or savings association. The term "bank" in section 3 of the FDI Act means any national bank, State bank, Federal branch, and insured branch and includes any former savings association. The term "savings association" means any Federal savings association, State savings association, and any corporation other than a bank that the FDIC and the OTS jointly determine to be operating in substantially the same manner as a savings association. 12 U.S.C. 1813.

[3] The S.A.F.E. Act's definition of depository institution includes Federal branches of foreign banks but not Federal agencies of foreign banks. Federal agencies are authorized by sections 1(b)(1) and 4(b) of the International Banking Act of 1978 (12 U.S.C. 3101(b)(1) and 3102(b)) and 12 CFR 28.11(g) and 28.13(a)(1) of the OCC's regulations to lend money, which would include originating mortgage loans, subject to the same duties, restrictions, penalties, liabilities, conditions, and limitations that would apply to a national bank. Thus, the Federal registration requirements apply to Federal agencies of foreign banks to the extent the registration requirements apply to national banks.

are not functionally regulated within the meaning of section 5(c)(5) of the Bank Holding Company Act, as amended (12 U.S.C. 1844(c)(5)); [1] branches and agencies of foreign banks (other than Federal branches, Federal agencies and insured State branches of foreign banks); commercial lending companies owned or controlled by foreign banks; [2] and their employees who act as mortgage loan originators. For the FDIC, this rule applies to insured State nonmember banks (including State-licensed insured branches of foreign banks) and their subsidiaries (except brokers, dealers, persons providing insurance, investment companies, and investment advisers) and their employees who are mortgage loan originators. For the OTS, this rule applies to savings associations and their operating subsidiaries, and their employees who are mortgage loan originators. For the FCA, this rule applies to FCS institutions that originate residential mortgage loans under sections 1.9(3), 1.11 and 2.4(a)(2) and (b) of the Farm Credit Act of 1971, as amended (12 U.S.C. 2017(3), 2019, and 2075(a)(2) and (b)), and their employees who are mortgage loan originators.[3] For the NCUA, this rule applies to credit unions and their employees who are mortgage loan originators. Because non-Federally insured credit unions generally are not Federally regulated institutions, special registration conditions apply to them as discussed below.

As discussed in Section II, a number of commenters objected to the application of this registration requirement to employees of Agency-regulated depository institutions because, in general, they are subject to regular examinations, would be overly burdened by the registration requirement, and already closely supervise the activities of their employees. Some commenters noted that this registration requirement would penalize them for the inappropriate actions of other lenders that led to the enactment of the S.A.F.E. Act.

The Agencies note that the registration of mortgage loan originators employed by Agency-regulated institutions is explicitly required by the S.A.F.E. Act. The statute imposes a registration requirement, rather than a licensing requirement, on the employees of Agency-regulated institutions. The Agencies note that such institutions (other than non-Federally insured credit unions) already are subject to a Federal regime of examination and supervision. The S.A.F.E. Act does not authorize the Agencies to create exceptions to the registration requirement other than the *de minimis* exception described below.

Some credit union-related commenters discussed whether the final rule should apply to credit union service organizations (CUSOs). The NCUA notes that it answered these questions in a public legal opinion letter 08–0843, dated October 8, 2008, available on NCUA's Web site, *http://www.ncua.gov.* The S.A.F.E. Act treats employees of depository institution subsidiaries the same as employees of the depository institution, if the subsidiary is owned and controlled by the depository institution *and* regulated by a Federal banking agency.[1] In the case of CUSOs, however, NCUA does not have direct regulatory oversight or enforcement authority. Instead, NCUA regulation permits Federal credit unions to invest in or lend only to CUSOs that conform to the limits specified in the CUSO rule, 12 CFR Part 712.[2] NCUA has not, historically, asserted that CUSOs or their employees are exempt from applicable State licensing regimes, and the S.A.F.E. Act does not alter that approach. Nor do NCUA regulations have any applicability to CUSOs owned by State-chartered credit unions.[3] Accordingly, individuals employed by CUSOs that engage in residential mortgage loan origination activities, whether the CUSO is owned by a State or a Federal credit union, would need to be licensed in accordance with applicable State requirements.

Some commenters also asked whether non-Federally insured credit unions must register with the Registry. NCUA's proposed rule applied to Federally insured credit unions and their employees who are mortgage loan originators but commenters requested NCUA include non-Federally insured credit unions and their employees who are mortgage loan originators in the scope of NCUA's final rule. The S.A.F.E. Act requires the Agencies to develop and maintain a system for registering employees of a depository institution, defined to include "any credit union." [4] Consistent with the S.A.F.E. Act and in response to comments, NCUA's final rule provides for a system for registering employees of any credit union. NCUA's final rule applies to Federally insured credit unions and their employees who are mortgage loan originators and non-Federally insured credit unions and their employees who are mortgage loan originators when certain conditions are met and formal agreements reached.

When drafting its final rule, NCUA considered that, with the exception of non-Federally insured credit unions, entities covered by the Federal registration system are subject to Federal oversight. Entities subject to the Federal registration system are labeled throughout the rule as "Agency-regulated institutions." Unlike Federal credit unions and Federally insured

[1] The S.A.F.E. Act, by its terms, applies the Federal registration requirements to employees of a subsidiary that is owned and controlled by a State member bank and regulated by the Board. For purposes of the scope of the Board's rules, these subsidiaries are described as those that are not functionally regulated within the meaning of section 5(c)(5) of the Bank Holding Company Act. Subsidiary has the meaning given that term in section 2 of the Bank Holding Company Act (12 U.S.C. 1841), as applied to State member banks.

[2] The Board notes that its final rule covers branches and agencies of foreign banks (other than Federal branches, Federal agencies, and insured State branches of foreign banks) and commercial lending companies owned or controlled by foreign banks pursuant to its authority under the International Banking Act (IBA) (Chapter 32 of Title 12) to issue such rules it deems necessary in order to perform its respective duties and functions under the chapter and to administer and carry out the provisions and purposes of the chapter and prevent evasions thereof. 12 U.S.C. 3108(a). The Board notes that the IBA provides, in relevant part, that the above entities shall conduct their operations in the United States in full compliance with provisions of any law of the United States which impose requirements that protect the rights of consumers in financial transactions, to the extent that the branch, agency, or commercial lending company engages in activities that are subject to such laws, and apply to State-chartered banks, doing business in the State in which such branch or agency or commercial lending company, as the case may be, is doing business. 12 U.S.C. 3106a(1). Under the Board's final rule, the above entities would be subject to the same Federal registration requirements as Federal branches, Federal agencies, and insured State branches of foreign banks, which are covered in the OCC and FDIC rules, respectively.

[3] Some FCS associations may not exercise their statutory authority to make residential mortgage loans, and FCS banks no longer engage in residential mortgage origination activities because they have transferred their direct lending authority to their affiliated associations. The FCA emphasizes that employees of FCS banks and associations that do not engage in residential mortgage loan origination activities are not subject to the registration requirements of the S.A.F.E. Act and these regulations. The Federal Agricultural Mortgage Corporation (Farmer Mac) is an FCS institution that among other activities operates a secondary market for rural residential mortgage loans. The FCA determines that Farmer Mac employees are not subject to the registration requirements of the S.A.F.E. Act and these implementing regulations because Farmer Mac does not engage in mortgage loan origination activities for rural residents. The Farmer Mac secondary market is modeled after Fannie Mae and Freddie Mac, and the provisions of the S.A.F.E. Act do not expressly apply to employees at Fannie Mae and Freddie Mac.

[1] Section 1503(7)(A)(ii) of the S.A.F.E. Act (12 U.S.C. 5102(7)(A)(ii)).

[2] 12 CFR part 712.

[3] In April 2008, the NCUA Board issued a proposed rule that would extend some provisions of the CUSO rule to State-chartered institutions. *See* 73 FR 23982 (May 1, 2008). The proposal has not yet been finalized.

[4] Sections 1507(a)(1) and 1503(1) and (2) of the S.A.F.E. Act (12 U.S.C. 5106(a)(1) and 5102(1) and (2)).

State-chartered credit unions, non-Federally insured credit unions are neither Federally insured nor subject to NCUA's oversight. In order for non-Federally insured credit unions and their employees who are mortgage loan originators to qualify for Federal registration, they must be subject to oversight for purposes of compliance with NCUA's rule. Therefore, due to the unique nature of non-Federally insured credit unions compared with all other credit unions, NCUA is working with State supervisory authorities in those States with non-Federally insured credit unions to implement an oversight program to enable them to participate in the Federal registration system.

The oversight program will require a State supervisory authority seeking to allow non-Federally insured credit unions in its State to participate in the Federal registration system to enter into a memorandum of understanding (MOU) with NCUA. The MOU will need to address various requirements such as, but not limited to: The requirement for an applicable State supervisory authority to maintain such an MOU to allow non-Federally insured credit unions and their employees in its State to have continuous access to, and use of, the registry; examination of the non-Federally insured credit unions' compliance with the rule by either the State supervisory authority or NCUA; non-Federally insured credit unions' payment of examination fees and payment for any necessary Registry modifications; and enforcement authority and penalties for non-Federally insured credit unions for noncompliance. Any information provided by the Registry to the public about a non-Federally insured credit union and its employees must include a clear and conspicuous statement that the non-Federally insured credit union is not insured by the National Credit Union Share Insurance Fund.

If any State supervisory authority where non-Federally insured credit unions are located fails to enter into or maintain an agreement with NCUA for this registration process and oversight, the non-Federally insured credit unions and their employees in that State cannot register or maintain an existing registration under the Federal system. They instead must use the appropriate State licensing and registration system, or if the State does not have such a system, the licensing and registration system established by the Department of Housing and Urban Department (HUD) for mortgage loan originators and their employees.[1] In addition, NCUA's final rule requires that the State supervisory authorities who seek to have non-Federally insured credit unions in their States participate in the Federal registration system enter into the applicable agreement with NCUA on or before the date the Agencies provide in a public notice that the Registry is accepting initial registrations.

Finally, NCUA acknowledges that, while it is an added requirement for non-Federally insured credit unions to have their State supervisory authorities enter into an agreement with NCUA, this is necessary to have any oversight or enforcement authority at all over these entities. Absent any agreement, non-Federally insured credit unions cannot participate in the Federal registration system. They are not subject to a Federal regime of examination and supervision, and are unlike any other Agency-regulated depository institutions covered under this rule. Therefore, they are subject to a different procedure to participate in the same Federal registration system.

Section 1507 of the S.A.F.E. Act (12 U.S.C. 5106) requires the Federal banking agencies to make such *de minimis* exceptions "as may be appropriate" to the Act's registration requirements.[1] Paragraph (c)(2) of § __.101 of the proposed rule provided a *de minimis* exception based on an individual's and, in the aggregate, an institution's total number of residential mortgage loans originated in a rolling 12-month period. Specifically, the proposal provided that the registration requirements would not apply to an employee of an Agency-regulated institution if, during the last 12 months: (1) The employee acted as a mortgage loan originator for 5 or fewer residential mortgage loans; and (2) the Agency-regulated institution employs mortgage loan originators who, while excepted from registration pursuant to this section, in the aggregate, acted as a mortgage loan originator in connection with 25 or fewer residential mortgage loans.

The Agencies received many, and varied, comments on this *de minimis* exception. Most commenters supported an exception to the rule's requirements. However, a majority of the commenters did not agree with the proposal's formulation of this exception, nor did they agree on an alternative. Specifically, some commenters requested that the Agencies raise the threshold number of loans originated by an individual mortgage loan originator and/or the institution so that more low-volume originators would qualify for the exception. These commenters indicated that, because of its narrowness, too few institutions would be able to use the exception as proposed and others would unnecessarily register employees solely to avoid accidental non-compliance with the rule. Some, however, thought that the proposed threshold numbers were too high, and could cause an institution to spread its originations over numerous employees to avoid registration. Still others said that the proposed *de minimis* exception would be fairer, and much easier to apply, if the threshold limitation applied only to the employee or to the institution, but not both. A Federal government agency commenter found that the proposed definition of *de minimis* would make the rule unduly burdensome on small community banks.

A number of commenters also suggested that the final rule base a *de minimis* exception on a percentage of total loans or the total loan volume made at each institution, instead of the number of loans. Some trade associations and smaller institutions requested that the *de minimis* exception be based on an institution's asset-size, with suggestions ranging from the Home Mortgage Disclosure Act[1] threshold for institutions regulated by a Federal banking agency, currently set by the Board at $39 million in assets,[2] to $1 billion, which would be consistent with exceptions for small institutions in other provisions of law. Other commenters opposed an asset-based approach, with larger Agency-regulated institutions noting that the exceptions should not be structured to benefit only small institutions.

Other commenters wanted the exception to be applied to institutions

[1] HUD published its proposed rule to establish this system on December 15, 2009. *See* 74 FR 66548.

[1] *See* S.A.F.E. Act at sections 1507(c) (12 U.S.C. 5106(c)) (*de minimis* exceptions), 1504(a)(1)(A) (12 U.S.C. 5103(a)(1)(A)) (requirement to register), 1504(a)(2) (12 U.S.C. 5103(a)(2)) (requirement to obtain a unique identifier). As discussed in the Supplementary Information section of the proposed rule, the FCA has authority under section 5.17(a)(11) of the Farm Credit Act of 1971, as amended, 12 U.S.C. 2252(a)(11), to apply the *de minimis* exception to FCS institutions. Section 5.17(a)(11) of the Farm Credit Act authorizes the FCA to "exercise such incidental powers as may be necessary or appropriate to fulfill its duties. * * *" In this case, the FCA is exercising its incidental powers to fulfill the requirement in the S.A.F.E. Act that it work together with the Federal banking agencies to develop and maintain a system for registering residential mortgage loan originators at Agency-regulated institutions with the Registry. A coordinated and uniform approach to the *de minimis* exception among the Agencies is appropriate because it best fulfills the objectives of the S.A.F.E. Act.

[1] 12 U.S.C. 2801 *et seq.*

[2] *See* 12 CFR 203.2 (Regulation C).

with no prior history of mortgage origination fraud or to institutions with good performance histories from previous supervisory examinations, regardless of the number of loans originated. Some commenters also suggested that the exception should apply only to individuals who do not regularly or principally function as a mortgage loan originator. Some commenters noted that the exception could instead be based on the percentage of time an employee spends engaged in the origination of residential mortgage loans.

The Agencies also received conflicting comments on whether to aggregate a subsidiary's loans with the parent institution for determining *de minimis* qualification. One commenter opposed such aggregation, while another stated that an institution should be required to aggregate its loan data with that of its subsidiaries so that institutions could not "game" the system by creating new subsidiaries each time a subsidiary approaches the *de minimis* limit. Still other commenters pointed out that it would be very time consuming and burdensome to game the *de minimis* limit—rendering gaming opportunities essentially unrealistic.

Many commenters noted the complexity of the proposed exception. One commenter stated that the *de minimis* exception would not have any significant effect because the complexity of complying with it would outweigh its benefits. Others noted that the proposed exception would be difficult for an institution to monitor and maintain. Some commenters appeared to misinterpret the proposed aggregate exception.

The Agencies agree that the *de minimis* exception should be simplified, and, in particular, that it should be structured so that it may be utilized by an individual who does not regularly or principally function as a mortgage loan originator employed by any Agency-regulated institution, regardless of the size or loan volume of the institution. Therefore, the final rule eliminates the aggregate exception and includes only the first prong of the proposed *de minimis* exception, which applies only to individuals. The final rule also provides that this exception only applies if the employee has never before been registered or licensed through the Registry.

Final § __.101(c)(2) thus provides that the registration requirements of this section do not apply to an employee of an Agency-regulated institution who has never been registered or licensed through the Registry as a mortgage loan originator and who has acted as a mortgage loan originator for 5 or fewer residential mortgage loans during the last 12 months. In order to prevent manipulation of the registration requirement by structuring this exception to apply to multiple employees who each would not meet the exception's threshold for registration, the final rule prohibits any Agency-regulated institution from engaging in any act or practice to evade the limits of the *de minimis* exception. The Agencies believe that replacing the proposed institution limit with this anti-evasion prohibition is appropriate and will discourage circumvention of registration requirements without increasing an institution's administrative burden.

Monitoring compliance with the exception as revised should be less burdensome for Agency-regulated institutions. In addition, in the Agencies' view, this revised exception better balances the usefulness of the exception to Agency-regulated institutions and their mortgage loan originators with the consumer protection and fraud prevention purposes of the S.A.F.E. Act. Although the final rule specifically applies this anti-evasion provision to the *de minimis* exception, Agency-regulated institutions must not engage in any act or practice to evade any other requirement of the S.A.F.E. Act or this final rule.

The Agencies note that, as with the proposal, an employee must register with the Registry prior to engaging in mortgage loan origination activity that exceeds the exception limit. In addition, the Agencies note that the *de minimis* exception contained in the final rule is voluntary; it does not prevent a mortgage loan originator who meets the criteria for the exception from registering with the Registry if the originator chooses to do so or if his or her employer requires registration.

The Agencies note that the Federal Housing Finance Agency (FHFA) has directed Fannie Mae and Freddie Mac to require all mortgage loan applications to include the mortgage loan originator's unique identifier. For Agency regulated institutions, Fannie Mae and Freddie Mac have announced that this requirement will apply to applications dated on or after the date the Agencies require mortgage loan originators to obtain unique identifiers.[1] Agency-regulated institutions should be aware of this requirement and any future guidance that FHFA may issue to address the Agencies' implementation of the Federal registration process, including the *de minimis* exception.

The Agencies received a comment from one large financial institution requesting that we clarify whether the failure of a mortgage loan originator to register pursuant to this rulemaking has any substantive impact on a mortgage loan made by an institution that employs that originator. Neither the S.A.F.E. Act nor this final rule provides that a mortgage loan originator's failure to register as required affects the validity or enforceability of any mortgage loan contract made by the institution that employs the originator.

A few commenters suggested that in addition to the registration requirements, the final rule should impose educational and testing requirements on mortgage loan originators, as the S.A.F.E. Act does for State-licensed originators. The Agencies decline to impose such requirements. The S.A.F.E. Act does not include educational or testing requirements for mortgage loan originators employed by Agency-regulated institutions. In addition, as noted previously, the statute imposes different requirements on mortgage loan originators employed by Agency-regulated institutions. The Agencies note that these institutions already are subject to extensive Federal oversight, including regular on-site examination of their mortgage lending activities.

Section __.102—Definitions

Section __.102 defines the terms used in the final rule. If a term is defined in the S.A.F.E. Act, the Agencies generally have incorporated the same definition in the final rule. The final rule also includes other definitions currently used by the NMLS in order to promote consistency and comparability, insofar as is feasible, between Federal registration requirements and the States' licensing requirements.

Annual renewal period. Proposed § __.102(a) required that a mortgage loan originator renew his or her registration annually during the annual renewal period and defined this period as November 1 through December 31 of each year. This is the same annual renewal period currently provided by the NMLS to mortgage loan originators regulated by a State.

[1] *See* FNMA LL 02–2009: New Mortgage Loan Data Requirements (02/13/09); Fannie Mae Announcement 09–11, Mortgage Loan Data Requirements Update (10/6/09) and Announcement 09–11, Mortgage Loan Data Requirements Related FAQs (2/4/10); and Freddie Mac Single-Family Seller/Servicer Guide Bulletin, No: 2009–27 (12/4/09). The Agencies contemplate that the Registry will provide aggregate public data on unique identifier information stored in the system to Fannie Mae and Freddie Mac for compliance purposes.

This time period for renewals generated many comments. A few commenters suggested that the renewal period for Agency-regulated institutions should be at a different time of year than for originators regulated by a State. Others stated that the renewal period should be based upon the original registration date or original hire date, noting that a staggered registration process would be less burdensome for the Registry. Another commenter suggested that the employing institution determine its own renewal period for its employees. Still other commenters requested that this renewal period be lengthened from 60 to 90 days.

The Agencies decline to change the dates for the annual renewal period. As indicated above, the current system for originators regulated by a State is configured for an annual renewal period from November 1 through December 31. A different renewal period for originators employed by Agency-regulated institutions would involve functionality changes to the existing system, adding costs and lengthening the implementation time. In addition, the Agencies note that different renewal periods could cause confusion and added burden to those originators who may work for both a State-regulated and Agency-regulated institution or who may switch from a State-regulated institution to an Agency-regulated institution during the year, and to employers of such originators, as well as for institutions that control both State- and Agency-regulated institutions. For these same reasons, the Agencies also decline to increase the renewal period from 60 to 90 days. Therefore, the final rule retains the proposed renewal period of November 1 through December 31 of each year.

Mortgage loan originator. The proposed definition of "mortgage loan originator" was based on the definition of the term "loan originator" included in the S.A.F.E. Act at section 1503(3) (12 U.S.C. 5102(3)). As defined by the S.A.F.E. Act, this term means an individual who takes a residential mortgage loan application and offers or negotiates terms of a residential mortgage loan for compensation or gain. The term does not include an individual who is not a mortgage loan originator and: (1) Performs purely administrative or clerical tasks on behalf of an individual who is a mortgage loan originator; (2) performs only real estate brokerage activities (as defined in section 1503(3)(D) of the S.A.F.E. Act (12 U.S.C. 5102(3)(D)) [1] and is licensed or registered as a real estate broker in accordance with applicable State law, unless the individual is compensated by a lender, a mortgage broker, or other loan originator or by any agent of such lender, mortgage broker, or other mortgage loan originator; or (3) is solely involved in extensions of credit related to timeshare plans, as that term is defined in 11 U.S.C. 101(53D).[1]

For purposes of the definition of mortgage loan originator, section 1503(3)(C) of the S.A.F.E. Act (12 U.S.C. 5102(3)(C)) defines "administrative or clerical tasks" to mean: (1) The receipt, collection, and distribution of information common for the processing or underwriting of a loan in the mortgage industry; and (2) communication with a consumer to obtain information necessary for the processing or underwriting of a residential mortgage loan. The proposal included this definition as well, with one nonsubstantive difference—the proposal used the phrase "residential mortgage industry" instead of "loan in the mortgage industry" in the first prong of the definition.

The Agencies included an appendix to the proposal that listed examples of the types of activities the Agencies consider to be both within and outside the scope of residential mortgage loan origination activities. The final rule retains this appendix with certain changes as discussed in this **SUPPLEMENTARY INFORMATION** section. Individuals who receive "compensation or gain" as used in the definition of mortgage loan originator and described in this appendix include individuals who earn salaries, commissions or other incentive, or any combination thereof.

The Agencies specifically requested comment on whether the definition of "mortgage loan originator" should cover individuals who modify existing residential mortgage loans, engage in approving loan assumptions, or engage in refinancing transactions and, if so, whether these individuals should be excluded from the definition. While a few commenters believed the Agencies should cover individuals engaged in such transactions, the majority of commenters on this issue stated that this rulemaking should not cover these individuals. In general, they indicated that mortgage loan modifications and assumptions are very different from mortgage loan originations, and that employees engaged in these transactions do not meet the S.A.F.E. Act's definition of mortgage loan originator. Specifically, commenters indicated that these employees neither accept residential mortgage loan applications nor negotiate the terms of a new residential mortgage loan. Instead, they renegotiate an existing loan with the goals of mitigating any loss to the institution and, in the case of modifications, providing the borrower with a more affordable payment option or other type of modification, or, in the case of assumptions, replacing the party responsible for repaying the mortgage loan. Many commenters indicated that their employees who engage in modifications and assumptions do not ever originate mortgage loans, and that modifications and assumptions are performed in different departments of the institution. Many commenters also noted that applying the S.A.F.E. Act's registration requirements to employees engaged in loan modifications and assumptions could significantly hamper loan modification efforts.

The determining factor in whether the S.A.F.E. Act applies to residential mortgage loan-related transactions is whether the employee engaged in the transaction meets the definition of "mortgage loan originator." In general, neither modifications nor assumptions result in the extinguishment of an existing loan and the replacement by a new loan, but rather the terms of an existing loan are revised or the loan is assumed by a new obligor. Thus, Agency-regulated institution employees

[1] The S.A.F.E. Act defines "real estate brokerage activity" to mean any activity that involves offering or providing real estate brokerage services to the public, including: (i) Acting as a real estate agent or real estate broker for a buyer, seller, lessor, or lessee of real property; (ii) bringing together parties interested in the sale, purchase, lease, rental, or exchange of real property; (iii) negotiating, on behalf of any party, any portion of a contract relating to the sale, purchase, lease, rental, or exchange of real property (other than in connection with providing financing with respect to any such transaction); (iv) engaging in any activity for which a person engaged in the activity is required to be registered or licensed as a real estate agent or real estate broker under any applicable law; and (v) offering to engage in any activity, or act in any capacity, described in clause (i), (ii), (iii), or (iv), above. S.A.F.E. Act at section 1503(3)(D) (12 U.S.C. 5102(3)(D)). Nothing in this rule would constitute an authorization for Agency-regulated institutions to engage in real estate brokerage, or any other activity, for which the institution does not have independent authority pursuant to Federal or State law, as applicable.

[1] "Timeshare plan" is defined in 11 U.S.C. 101(53D) as an interest purchased in any arrangement, plan, scheme, or similar device, but not including exchange programs, whether by membership, agreement, tenancy in common, sale, lease, deed, rental agreement, license, right to use agreement, or by any other means, whereby a purchaser, in exchange for consideration, receives a right to use accommodations, facilities, or recreational sites, whether improved or unimproved, for a specific period of time less than a full year during any given year, but not necessarily for consecutive years, and which extends for a period of more than three years. A "timeshare interest" is that interest purchased in a timeshare plan which grants the purchaser the right to use and occupy accommodations, facilities, or recreational sites, whether improved or unimproved, pursuant to a timeshare plan.

engaged in these activities typically do not take loan applications, within the meaning of the S.A.F.E. Act. Therefore, the Agencies conclude that the S.A.F.E. Act's definition of "mortgage loan originator" generally would not include employees engaged in loan modifications or assumptions because they typically would not meet the two-prong test of this definition. However, if an employee engaged in a transaction labeled a loan "modification" or "assumption" can be found to meet the definition of "mortgage loan originator," due to the nature of the specific transaction in question, he or she would be subject to the S.A.F.E. Act and this final rule. The substance of a transaction, not the label attached to it, is determinative of whether the Agency-regulated institution employee associated with it is a mortgage loan originator for purposes of this rule. For example, the Agencies believe that Agency-regulated institution employees engaged solely in bona fide cost-free loss mitigation efforts that result in reduced and sustainable payments for the borrower generally would not meet the definition of "mortgage loan originator." In this regard, it should be noted that third parties involved in foreclosure prevention activities for compensation or gain, although outside the scope of this rulemaking, may be subject to licensing and registration pursuant to State law.

The Agencies sought comment on whether the individuals who engage in certain refinancing transactions, specifically cash-out refinancing with the same lender, should be excluded from the definition of residential mortgage loan originator. Some industry commenters did not believe that such an exclusion was appropriate primarily because of the nature of a refinancing as a new loan and the potential for consumer abuse in these transactions. Other commenters also requested that we exclude individuals engaged in refinancings from the final rule's definition of mortgage loan originator, and that refinancings be excluded from the final rule's definition of residential mortgage loan, if the refinancing involves the same lender and the borrower obtained no cash proceeds. We decline to make this change. Refinancings are new loans, regardless of the lender, the loan terms, or proceeds, that involve a new application and an offer or negotiation of new loan terms. If an individual engaged in a refinancing transaction of a residential mortgage loan meets the two prongs of the definition of mortgage loan originator, he or she must comply with the requirements of the S.A.F.E. Act and this final rule.[1]

Other commenters suggested that the Agencies exclude loan servicing personnel from the requirements of this rulemaking. We decline to take this suggested approach because the S.A.F.E. Act definition is based on the activities of mortgage loan origination, rather than the job classification of the individual. An individual, regardless of job title, is a mortgage loan originator if he or she engages in the activities of mortgage loan origination within the meaning of the S.A.F.E. Act. For example, if a loan servicing employee of an Agency-regulated institution mainly performs loan servicing activities but also occasionally engages in residential mortgage loan origination, that person is a mortgage loan originator, regardless of whether he or she is called "servicing personnel." On the other hand, for example, as discussed above in connection with loan modifications, a loan servicing employee engaged solely in bona fide cost-free loss mitigation efforts which result in reduced and sustainable payments for the borrower generally would not meet the definition of "mortgage loan originator." Loan servicing employees of Agency-regulated institutions must comply with the registration requirements of the final rule if they meet both prongs of the definition of "mortgage loan originator," unless they qualify for the *de minimis* exception under § __.101(c)(2) of the final rule. Some commenters requested clarification that, when a servicing employee of an Agency-regulated institution works with a borrower to collect unpaid taxes or other costs pursuant to a repayment or collection plan, the employee is not acting as a mortgage loan originator under the Agencies' rules. The Agencies agree that such activities would generally not meet the two-prong test of this definition.

Some commenters asked the Agencies to explain whether the S.A.F.E. Act and this rule apply to residential mortgage loan originations made through an automated underwriting system, whereby an applicant inquires about, applies for, and/or receives a decision on an application electronically through an institution's Web site.[1] Although some institutions may choose to establish an automated system to collect application information and make an initial decision on a loan application, from a risk management and compliance perspective, an institution is expected to set the system parameters and monitor system output for compliance with various laws, regulations, and guidance on an ongoing basis. Such institutions are expected to register employees involved in that process who meet the definition of "mortgage loan originator," as appropriate. As indicated above, the Agencies note that Fannie Mae and Freddie Mac are requiring all residential mortgage loan applications dated on or after the compliance date for the unique identifier requirement to include the mortgage loan originator's unique identifier.[1] Institutions should keep apprised of any future guidance FHFA may issue to address this requirement.

For the reasons discussed above, the final rule includes the definition of "mortgage loan originator" as proposed, with one technical change to the definition of "administrative or clerical tasks" to make it identical to the definition of this term in section 1503(3)(C) of the S.A.F.E. Act (12 U.S.C. 5102(3)(C)).

Nationwide Mortgage Licensing System and Registry or *Registry.* Section __.102(c) of the proposed rule's definition of these terms is based on the definition included in section 1503(5) of the S.A.F.E. Act (12 U.S.C. 5102(5)). Specifically, these terms mean the system developed and maintained by CSBS and the AARMR for the State licensing and registration of State-licensed mortgage loan originators and the registration of mortgage loan originators pursuant to section 1507 of the S.A.F.E. Act (12 U.S.C. 5106). As explained above, CSBS and the AARMR have established an online system, NMLS, that currently supports the licensing and registration of mortgage loan originators regulated by a State. The Agencies are working with CSBS to modify the NMLS to support the registration of mortgage loan originators employed by Agency-regulated institutions, and will rename this system the Nationwide Mortgage Licensing System and Registry. The Agencies received no comments on this definition and adopt it as proposed.

Registered mortgage loan originator. Pursuant to section 1503(7) of the S.A.F.E. Act (12 U.S.C. 5102(7)), the proposed rule defined this term to mean any individual who meets the definition

[1] Some commenters noted that the Agencies should require only one mortgage loan originator for each mortgage loan. The Agencies decline to take this approach because the S.A.F.E. Act defines a mortgage loan originator according to the two-prong test set forth in the statute.

[1] Section 107(5)(A)(x) of the Federal Credit Union Act (12 U.S.C. 1757(5)(A)(x)) requires all loans to be approved by a credit committee or loan officer. For all Federal credit unions, and to the extent State-chartered credit unions operate under a similar State law or regulation, the statutory and regulatory definition of mortgage loan originator is met and the S.A.F.E Act does apply.

[1] *See* footnote 26.

of mortgage loan originator, is an employee of an Agency-regulated institution, and is registered pursuant to the requirements of this rule with, and maintains a unique identifier through, the Registry. This definition is the same as that included in the S.A.F.E. Act, except that the Agencies have modified it to apply only to individuals registered pursuant to regulations issued by the Agencies. The Agencies received no comments on this definition and adopt it as proposed.

Residential mortgage loan. As in section 1503(8) of the S.A.F.E. Act, (12 U.S.C. 5102(8)), the proposal defined "residential mortgage loan" as any loan primarily for personal, family, or household use that is secured by a mortgage, deed of trust, or other equivalent consensual security interest on a dwelling (as defined in section 103(v) of the Truth in Lending Act (TILA) (15 U.S.C. 1602(v)) [1] or residential real estate upon which is constructed or intended to be constructed a dwelling. In addition, the proposal specifically included refinancings, reverse mortgages, home equity lines of credit and other first and second lien loans secured by a dwelling in this definition in order to clarify that originators of these types of loans are covered by the rule's requirements.

One commenter suggested that ancillary liens on an underlying mortgage loan or liens taken to provide consumers with potential tax advantages should not be considered residential mortgage loans. In addition, another commenter asked that the definition of residential mortgage loan include an exception to exclude seller-sponsored financing of the sale of lender-owned property. The Agencies decline to adopt these exclusions to the definition of "residential mortgage loan" and adopt this definition as proposed. These types of loans clearly fall within the statutory definition of "residential mortgage loans," and the S.A.F.E. Act makes no exceptions for these two situations. We do clarify, however, that this definition does not include loans for business, commercial, or agricultural purposes that use as collateral property that meets the definition of a "dwelling."

As indicated in the **SUPPLEMENTARY INFORMATION** section to the proposed rule, the FCA emphasizes that section 1503(8) of the S.A.F.E. Act (12 U.S.C. 5102(8)) and § __.102(e) do not amend or supersede sections 1.11(b) and 2.4(b) of the Farm Credit Act of 1971, as amended (12 U.S.C. 2019(b) and 2075(b)), and their implementing regulation, 12 CFR 613.3030(c), which establish the purposes for which FCS institutions may originate residential mortgage loans for eligible rural home borrowers.

Unique Identifier. The proposed rule's definition of this term was almost identical to that in section 1503(12) of the S.A.F.E. Act (12 U.S.C. 5102(12)). The Agencies received no comments on this definition and adopt it as proposed. Specifically, the final rule defines "unique identifier" to mean a number or other identifier that: (1) Permanently identifies a registered mortgage loan originator; (2) is assigned by protocols established by the Registry and the Agencies to facilitate electronic tracking of mortgage loan originators, and uniform identification of, and public access to, the employment history of and the publicly adjudicated disciplinary and enforcement actions against mortgage loan originators; and (3) must not be used for purposes other than those set forth in the S.A.F.E. Act.

Other terms. The Agencies note that § __.103(d) of the proposed and final rule uses the terms "control" and "financial services-related" in the descriptions of the information that is required of an employee who is a mortgage loan originator. These terms are currently defined in the Web-based MU4 form collecting information on State-licensed mortgage loan originators. In order to promote consistency of the information collected for Agency-regulated and State-licensed mortgage loan originators, the Agencies reiterate that the MU4 form's definitions of those two terms also will be used in the Web-based form collecting information on Agency-regulated mortgage loan originators and, therefore have not defined them in this rulemaking.[1]

A number of commenters requested that the Agencies define "employee" for purposes of this rulemaking to provide more clarity regarding the individuals covered by the rule. Agency-regulated institutions must have a process for identifying which employees of the institution are required to be registered mortgage loan originators.[2] As the Supreme Court has explained, "where Congress uses terms that have accumulated settled meaning under * * * the common law, a court must infer, unless the statute otherwise dictates, that Congress means to incorporate the established meaning of these terms * * *. In the past, when Congress has used the term 'employee' without defining it, we have concluded that Congress intended to describe the conventional master-servant relationship as understood by common-law agency doctrine." [3] Section 7.07(3)(a) of the Restatement (Third) of Agency explains that "an employee is an agent whose principal controls or has the right to control the manner and means of the agent's performance of work." [1] The Agencies thus intend that the meaning of "employee" under the S.A.F.E. Act and this rule is consistent with the right-to-control test under the common law agency doctrine. The Agencies note in this regard that the IRS uses the common law right-to-control test as its basis for classification of workers as employees.[2] The result of this test generally determines whether an institution files a W–2 or a 1099 for an individual. The Agencies therefore expect an Agency-regulated institution would identify a mortgage loan originator as an individual subject to this final rule if, following consideration of the relevant facts, the institution determines that the individual is an employee of the Agency-regulated institution.[3]

[1] TILA defines "dwelling" as a residential structure or mobile home which contains one-to-four family housing units, or individual units of condominiums or cooperatives. 15 U.S.C. 1602(v). Board regulations and commentary include in this definition any residential structure that contains one to four units, whether or not that structure is attached to real property, and includes an individual condominium unit, cooperative unit, mobile home, and trailer, if it is used as a residence. *See* 12 CFR 226.2(a)(19) (Regulation Z).

[1] The Registry currently defines "control" as the power, directly or indirectly, to direct the management or policies of a company, whether through ownership of securities, by contract, or otherwise. Any *person* that (i) is a general partner or executive officer, including Chief Executive, Chief Financial Officer, Chief Operations Officer, Chief Legal Officer, Chief Credit Officer, Chief Compliance Officer, Director, and individuals occupying similar positions or performing similar functions; (ii) directly or indirectly has the right to vote 10% or more of a class of a voting security or has the power to sell or direct the sale of 10% or more of a class of voting securities; or (iii) in the case of a partnership, has the right to receive upon dissolution, or has contributed, 10% or more of the capital, is presumed to control that company. The Registry's current definition of "Financial services-related" means pertaining to securities, commodities, banking, insurance, consumer lending, or real estate (including, but not limited to, acting as or being associated with a bank or savings association, credit union, Farm Credit System institution, mortgage lender, mortgage broker, real estate salesperson or agent, appraiser, closing agent, title company, or escrow agent).

[2] *See* § __.104(a).

[3] *Nationwide Mutual Ins. Co.* v. *Darden,* 503 U.S. 318, 322–23 (1992) (citing *Community for Creative Non-Violence* v. *Reid,* 490 U.S. 730, 739–40 (1989) (other citations omitted).

[1] Restatement (Third) of Agency § 7.07(3)(a) (2006).

[2] IRS Publication 1779; *see also* Form SS–8, *Determination of Worker Status for Purposes of Federal Employment Taxes and Income Tax Withholding.*

[3] Agency-regulated institutions that are credit unions sometimes rely upon volunteers to originate mortgage loans. The right-to-control test under the common law agency doctrine likewise applies to these credit unions. Credit union management

Section __.103—Registration of Mortgage Loan Originators

Section 1504(a) of the S.A.F.E. Act (12 U.S.C. 5103(a)) prohibits an individual who is an employee of an Agency-regulated institution from engaging in the business of a loan originator without registering as a loan originator with the Registry, maintaining annually such registration, and obtaining a unique identifier through the Registry. As in the proposal and described more specifically below, § __.103 of the final rule imposes the responsibility for complying with these requirements on both the individual employee and the employing institution. In addition, both the employee and the employing institution must submit information to the Registry for each registration to be complete. The Agencies note that an employee of an Agency-regulated institution who is not actively engaged in residential mortgage loan activity is not prohibited from registering with the Registry.

Employee registration requirement. In general, § __.103(a)(1) of the proposed rule required an employee of an Agency-regulated institution who acts as a mortgage loan originator to register with the Registry, obtain a unique identifier, and maintain his or her registration. This section further provided that any employee who is not in compliance with the registration and unique identifier requirements set forth in the proposed rule is in violation of the S.A.F.E. Act and this rule.[1] The Agencies note that this registration requirement would not apply if the employee qualifies for the *de minimis* exception.

The Agencies did not receive substantive comments specifically on this section and therefore adopt it as proposed.

Institution requirement. Proposed paragraph (a)(2) of § __.103 provided that an Agency-regulated institution must require its employees who are mortgage loan originators to register with the Registry, maintain this registration, and obtain a unique identifier in compliance with this final rule. This provision also prohibited an Agency-regulated institution from permitting its employees to act as mortgage loan originators unless registered with the Registry pursuant to this final rule, after the applicable implementation periods specified in §§ __.103(a)(3) and (a)(4)(ii) expire.

One commenter objected to this requirement as not being based on statutory language. Although the S.A.F.E. Act does not contain the same express prohibition as in the Agencies' proposed rule, determining the scope of mortgage loan origination activities that subject an individual or institution to the Act's requirements is well within the Agencies' authority to implement the statute. The imposition of this requirement on Agency-regulated institutions implements the purposes of the S.A.F.E. Act and ensures Agency-regulated institutions and their employees comply with all applicable laws. This commenter also stated that this requirement would be difficult to enforce because an employing institution may not know of the activities of its employees outside of their scope of employment at that institution. We agree with this commenter that the language in § __103(a)(2)(ii) should be clarified so that an institution's oversight of a mortgage loan originator applies only to the extent the originator is acting within the scope of his or her employment at that institution. We therefore adopt § __.103(a)(2)(ii) with this one change.

Implementation period for initial registrations. Proposed § __.103(a)(3) provided a 180-day implementation period for initial registrations beginning on the date the Agencies provide public notice that the Registry is accepting initial registrations. The Agencies have adopted this provision as proposed with one minor change to clarify that the implementation period begins on the date that the Agencies provide in their public notice, not the actual date of the public notice. Pursuant to the proposal, an employee could continue to originate residential mortgage loans without complying with the rule's registration requirement before and during this 180-day period. After this 180-day period expires, any existing employee or newly-hired employee of an Agency-regulated institution who is subject to the registration requirements would be prohibited from originating residential mortgage loans without first meeting such requirements.

The Agencies specifically requested comment on whether this 180-day implementation period would provide Agency-regulated institutions and their employees with adequate time to complete the initial registration process. The Agencies also inquired as to whether an alternative schedule for implementation and initial registrations would be appropriate, what such an alternative schedule should be, and whether, and how, a staggered registration process should be developed.

The Agencies received many comments on this implementation period. Some commenters supported a 180-day period. Others supported the proposed 180-day implementation period provided that certain conditions are met, such as excluding loan modification and mitigation employees from the registration requirements, allowing batch processing, simplifying the employer verification requirements, and immediate confirmation of registration without delay for fingerprint or background check results.

Other commenters, however, stated that the proposed 180-day implementation period would not provide sufficient time to register the large number of employees subject to the registration requirement, properly train all employees, develop compliance policies, and program and implement system controls. Many noted that a longer period would prevent the Registry from being overwhelmed with registrations. Two commenters, including one Federal agency, stated that additional time will particularly benefit smaller financial institutions. Another commenter indicated that the time, effort, and resources required to meet new systems requirements can be extensive, and that a 180-day implementation period for such major changes would be extremely difficult for larger institutions. These commenters suggested an implementation period of nine months to one year. One commenter stated that each Agency should have the flexibility to grant additional time to register in the event the Registry becomes backlogged or inundated with a large volume of registrations. No commenter requested a shorter implementation period.

The Agencies understand that Agency-regulated institutions and their mortgage loan originator employees will face certain implementation issues in complying with the registration requirements established by this rulemaking. However, as indicated above, due to various system

establishes the policies, procedures, and practices that volunteers use in performing their functions. Therefore, these volunteers qualify as employees of the Agency-regulated institution for purposes of the S.A.F.E. Act and this rule.

[1] The OCC, Board, FDIC, and OTS have the authority to take enforcement actions against their respective Agency-regulated institutions and individual employees of those institutions who violate the S.A.F.E. Act and this final rule, pursuant to 12 U.S.C. 1818. The FCA has authority to take enforcement actions against Farm Credit System institutions and individual employees who violate the S.A.F.E. Act and this final rule pursuant to Title V, Part C of the Farm Credit Act of 1971, as amended, 12 U.S.C. 2261 *et seq.* The NCUA has the authority to take enforcement actions against Federally-insured credit unions and their employees who violate the S.A.F.E. Act and this final rule under 12 U.S.C. 1786. For privately insured credit unions, memoranda of understanding between NCUA and applicable State supervisory authorities will establish enforcement authority.

modifications and enhancements required to make the existing system capable of accepting Federal registrants, the system is not expected to be available to accept Federal registrations before January 2011. The 180-day implementation period will not begin until the system is available to accept Federal registrations. This in effect provides institutions with an implementation period longer than 180 days as institutions and their employees can begin to implement the final rule's requirements before the Registry is operational, *i.e.,* develop policies and procedures, train employees, gather information needed for registration, and program and implement system controls before registration is required. In addition, CSBS and SRR will provide information to, and assist Agency-regulated institutions in preparation for, registration during this period. The Agencies believe that this additional time will provide mortgage loan originators, and the Agency-regulated institutions that employ them, adequate opportunity to prepare for the registration requirements. Any extension of the 180-day implementation period provided in the final rule will only further delay the registration of residential mortgage loan originators and, as a result, the consumer protection benefits of the S.A.F.E. Act. In addition, as described below, batch processing of at least some information likely will be available, which should make the registration process more efficient for both the institution and the registering employee. For these reasons, the Agencies decline to provide an implementation period longer than the proposed 180 days.

Many commenters indicated support for a staggered implementation period. Some noted that this could be based on institution size, loan origination volume, or employee qualifiers (such as birth date or last name). Some of these commenters, however, noted that they would support a staggered schedule only if it would provide a registration period of equal length for all registrants. Other commenters supported a staggered process that would give smaller institutions or institutions that do not originate many residential mortgage loans the greatest amount of time to comply with the requirements.

The Agencies agree that a staggered implementation process for those institutions that prefer one would be useful. Such a process would allow institutions to register their employees within specific time periods during the implementation period with the assistance of dedicated staff. Staggered registration would limit the number of originators registering at any one time and spread the registration of originators throughout the implementation period. Although such a schedule mostly would benefit those institutions with the largest number of mortgage loan originators, it also should enable the Registry to accommodate all registrations in a more timely and efficient manner, thereby benefiting all institutions. Accordingly, the Agencies will work with CSBS and SRR to develop a staggered registration schedule for institutions, in particular those that are estimated to have a large number of mortgage loan originators subject to Federal registration, that request such a schedule. This staggered process would occur within the 180-day implementation period in order not to delay the registration of mortgage loan originators and the ability of consumers to fully utilize the Registry. Because institutions that request a staggered registration process would have a dedicated period during which to register within the 180-day period, registration burdens may be eased for these institutions, lessening their need for the full 180-day registration period. Details on this staggered approach will be provided to applicable institutions when they have been finalized and may include the availability of this dedicated staff prior to the start of the registration period.

Special rule for previously registered employees. Under paragraph (a)(4) of § __.103 of the proposed and final rule, properly registered or licensed mortgage loan originators would not have to register again with the Registry when they change employment by moving from one Agency-regulated institution to another or from a State-regulated institution to an Agency-regulated institution, regardless of whether the change in employment is made voluntarily, through an acquisition or merger of the employee's prior employer, or through a reorganization where previously State-licensed mortgage loan originators become subject to the registration requirements of Agency-regulated institutions. Instead, the employee and employing institution need only update information in the Registry and complete the required authorizations and attestation.

Specifically, proposed paragraph (a)(4) of § __.103 provided that if a new employee of an Agency-regulated institution had previously registered with, and obtained a unique identifier from, the Registry prior to becoming an employee of that institution and has maintained that registration (or license, if previously employed by a non-Agency-regulated institution), the registration requirements of this final rule are deemed to be met provided that: (1) The employee's employment information in the Registry is updated and the employee has completed the required authorizations and attestation; (2) new fingerprints of the employee are provided to the Registry for a background check, except in the case of mergers, acquisitions or reorganizations; (3) information concerning the new employing institution is provided to the Registry pursuant to § __.103(e)(1)(i), to the extent the institution has not previously met these requirements, and § __.103(e)(2)(i); [1] and (4) the registration is maintained pursuant to the requirements of §§ __.103(b) and (e)(1)(ii) as of the date that the employee becomes employed by the institution.

Some commenters requested that the Agencies reduce these requirements in order to further facilitate the movement of employees from one institution to another and prevent unnecessary interruption of mortgage origination activity. However, the Agencies believe that the current provision adequately reduces regulatory burden on Agency-regulated institutions as well as the residential mortgage industry when registered mortgage loan originators change employers and will allow a mortgage origination transaction in process at the time of the employment change to proceed smoothly. It requires less than what would be needed to complete a new registration and requires only that information necessary to update the employee's registration and confirm the identity of the originator and the employer, thereby preventing fraudulent information from being submitted to the Registry. However, we have amended § __.103(a)(4)(i)(B) to provide that new fingerprints are not required to be submitted, pursuant to § __.103(d)(1)(ix), if the registered loan originator has fingerprints on file with the Registry that are less than three years old. The Registry will use these existing prints for purposes of the background check. This three-year age limit is consistent with the procedures to be used by SRR for mortgage loan originators licensed by a State. We note that, as proposed, the final rule does not

[1] These provisions require: The institution's name; main office address; IRS Employer Tax Identification Number; Research Statistics Supervision Discount (RSSD) number; identification of the institution's primary Federal regulator; contact information for individuals at the institution for Registry purposes; applicable subsidiary information, and confirmation that it employs the registrant. Information regarding an institution's RSSD number is available from the Board.

require fingerprints or a new background check when the change in employers is due to an acquisition, merger, or reorganization because these transactions carry a lower risk of fraud and identity theft. The Agencies note that institutions should still conduct prudent screening of prospective employees to confirm their identities.

In response to a comment, the Agencies note that paragraph (a)(4) of § __.103 applies when an employee of an Agency-regulated institution becomes an employee of another Agency-regulated institution, regardless of whether the entities are affiliated. Similarly, when an employee of a subsidiary of an Agency-regulated institution becomes an employee of the institution, the requirements of § __.103 apply.

In order to reduce regulatory burden and to prevent an interruption in mortgage origination activity, the proposed § __.103(a)(4)(ii) provided a 60-day grace period to comply with the § __.103(a)(4)(i) requirements when a registered mortgage loan originator becomes an employee of an Agency-regulated institution as a result of an acquisition, merger, or reorganization. Some commenters agreed that this 60-day grace period is appropriate and provides the proper balance between implementing the purpose of the S.A.F.E. Act and protecting consumers. Other commenters, however, requested that this period be extended to 90 or 180 days due to the complexity and protracted nature of the merger and acquisition process. Some commenters also requested that a 60-day grace period apply to all changes in employment, regardless of whether the change is the result of a merger or acquisition transaction.

Final § __.103(a)(4)(ii) retains the proposed 60-day grace period for a change in employers due to acquisitions, mergers, or reorganizations. The Agencies find that 60 days is an adequate time for institutions and their employees to update registrations in the case of these transactions and agree with the commenters who stated that this time period balances the purposes of the S.A.F.E. Act and consumer protection.

Additionally, the Agencies find that a grace period is not necessary when a mortgage loan originator changes employers for other reasons. This situation does not raise the same compliance burden as does an acquisition, merger, or reorganization, in which a large number of employees are switching employers at the same time. Therefore, as proposed, the final rule requires that these registered mortgage loan originators comply with the requirements of § __.103(a)(4) before they may originate residential mortgage loans for their new employer.

Another commenter requested that the Agencies permit an employer to submit one update concerning all affected employees in the case of an acquisition, merger, or reorganization, rather than having each individual employee submit what is largely identical information about their change in employer. The Agencies agree that this approach would reduce burden for the employee, institution, and the Registry. We specifically have instructed CSBS and SRR to develop a process for these transactions that would allow the bulk transfer of business location and contact information for all mortgage loan originators from one institution to another. However, each individual employee still must complete the authorization and attestation for their own updated registration record.

The Agencies adopt proposed § __.103(a)(4) with the addition of the language discussed above related to fingerprints in § __.103(a)(4)(i)(B). The Agencies also have modified § __.103(a)(4) to clarify that an employee of a bank who has been properly registered or licensed as a mortgage loan originator need only update information in the Registry, and complete the required authorizations and attestation, whether that employee is a new employee of the Agency-regulated institution or becomes subject to this final rule while an employee of the institution.

The Agencies note that the registration of a mortgage loan originator who leaves any employer will be recorded as inactive in the Registry until he or she is hired by another entity, his or her record is updated in accordance with the final rule's requirements, and the new employer acknowledges employing the mortgage loan originator through the Registry. The individual will be prohibited from acting as a mortgage loan originator at an Agency-regulated institution until such time as the registration is reactivated, unless covered by the 60-day grace period for acquisitions, mergers, and reorganizations.

Maintaining Registration. Under proposed § __.103(b)(1)(i), a registered mortgage loan originator must renew his or her registration with the Registry during the annual renewal period, November 1 through December 31 of each year. To renew, the employee must confirm that the information previously submitted to the Registry remains accurate and complete, updating any information as appropriate. Any registration that is not renewed during this period will become inactive, and the individual will be prohibited from acting as a mortgage loan originator at an Agency-regulated institution until such time as the registration requirements are met. However, an individual who fails to update information during this period may renew his or her registration at any time and does not need to wait until the start of the next annual renewal period. Inactive mortgage loan originators will not be assigned a new unique identifier if they reactivate their registration.

Some commenters opposed the requirement to renew registrations annually as overly burdensome and unnecessary. Some suggested alternatively that a registration remain valid until there is a change in employment status or other change that requires an update of database information. Others recommended that the renewal be every two, three, or five years, or based on the experience of the originator. The Agencies understand that an annual renewal process requires an expenditure of time and resources by individual originators and their employing Agency-regulated institutions. However, section 1504 of the S.A.F.E. Act (12 U.S.C. 5103), requires that mortgage loan originators maintain their registration annually. Therefore, the Agencies can not eliminate, or lengthen, the time between renewals. For this reason, the Agencies adopt § __.103(b)(1)(i) as proposed without revision. We note that the automated processing of annual renewals, as more fully described below, could lessen the impact on the resources needed for these renewals.

One commenter suggested that the final rule not require a mortgage loan originator to renew his or her registration during this annual renewal period if registration was made less than six months prior to the end of the renewal period. The Agencies believe this change is reasonable and within the scope of the S.A.F.E. Act. We have amended the final rule accordingly by adding new paragraph (b)(3) to final § __.103. However, a mortgage loan originator still is required to update his or her registration during this six month period if any information provided to the Registry at the time of registration changes, pursuant to § __ .103(b)(1)(ii), described below.

In addition to the annual renewal, proposed § __.103(b)(1)(ii) provided that a registration must be updated within 30 days of the occurrence of any of the following events: (1) A change in the employee's name; (2) the registrant

ceases to be an employee of the institution; or (3) any of the employee's responses to the information required for registration pursuant to paragraphs (d)(1)(iii) through (viii) of § __.103 become inaccurate.

A few commenters requested that the Agencies increase this 30-day period for updates to 60 or 90 days. The Agencies believe that the Registry should be updated as soon as possible and therefore have not adopted this requested change. Updates are needed on only a case-by-case basis and therefore, unlike in the case of mergers and acquisitions, should not be burdensome to registrants or employing institutions. In addition, the 30-day updating period is consistent with what is required currently for State-licensed mortgage loan originators. Therefore, final § __.103(b)(1)(ii) includes a 30-day update requirement, as proposed.

Proposed § __.103(b) also required any employee who registers with the Registry to maintain his or her registration unless the employee is no longer a mortgage loan originator. As a result of this provision, once an employee registers as a loan originator with the Registry, the employee will be required to continue this registration until he or she is no longer engaged in the activity of a mortgage loan originator, even if, in any subsequent 12-month period, the employee originates fewer mortgage loans than the number specified in the *de minimis* exception provision. The purpose of this requirement is to prevent the creation of a timing loophole that could allow mortgage loan originators to avoid registration requirements.

As indicated in the proposal's **SUPPLEMENTARY INFORMATION** section, the Agencies have considered whether the rule should provide for a temporary waiver of the rule's registration requirements or for extension of the initial registration or renewal period, in case of emergency, system malfunction, or other event beyond the control of the Agency-regulated institution or the mortgage loan originator. One commenter expressed support for this concept but noted that such an exception should be narrowly drawn so as not to create a loophole in the registration requirement and suggested that each Agency select an official who has authority to designate an emergency deadline extension for good cause. Another commenter also supported a waiver when events beyond the institution's control made timely registration impossible.

The Agencies agree that on rare occasions there may be exigent circumstances or situations when the Agencies may deem it appropriate to temporarily waive or suspend the requirements of this rule or extend the initial registration or renewal periods. The Agencies do not believe, however, that the final rule must include specific language to effectuate such waivers, suspensions, or extensions. As is the Agencies' practice in other supervisory contexts, if a situation arises that warrants such an action, such as a serious interruption of communication, computer, or fingerprint collection systems at one or more institution(s) caused by circumstances beyond the institution's control, or an extended interruption of Registry service, the Agencies will announce the availability of waivers, suspensions, or extensions of time. In addition, Agency-regulated institutions may contact their regulators to discuss possible relief on a case-by-case basis.

Effective date of registrations and renewals. Proposed § __.103(c) provided that a registration is effective on the date that the registrant receives notification from the Registry that all employee and institution information required by paragraphs (d) and (e) of § __.103 has been submitted and the registration is complete, and that a renewal or update of a registration is effective on the date the registrant receives notification from the Registry that all applicable information required by paragraphs (b) and (e) of § __.103 has been submitted and the renewal or update is complete.

We have made two changes to this provision in the final rule. Because the Registry is not technically capable of determining when a registrant actually receives its notification that the registration is complete, we have amended this provision to indicate that a registration is effective when the Registry transmits notification to the registrant that the registrant is registered. In addition, we have streamlined this provision to clarify that this notification of registration completes the registration process. We have made similar changes to § __.103(c)(2) regarding renewals and updates.

We note that, except as provided by the 180-day implementation period in § __.103(a)(3) or the 60-day grace period provided in § __.103(a)(4), an employee must not engage in residential mortgage loan origination activity if his or her registration is not yet effective or has not been renewed or updated pursuant to this rule.

A number of commenters requested further clarification of this effective date, and specifically requested that the effectiveness of the registration not be delayed for the processing of a registrant's fingerprints or receipt of a criminal background check. The Agencies did not intend to delay the effective date for fingerprint or criminal background check processing. There is no requirement for the processing of these fingerprints or the completion of a background check before a registration becomes effective. Nor, as indicated previously in this **SUPPLEMENTARY INFORMATION** section, is the effectiveness of a registration contingent on Agency or Registry review or approval of the information submitted to the Registry. Pursuant to the rule, in order to register, the information required by § __.103(d) and (e) must be submitted, and, in order to renew or update a registration, the information required by § __.103(b) must be submitted. The Registry will conduct a completeness check of the information submitted by or on behalf of the registrant. At the time the Registry determines all required information has been submitted and all Registry requirements have been met, such as payment of applicable fees charged by the Registry, it will transmit notification electronically to the registrant that he or she is registered or that his or her registration is renewed or updated, as applicable. The employing institution will be responsible for reviewing the criminal history background report once it is completed, and taking any necessary action based on the findings of this report, pursuant to the institution's policies and procedures, as required by this final rule. We note that the registrant will obtain a unique identifier during the registration process and not when the registration is complete.

Section 1510 of the S.A.F.E. Act (12 U.S.C. 5109), expressly authorizes the Registry to "charge reasonable fees to cover the costs of maintaining and providing access to information from the [Registry], to the extent that such fees are not charged to consumers for access to such [Registry]." We anticipate that the Registry will charge fees for registration, change in employment, renewal, and fingerprint processing and background checks. Although some commenters specifically requested information on the anticipated costs associated with registering with the Registry, the Agencies are at this time unable to provide this information as the fees have yet to be established by CSBS and SRR. The Agencies are consulting with the CSBS and SRR regarding the fees that the Registry expects to impose. One commenter specifically asked the Agencies to grant Agency-regulated institutions the opportunity to comment on fees. CSBS

has indicated that it intends to provide an opportunity for the public to comment on these fees, and any future adjustments to such fees, before their imposition on Federal registrants and/or their employing institutions.[1]

Required employee information. Section 1507(a)(2) of the S.A.F.E. Act (12 U.S.C. 5106(a)(2)) specifically requires, in connection with the registration of a mortgage loan originator, the Agencies to furnish, or cause to be furnished, to the Registry information concerning an employee's identity, including fingerprints and personal history and experience. Final § __.103(d) implements this requirement and lists the categories of information that mortgage loan originators, or the employing Agency-regulated institution on behalf of the mortgage loan originator, will be required to submit to the Registry. Agency-regulated institutions may select one or more individuals to submit the employee information required by this paragraph to the Registry on behalf of each of their mortgage loan originators to facilitate the registration process. At the request of commenters, we have added a new paragraph (d)(3) to the final rule that specifically permits institutions to select such individuals to submit employee information on behalf of mortgage loan originators employed by the institution. The final rule specifically prohibits these selected individuals from acting as mortgage loan originators. We note that regardless of the manner that the information is provided to the Registry, the registering employee, and not the employing institution or other employees, must complete the authorizations and attestation required by § __.103(d)(2), and described below, for the registration to be complete.

Under proposed § __.103(d), the employing Agency-regulated institution would have been required to have its registering employees submit, or to submit on behalf of its employees, information regarding the employee's identity (name and former names, social security number, gender, and date and place of birth) and home and business contact information; date the employee became an employee of the Agency-regulated institution; financial services-related employment and financial history for the past 10 years; criminal history involving certain felonies and misdemeanors; history of financial services-related civil actions, arbitrations and regulatory and disciplinary actions or orders; financial services-related professional license revocations or suspensions; voluntary or involuntary employment terminations based on violations of law or industry standards of conduct; and certain actions listed above that are pending against the employee. This information is similar to that required by the current NMLS data collection form for mortgage loan originators regulated by a State, form MU4. The information applies to employees but includes responsive information prior to their employment at the Agency-regulated institution.

The Agencies received many comments on this provision. Although some supported the proposed list of information to be submitted to the Registry, many others requested that the Agencies narrow this list, stating that the extent of personal information required by the proposal is overbroad, intrusive, and burdensome. Commenters also requested that we clarify the information that is required to be submitted.

Based on the comments received, the Agencies have carefully reviewed this list and agree that some of this information is more relevant for licensing purposes than for registration. In particular, we found that the collection of some of this information, which would not be publicly available to consumers, is not necessary to implement the purposes and requirements set forth in section 1502 of the S.A.F.E. Act (12 U.S.C. 5101).

Based on this review, we have deleted proposed § __.103(d)(1)(iii) from the final rule, which would have required submission of the registrant's financial history information (such as bankruptcies, unsatisfied judgments, liens, paid-out bonds, *etc.*). This information would not be available to consumers under this rulemaking and is not required for registration by the statute. It therefore does not further the objectives of the S.A.F.E. Act.

In addition, the submission of employment termination information to the Registry is more appropriate for the purpose of licensing, as a State regulator would use this information to make a decision on licensure, conducting further inquiry, if appropriate. Because this sensitive information would not be made public, we have deleted proposed § __.103(d)(1)(x), which required submission of information regarding employment terminations to the Registry, from the final rule.

We also have not included in the final rule the requirement to provide information on pending matters. Because these matters are not final actions, requiring this information would effectively penalize mortgage loan originators before a decision had been rendered. We note that if a pending action does become final, it must be reported to the Registry and made publicly available within 30 days, pursuant to § __.103(b)(1)(ii).

The Agencies also have revised the requirement in proposed § __.103(d)(1)(iv) to provide information on the mortgage loan originator's felony and misdemeanor criminal history. The proposal provided that the registrant supply information regarding felony convictions or other final criminal actions involving a felony against the employee or organizations controlled by the employee; or misdemeanor convictions or other final misdemeanor actions against the employee or organizations controlled by the employee involving financial services, a financial services-related business, dishonesty, or breach of trust. After further review, the Agencies found the proposal's language too broad, and as a result, would have required the registrant to disclose convictions that are not directly relevant to his or her work as a mortgage loan originator. As such, this information is not necessary to meet the purposes or requirements of the S.A.F.E. Act.

Final and redesignated § __.103(d)(1)(iii) removes the distinction between felonies and misdemeanors and narrows the category of final actions an employee must disclose to the Registry to final criminal actions that involve dishonesty or breach of trust or money laundering. In addition, to fully encompass all relevant final criminal actions, the final rule amends this category of information to include an agreement to enter into a pretrial diversion or similar program in connection with the prosecution for such offense.[1] This language derives from section 19(a)(1) of the FDI Act (12 U.S.C. 1829), which, in general, prohibits the participation of individuals convicted of such offenses from participating in the affairs of an insured depository institution. The Agencies intend to rely on FDIC rules and guidance interpreting section 19(a)(1) of the FDI Act with respect to the interpretation of criminal offenses

[1] The agencies note that the NMLS currently charges fees for the licensing of State originators; however, fees for Federal registrants and their employing Agency-regulated institutions may differ from those currently imposed on State licensees. *See* the NMLS Web site at *http://www.stateregulatoryregistry.org* for information regarding fees imposed on State originators.

[1] An agreement to enter into a pretrial diversion or similar program is defined by the FDIC as a suspension or eventual dismissal of charges or criminal prosecution upon agreement of the accused to treatment, rehabilitation, restitution, or other noncriminal or nonpunative alternatives. FDIC Statement of Policy for Section 19 of the FDIC Act, 63 FR 66177 (Dec. 1, 1998).

covered under section 19 of the FDI Act.[2] Therefore, amending the proposal to include this language in the final rule provides clearer guidance to originators and their Agency-regulated institution employers of the types of criminal offenses required to be disclosed. For example, the FDIC excludes expunged, sealed and juvenile offenses and, therefore, the Agencies would not expect this information to be provided to the Registry.[3] The final rule also would not require acquittals to be reported.

The Agencies find the remaining information required by the proposal to be submitted to the Registry relevant to the registration process and the purposes and requirements of the S.A.F.E. Act. Section 1507(a)(2) of the S.A.F.E. Act (12 U.S.C. 5106(a)(2)) specifically requires that information regarding the registrant's identity, including personal history and experience, be furnished to the Registry. Identifying information, such as name (and any other names used, such as a nickname, full legal name, or maiden name), home address, address of principal business location and business contact information (business phone number and e-mail address) and the registrant's prior financial services-related employment history (not all of which will be made public) is necessary to meet this requirement. In addition to this information, the registrant's social security number, gender, and date and place of birth are necessary to conduct the criminal history background check required by section 1507(a)(2)(A) of the S.A.F.E. Act (12 U.S.C. 5106(a)(2)(A)). Likewise, the required information concerning final criminal actions (as amended), financial services-related civil judicial actions, publicly-adjudicated regulatory and disciplinary actions or orders, financial services-related professional license revocations or suspensions, and financial services-related customer-initiated arbitration and civil actions will be made public on the Registry, and, therefore, further the purpose of the S.A.F.E. Act to provide consumers with easily accessible information on disciplinary and enforcement actions against the originator. The Agencies therefore adopt the final rule with the requirement to provide this information to the Registry.

Pursuant to section 1507(a)(2)(A) of the S.A.F.E. Act (12 U.S.C. 5106(a)(2)(A)), proposed § __.103(d)(xii) (redesignated as § __.103(d)(ix) in the final rule) also required employees to provide fingerprints, in digital form if practicable, to the Registry for submission to the FBI and any governmental agency or entity authorized to receive such information for a State and national criminal history background check. The proposal permitted the use of fingerprints currently on file with the employing Agency-regulated institution if taken less than three years prior to the employee's registration with the Registry.

This requirement elicited many comments. Some commenters requested that the Agencies permit institutions to continue accessing existing fingerprint channels recognized and supported by existing relations with the FBI. Some commenters also suggested that the final rule should deem background checks conducted by the institution during the hiring process as compliant with the S.A.F.E. Act's fingerprint and background check requirement. Commenters also requested that the final rule permit the submission of fingerprints collected 10 or 15 years prior to registration. Many of the commenters argued that an age limit is unnecessary as fingerprints do not change over time. In addition, commenters noted that allowing the use of existing fingerprints, no matter when collected, will reduce registration costs and delays.

The S.A.F.E. Act specifically requires fingerprints to be furnished to the Registry for purposes of submission to the FBI, and any governmental agency or entity authorized to receive such information for a State and national criminal history background check.[1] The S.A.F.E. Act does not specifically require certain persons or entities to furnish these fingerprints, nor prohibit other entities from furnishing fingerprints to the Registry. However, the FBI only will accept fingerprints from entities authorized as channelers of this information.

In order to ensure that fingerprints are up-to-date, we have amended the redesignated § __.103(d)(1)(ix) to provide that fingerprints that are less than three years old may be used to satisfy the requirement to furnish fingerprints to the Registry. As indicated previously, this three-year age limit is consistent with the procedures to be used by SRR for mortgage loan originators licensed by a State. Institutions should consult their existing channelers regarding the furnishing of fingerprints that are less than three years old to the Registry.

CSBS and SRR are currently modifying the NMLS to act as a channeler for fingerprints of State license applicants, pursuant to the S.A.F.E. Act, and Federal registrants may use this same fingerprinting process when the NMLS is modified to accept Federal registrations.[2] The Agencies anticipate that CSBS and SRR will provide guidance to Agency-regulated institutions and their mortgage loan originators on the availability and details of this fingerprint process. CSBS and SRR intend that this fingerprinting process will be convenient and efficient for both State licensees and Federal registrants.[1]

Some commenters asked the Agencies to clarify whether the Registry may collect fingerprints and submit a request for a background check before the Agency-regulated institution employs a mortgage loan originator rather than waiting until after that individual is hired to submit fingerprints to the Registry. The Agencies have no objection to the Registry processing a background check just prior to the employment of a mortgage loan originator, should the Registry provide this service, and believe this could satisfy the requirements of the rule.

Some commenters also expressed the view that the Registry should have the capability to accept fingerprints in both paper and digital form. As in the proposed rule, the final rule does not require digital fingerprints, but does encourage the use of digital fingerprint submissions. If digital fingerprints are not available, the Registry will accept fingerprint cards, and will convert these cards to a digital format. The Agencies note that the rule's authorization to submit fingerprints in paper form is intended to assist smaller institutions for which compliance with a digital fingerprint requirement may not be feasible.

Employee authorization and attestation. Paragraph (d)(2)(i) of § __.103 requires the employee to provide authorization for the Registry and the employing Agency-regulated

[2] *See Id.* and 12 CFR 303.220–223.

[3] *Id.*

[1] Section 1507(a)(2)(A) of the S.A.F.E. Act (12 U.S.C. 5106(a)(2)(A)). The Agencies note that, in the event that a mortgage loan originator is unable to provide fingerprints due to a physical condition, he or she should provide identifying information to the Registry consistent with FBI protocols.

[2] Further information on the Registry's fingerprint and background check procedures can be found on the Registry's Web site at *http://www.stateregulatoryregistry.org/NMLS/.*

[1] SRR plans to contract with a nationwide vendor to take the fingerprints and forward them to the Registry, which will then obtain the criminal history background check based on these fingerprints. According to plans, this vendor will have locations throughout the country, may be made available on-site at institutions, and will provide a mail-in option for mortgage loan originators unable to provide their fingerprints in person.

institution to obtain information related to sanctions or findings in any administrative, civil, or criminal action, to which the employee is a party, and, in paragraph (d)(2)(ii) of this section, to attest to the correctness of all information submitted to the Registry pursuant to paragraph (d) of this section.

In order to provide relevant information to consumers and to implement the purposes of the S.A.F.E. Act, paragraph (d)(2)(iii) requires the employee to authorize the Registry to make available to the public the information required to be submitted to the Registry pursuant to § __.103(d)(1)(i)(A) and (C) and (d)(1)(ii) through (viii) (his or her name, other names used, name of current employer(s), current principal business location(s) and business contact information, 10 years of relevant employment history, and publicly adjudicated disciplinary and enforcement actions and arbitrations against the employee).

Although this rulemaking permits the employing institution or other institution employees to submit the information required by § __.103(d)(1) to the Registry on behalf of the registering employee, the employee, and not the employing institution or its other employees, must complete the attestation and authorizations required by § __.103(d)(2) for the registration to be complete. This task may not be delegated because it is necessary for the Registry to authenticate the employee's information.

The Registry plans to make this information available to the public in two phases. The first phase, implemented at the end of the initial registration period, would provide for public accessibility of the employee's name; other names used; name of current employer(s); current principal business location(s) and business contact information; and employment history. The remaining categories of information (publicly adjudicated disciplinary and enforcement actions and arbitrations against the employee) would be made public at a later date, once the Registry, in consultation with the Agencies, has designed and implemented a system through which the registrant may provide additional explanatory information to accompany a positive response to any of the disclosure questions regarding criminal history or the other information requested in paragraphs (d)(1)(iii) through (viii). The Agencies note that once the Registry makes this enhancement, registered mortgage loan originators will be able to provide this explanatory information at any time, including during the annual renewal process, and that this explanatory language may be made public. Relevant nonpublic information submitted to the Registry will be only accessible to the Agencies and State regulators of mortgage originators, as appropriate, and the submitting mortgage loan originator and his or her employing institution.[1]

The Agencies received many comments on the public availability of personal information, particularly on how the Registry will store and prevent the unauthorized use of this personal information, and how nonpublic personal information will be appropriately protected. One commenter specifically stated that the final rule should take appropriate measures to ensure that the electronic submissions to the Registry are properly encrypted, authorized, and authenticated, and that the Registry complies with the FBI Criminal Justice Information Services Security Policy (CJIS Security Policy).[2]

The Agencies are well aware of the security concerns associated with providing personal information to the Registry and are contracting with SRR to ensure appropriate data protection elements are incorporated within the Registry to ensure compliance with the requirements of the Federal Information Security Management Act (FISMA) of 2002, PL 107–347; the CJIS Security Policy; and the related Security and Management Control Outsourcing Standard.[3] FISMA requires each Federal agency to develop, document, and implement an agency-wide program to provide information security for the information and information systems that support the operations and assets of the agency, including those provided or managed by another agency, contractor, or other source. Specifically, FISMA directed the promulgation of Federal standards for: (1) The security categorization of Federal information and information systems based on the objectives of providing appropriate levels of information security according to a range of risk levels; and (2) minimum security requirements for information and information systems in each such category.[1]

As a channeler and outsourcer of fingerprints, the FBI requires the Registry to comply with its CJIS Security Policy. The CJIS provides the minimum level of information technology security requirements determined acceptable for the transmission, processing, and storage of the nation's criminal justice information systems data. The purpose of this policy is to establish uniformity and consistency in safeguarding criminal justice information security data which is accessed via networks throughout the Federal, State, and local user community. However, this policy does not prohibit more stringent security policies.

The requirements for protecting the privacy and security of the personal information obtained from employees of Agency-regulated institutions, and the confidential information obtained from the institutions themselves, are essentially similar whether a particular mortgage loan originator is State licensed or Federally registered. SRR and CSBS will institute security protocols to protect the privacy and security of such information.

The Agencies adopt § __.103(d)(2) as proposed, with the following conforming and clarifying changes. First, we have removed pending disciplinary and enforcement actions and arbitrations against the employee from the list of information the employee must authorize the Registry to make available to the public to conform with our amendment to § __.103(d)(1). Second, we have amended § __.103(d)(2)(ii) to require a registrant to attest to any update of their registration, in addition to their initial and renewal registrations. This requirement had inadvertently been left out of the proposed rule. Finally, we have added language to clarify that neither the employing institution, nor any of its other employees, may fulfill these attestation and authorization

[1] SRR plans to make this *public* information stored on the Registry available on an aggregate basis to interested parties for compliance purposes.

[2] CJISD–ITS–DOC–08140–4.5, December 2008.

[3] *See http://www.fbi.gov/hq/cjisd/web%20page/pdf/05132009_outsourcing_standard.pdf.*

[1] *See* the National Institute of Standards and Technology (NIST) publications FIPS Pub 200, *Minimum Security Requirements for Federal Information and Information Systems,* March 2006 and NIST Special Publication 800–53, *Recommended Security Controls for Federal Information Systems,* as amended. These standards specify minimum management, operational, and technical safeguards in 17 security-related areas needed to protect the confidentiality, integrity, and availability of Federal information systems and the information processed, stored, and transmitted by those systems. These security-related areas are: (1) Access control; (2) awareness and training; (3) audit and accountability; (4) certification, accreditation, and security assessments; (5) configuration management; (6) contingency planning; (7) identification and authentication; (8) incident response; (9) maintenance; (10) media protection; (11) physical and environmental protection; (12) planning; (13) personnel security; (14) risk assessment; (15) systems and services acquisition; (16) system and communications protection; and (17) system and information integrity.

requirements on behalf of the registering employee.

We also have added a new paragraph (d)(3) to clarify that an Agency-regulated institution may identify an employee or employees of the bank who may submit the employee information required by paragraph (d)(1)(i) to the Registry on behalf of the institution's employees, provided that this individual, and any employee delegated this authority, does not act as a mortgage loan originator, consistent with § __.103(e)(1)(i)(F). In addition, as more fully explained below, this new paragraph specifically authorizes an institution to submit to the Registry some or all of the employee information required by paragraph (d)(1)(i) and the institution's information required by § __.103(e)(2) for multiple employees in bulk through batch processing in a format to be specified by the Registry, to the extent such batch processing is made available by the Registry.

Required Agency-regulated institution information. The Agencies adopt proposed § __.103(e)(1) with the following amendments, discussed below.

Paragraph (e)(1) of § __.103 of the final rule requires the employing Agency-regulated institution to submit certain information to the Registry as a base record in connection with the registration of one or more mortgage loan originators. Specifically, the Agency-regulated institution must provide its name; main office address; business contact information, such as business phone number or e-mail address (not required by the proposed rule); primary Federal regulator; Employer Tax Identification Number (EIN) issued by the Internal Revenue Service; primary point of contact information; and contact information for "system administrators."

System administrators will have the authority to enter data required in paragraph (e) of this section on the Registry and will be responsible for keeping institution information and the list of employees registered with the Registry current. These individuals, however, may not act as mortgage loan originators. The Agencies recognize that some small institutions may not be able to comply with this latter requirement because all of their staff may be registered mortgage loan originators. Therefore, we have amended this provision to exempt institutions with 10 or fewer full time equivalent employees from the requirement that system administrators do not act as mortgage loan originators. However, this exemption does not apply to a subsidiary of an Agency-regulated institution as the staff at the parent institution could perform this function. In the Agencies' experience, institutions with more than 10 full time equivalent employees generally have sufficient staff resources to support the segregation of these functions. The system administrators may delegate their authority and assign as many additional system users as necessary to comply with the registration requirements of the S.A.F.E. Act and the final rule, provided the delegated administrators meet this paragraph's requirements. While the primary point of contact also can be one of the institution's system administrators, the institution's management is responsible for ensuring proper oversight of the system administrator's activities.

In addition, paragraph (e)(1)(i)(C) of § __.103 requires an Agency-regulated institution to provide its Research Statistics Supervision Discount (RSSD) number as identifying data for validating the base record. The RSSD database is maintained by the Board. The Agencies will provide the Registry with an extract of the Board's database, indexed by RSSD number, to facilitate an Agency-regulated institution's authorized access to the Registry and its establishment of a new base record. Upon receiving the information for a new base record from an Agency-regulated institution, the Registry will confirm the information by comparing the application with RSSD data supplied by the Agencies. The Agencies will establish a mechanism by which Agency-regulated institutions that do not have an RSSD number will be added to the RSSD database.

If the institution is a subsidiary of an Agency-regulated institution, the final rule requires the subsidiary to indicate that it is a subsidiary of the parent and to provide its parent institution's RSSD number in addition to its own RSSD number, if it has one. It is not required to obtain its own RSSD number. The proposal had required that the subsidiary provide its parent's name. We have revised this provision in the final rule to require the subsidiary instead to provide its parent's RSSD number, which is a more accurate method of identifying the parent institution than by name.

Some Farm Credit System-affiliated commenters requested that the Agencies consider using the FCA's existing identification system as an alternative for the RSSD number for FCS institutions. The Agencies decline to make this modification. Validation of Agency-regulated institutions will be most efficient and complete if all institutions can be identified through a single identification system. The FCA will provide FCS institutions with information on how to obtain an RSSD number for the purposes of this rulemaking. The Agencies received no other significant comments on § __.103(e).

We also have amended proposed § __.103(e)(1) to require system administrators to follow NMLS protocols to verify their own identity and to attest that they have the authority to enter data on behalf of the Agency-regulated institution, that the information submitted pursuant to paragraph (e) is correct, and that the Agency-regulated institution will keep the information required by paragraph (e) current and will file accurate supplementary information on a timely basis. In addition, we have amended this paragraph to require institutions to renew the information they have submitted to the Registry pursuant to § __.103(e) on an annual basis. We have added these two requirements to conform to system protocols identified by CSBS and SRR.

As in the proposal, renumbered paragraph (e)(1)(iii) of § __.103 requires an Agency-regulated institution to update any information it has submitted within 30 days of the date that the information becomes inaccurate.

As proposed, § __.103(e)(2) of the final rule requires an Agency-regulated institution to provide information to the Registry for each employee who acts as a mortgage loan originator. The Agency-regulated institution must: (1) Confirm that it employs the registrant, after all the information required by paragraph (d) of this section has been submitted to the Registry; and (2) within 30 days of the date the registrant ceases to be an employee of the institution, provide notification that it no longer employs the registrant and the date the registrant ceased being an employee. This information will link the registering mortgage loan originator to the Agency-regulated institution in order to confirm that the registration of the employee is valid and legitimate. The Agencies note that the Registry's system protocols will not permit the Agency-regulated institution to confirm that it employs the registrant unless all of the employee's information required by paragraph (d) of this section has been submitted to the Registry and the employee has attested to the accuracy of the information. As indicated below, batch processing of certain information for multiple employees will likely be available to facilitate compliance with this provision.

Batch Processing of Registrations. The **SUPPLEMENTARY INFORMATION** section of

the proposed rule sought comment on whether to permit a "batch" process for Agency-regulated institutions to submit to the Registry, in bulk, some or all of the required employee and institution information as a way to mitigate the initial and ongoing registration burden on Agency-regulated institutions and their employees. Commenters overwhelmingly supported the concept of batch processing, indicating that such a capability would make registration faster, simpler, more efficient, and less costly. They also stated that it would enable them to better control and manage the registration process, pursuant to the policies and procedures required by this rulemaking.

The Agencies agree that some form of batch processing would be helpful for the registration process to run smoothly and efficiently and for all initial registrations to be completed within the 180-day initial registration period. Batch processing would be especially beneficial to larger institutions who must register tens of thousands of employees. The Agencies therefore are working with CSBS and SRR to ensure that the Registry supports the batch processing of large numbers of registrations by Agency-regulated institutions. As indicated above, we have added a new § __.103(d)(3) to specifically permit institutions to submit a portion of the information required by paragraphs (d)(1)(i) and (e)(2) of § __.103 for multiple employees in bulk through batch processing, to the extent such batch processing is made available by the Registry.

Specifically, it is our intent that the Registry will be able to provide Agency-regulated institutions the capability to submit batch registration of a portion of the information for multiple mortgage loan originators and to electronically notify the originators of the need to complete the registration. The Agencies expect the batch file to contain at least enough information to establish a mortgage loan originator record (such as the institution's name and RSSD number and employee name, SSN, and e-mail address). We also expect that the Registry will provide the capability for an Agency-regulated institution to confirm its relationship with mortgage loan originators either individually or in bulk. The Agencies, CSBS, and SRR are in the process of specifying the details and means of this batch processing. Batch processing should be available for institutions at the start of the initial registration period, and we will provide further information on batch processing prior to that time.

Section__.104—Policies and Procedures

Proposed § __.104 required Agency-regulated institutions that employ mortgage loan originators to adopt and follow written policies and procedures designed to ensure compliance with the requirements of the final rule. The proposal stated that the policies and procedures must be appropriate to the nature, size, complexity, and scope of the mortgage lending activities of the Agency-regulated institution and must, at a minimum, include eight specified provisions.

The Agencies received many comments on these required policies and procedures. Although some supported them, others found the requirement to have detailed written plans for how to comply with the final rule unnecessary and overly burdensome, especially in light of other regulatory requirements imposed on financial institutions. A few commenters suggested that the Agencies develop model guidelines for, or samples of, these policies and procedures to reduce implementation and compliance costs for Agency-regulated institutions and to reduce burden on examiners in monitoring compliance. Commenters also requested further clarification of specific provisions and an explanation as to the reason for the provision.

The Agencies continue to believe that requiring Agency-regulated institutions to establish policies and procedures is an appropriate way to ensure and monitor compliance with this final rule. Appropriate policies and procedures provide an institution and its employees with the expectations of the institution's board and include the specific implementing guidance that is applicable to the activities of that institution. Furthermore, such policies and procedures are necessary to enable Agency examiners to evaluate the effectiveness of institutions' implementation of the S.A.F.E. Act requirements that apply to them. Institutions have the responsibility to adopt policies and procedures appropriate to their operations. The final rule therefore includes a policies and procedures requirement. Comments on specific provisions are addressed below.

First, proposed § __.104(a) required policies and procedures to establish a process for identifying which employees of the institution are required to be registered mortgage loan originators. This provision highlights a basic and necessary action each institution must take to comply with the rulemaking. We did not receive specific substantive comments on this requirement and therefore adopt § __.104(a) as proposed.

Second, proposed § __.104(b) required policies and procedures to require that all employees of the institution who are mortgage loan originators be informed of the registration requirements of the S.A.F.E. Act and the proposed rule and be instructed on how to comply with these requirements and procedures, including registering as a mortgage loan originator prior to engaging in any mortgage loan origination activity. As with the first provision, this action is necessary for Agency-regulated institutions to comply with the rule and facilitates employee compliance. We did not receive substantive comments addressing this requirement and therefore adopt § __.104(b) as proposed.

Third, proposed § __.104(c) required that policies and procedures must establish procedures to comply with the unique identifier requirements in § __.105. Once again, this provision merely reiterates that Agency-regulated institutions must ensure compliance with a requirement of the rulemaking. We received no specific comments on this requirement and therefore adopt it as proposed.

Fourth, proposed § __.104(d) required policies and procedures to establish reasonable procedures for confirming the adequacy and accuracy of employee registrations, including updates and renewals, by comparison with the institution's records. We adopt this provision as proposed. However, to address the many comments on this requirement, the Agencies clarify that they will consider an institution to have reasonable procedures if it confirms the information supplied to the Registry that is in the institution's personnel files. Typically this information would include the employee's identifying information, such as the employee's name; home address; business address and contact information; social security number; gender; date and place of birth; and financial services-related civil actions, arbitrations and regulatory actions taken against the institution's employee, if any. As noted in the **SUPPLEMENTARY INFORMATION** section of the proposed rule, to comply with this requirement, institutions need only compare the information supplied by the employee to the Registry with the information contained in the institution's own records. The final rule does not require, nor do the Agencies expect, Agency-regulated institutions to obtain private database searches on their employees to confirm employee registration information.

Fifth, proposed § __.104(e) required institutions to establish reasonable

procedures and tracking systems for monitoring compliance with registration requirements and procedures. Under this regulatory provision, Agency-regulated institutions will be expected to demonstrate compliance with the registration and renewal requirements of this final rule, such as by maintaining appropriate records. The action required by this provision is one that an institution must take to ensure compliance with the rule and may be done in a number of different ways, such as by using an institution's existing tracking systems. Having received no substantive comments on this requirement, the Agencies adopt it as proposed.

Sixth, proposed § __.104(f) required policies and procedures that provide for periodic independent testing of the Agency-regulated institution's policies and procedures for compliance with the S.A.F.E. Act and the final rule and for such testing to be conducted by institution personnel or by an outside party. This compliance testing is standard procedure for Agency-regulated institutions as part of their internal controls, and we adopt it as proposed with one change. We have clarified that this compliance testing must be done on an annual basis, a necessary internal audit interval.

Seventh, proposed § __.104(g) required policies and procedures to provide for appropriate disciplinary action against any employee who fails to comply with the registration requirements of the S.A.F.E. Act, this rule, or the related policies and procedures of the institution, including prohibiting such employees from acting as mortgage loan originators or other appropriate disciplinary actions. The action required by this provision is one that an institution would need to take to ensure compliance with the rule. Having received no substantive comments on this requirement, we adopt it as proposed.

Finally, proposed § __.104(h) required policies and procedures to establish a process for reviewing the criminal history background reports on employees received from the FBI through the Registry, taking appropriate action consistent with applicable law and rules with respect to these reports, maintaining records of these reports, and documenting any action taken with respect to such employees consistent with applicable recordkeeping requirements, if any. A few commenters requested clarification on this requirement. As noted by other commenters, section 19 of the FDI Act (12 U.S.C. 1829), in general, prohibits insured depository institutions from employing a person who has been convicted of any criminal offense involving dishonesty or a breach of trust or money laundering or has entered into a pretrial diversion or similar program in connection with a prosecution for such offense. Similarly, section 5.65(d) of the Farm Credit Act (12 U.S.C. 2277a–14 (d)), states "[e]xcept with the prior written consent of the Farm Credit Administration, it shall be unlawful for any person convicted of any criminal offense involving dishonesty or a breach of trust to serve as a director, officer, or employee of any System institution." For Federally insured credit unions, NCUA intends to rely upon 12 U.S.C. 1786(i) and 12 CFR 741.3(c). We have revised this provision of the final rule to include references to the appropriate statutory provision.

The Agencies have added a new provision to clarify the responsibilities of Agency-regulated institutions regarding their contracts relating to mortgage loan originations. Institutions must establish procedures designed to ensure that any third party with which it has arrangements related to mortgage loan origination has policies and procedures to comply with the S.A.F.E. Act, including appropriate licensing and/or registration of individuals acting as mortgage loan originators. Agency-regulated institutions should monitor third party entities' compliance with these policies and procedures. This provision will ensure that individuals acting as mortgage loan originators on behalf of an Agency-regulated institution are either State licensed and registered and/or Federally registered.

One commenter requested that the final rule limit an institution's oversight of its employees' compliance with this rulemaking only to those activities of the employee that are within the scope of his or her employment at the institution. It is not our intention to require the institution to enforce the final rule's requirements with respect to activities of its employees that are conducted outside of the employee's scope of employment with that institution and beyond the institution's control, and we have added language to § __.104 to clarify this.

This final rule's requirement to adopt these policies and procedures applies to all Agency-regulated institutions that employ individuals who act as mortgage loan originators, regardless of the application of any *de minimis* exception to their employees. These policies and procedures should be in place at an institution prior to the registration of its employees pursuant to this rule.

Furthermore, the Agencies note that, consistent with the S.A.F.E. Act, the Registry will not screen or approve registrations received from employees of Agency-regulated institutions. Instead, it will be the repository of, and conduit for, information on those employees who are mortgage loan originators at Agency-regulated institutions. Pursuant to §§ __.104(d) and (h) of the final rule, it will be the responsibility of the Agency-regulated institution to establish reasonable procedures for confirming the adequacy and accuracy of employee registrations as well as to establish a process for reviewing any criminal history background reports received from the Registry.

Section __.105—Use of Unique Identifier

The Agencies proposed in § __.105(a) to require an Agency-regulated institution to make the unique identifier(s) of its registered mortgage loan originator(s) available to consumers in a manner and method practicable to the institution. Proposed § __.105(b) required a registered mortgage loan originator to provide the originator's unique identifier to a consumer upon request, before acting as a mortgage loan originator, and through the originator's initial written communication with a consumer, if any.

Although a mortgage loan originator may change his or her name, change employment, or move, the unique identifier assigned to the originator by the Registry at the originator's original registration will remain the same. Once public access to the Registry is fully functional, the unique identifier will enable consumer access to an individual mortgage loan originator's profile stored in the Registry, including the mortgage loan originator's publicly available registration information, any State mortgage licenses held (active or inactive), employment history, and publicly adjudicated disciplinary and enforcement actions. If a mortgage loan originator is simultaneously employed by more than one State or Agency-regulated institution, that information also will be readily visible to the consumer.

We received a number of comments on this requirement—some noting that it is cumbersome and of limited benefit to the consumer. However, the S.A.F.E. Act requires each mortgage loan originator to obtain a unique identifier to facilitate the electronic tracking of loan originators, and the uniform identification of, and public access to, the employment history and publicly adjudicated disciplinary and enforcement actions against a mortgage loan originator. In order to effectuate this requirement, a mortgage loan

originator and the employing institution must ensure that the consumer has access to the originator's unique identifier. This access must be made available early enough in the relationship with the originator to enable the consumer to access the Registry before the consumer commits to the mortgage loan transaction. Because a consumer may not be aware of the Registry, it is important that both the institution and originator make this information available to the consumer, and not only just upon the consumer's request, as suggested by a number of commenters. Therefore, we adopt this requirement as proposed, with one clarifying change described below.

As noted in the **SUPPLEMENTARY INFORMATION** section of the proposed rule, an Agency-regulated institution may comply with the § __.105(a) requirement in a number of ways. For example, the institution may choose to direct consumers to a listing of registered mortgage loan originators and their unique identifiers on its Web site; post this information prominently in a publicly accessible place, such as a branch office lobby or lending office reception area; and/or establish a process to ensure that institution personnel provide the unique identifier of a registered mortgage loan originator to consumers who request it from employees other than the mortgage loan originator. Furthermore, the Agencies intend § __.105(b)(3) of the rule to cover written communication from the originator specifically for his or her customers, such as a commitment letter, good faith estimate or disclosure statement, and not written materials or promotional items distributed by the Agency-regulated institution for general use by its customers. While, this provision does not require institutions to include the unique identifier on loan program descriptions, advertisements, business cards, stationary, notepads, and other similar materials, institutions are not prohibited from doing so. We also clarify that the requirement to provide the unique identifier to the consumer through the originator's initial written communication, if any, applies whether that communication is provided in writing on paper or through electronic means. We have clarified this requirement in the final rule. The Agencies also clarify that the unique identifier may be provided orally, except pursuant to paragraph (b)(3) under which the unique identifier would be provided with the written or electronic communication.

We note that the Board has proposed amendments to 12 CFR 226 (Regulation Z) that would require disclosure of the unique identifier as part of TILA disclosures, which generally must be provided to a borrower within three business days of the residential mortgage loan application and seven business days before consummation of the transaction.[1] In addition, as indicated above, Fannie Mae and Freddie Mac are requiring all mortgage loan applications taken on or after the compliance date for the unique identifier requirement to include the mortgage loan originator's unique identifier.[1] We therefore believe that providing consumers with the originator's unique identifier will not be difficult or burdensome.

Appendix—Examples of Mortgage Loan Originators

The proposed Appendix included a nonexclusive list of examples of activities that fall within or outside the S.A.F.E. Act's definition of a mortgage loan originator. Specifically, the Appendix provided examples of activities that are, and are not, illustrative of taking an application, and offering or negotiating terms of a mortgage loan for compensation or gain. The Agencies note that an employee of an Agency-regulated institution is only subject to the S.A.F.E. Act to the extent that both prongs of the two-part test for acting as a mortgage loan originator are met, and that employees who take applications but do not offer or negotiate terms of a mortgage loan, or vice versa, do not meet the definition. Commenters generally asked the Agencies to provide more detail to the examples and to address whether specific activities of Agency-regulated institution employees would be covered by the two-prong test of a mortgage loan originator.

The Agencies have made several modifications to the examples of taking an application. The modified examples clarify that taking an application occurs when the mortgage loan originator receives information in connection with a request for a mortgage loan that will be used to determine whether the consumer qualifies for a loan. The Agencies note that the information may be provided by another person on behalf of the consumer.

Some commenters questioned whether an employee takes an application if that employee only collects limited data about the consumer or does not decide what data to collect. Another commenter suggested that when an employee collects the limited information about the consumer that is required by an automated loan approval system and quotes interest rates and fees for a specific mortgage loan product as generated by the system, that employee should not be considered to be engaged in taking an application. The Agencies disagree, as the limited information described by the commenter is sufficient to qualify the consumer for a specific mortgage product and terms. The example of taking an application was revised to address the receipt of information to be used to determine whether the consumer qualifies for a mortgage loan, which includes situations where there are limitations on the data collected or on the employee's discretion, as described by the commenter.

Similarly, these commenters also requested clarification as to whether an employee takes an application when the employee enters information into an online application in the process of receiving information from the consumer. The Agencies have provided clarification that the example of taking an application applies even if the employee is inputting information into an online or other automated approval system on behalf of the consumer. The Agencies do not intend this example to address employees who are engaged in the clerical act of inputting information from a loan application into an automated approval system on behalf of a loan officer. Furthermore, contrary to the suggestions of some commenters, the Agencies have clarified that an employee may take an application even if the employee is not engaged in approval of the mortgage loan. An employee also may take an application even if the employee does not take an application fee.

The Agencies also have clarified that, contrary to the suggestion of some commenters, an employee may take an application even if the employee has received the consumer's information indirectly in order to make an offer or negotiate terms of a mortgage loan. An employee may receive the consumer's information indirectly, for example, through another employee, a broker, or an automated system.

The Agencies also have provided further detail regarding the examples of activities that do not constitute taking an application. In response to questions raised by commenters, the Agencies have further clarified that the following activities would not constitute taking an application: (1) Assisting a consumer who is filling out an application by explaining the qualifications or criteria necessary to obtain a mortgage loan product, (2) describing the steps that a

[1] *See http://www.federalreserve.gov/newsevents/press/bcreg/20090723a.htm.*

[1] *See* footnote 26.

consumer would need to take to provide information to be used to determine whether the consumer qualifies for a mortgage loan or otherwise explaining the mortgage loan application process, and (3) responding to an inquiry regarding a prequalified offer that a consumer has received from an Agency-regulated institution, collecting only basic identifying information about the consumer and forwarding the consumer to a mortgage loan originator.

The Agencies also have revised the examples of offering or negotiating terms of a mortgage loan in response to the comments. The Agencies have revised one example to clarify that providing a disclosure of the mortgage loan terms after application pursuant to the Truth in Lending Act is included in presenting a mortgage loan offer. A number of commenters asked the Agencies to modify the examples to carve out employees who are limited in their ability to negotiate or finalize the terms of a mortgage loan. Some commenters posited that employees should be excluded if they only offer the loan rate to a consumer but are not permitted to negotiate the rate, or only quote a rate approved by an automated online system. Similarly, a commenter expressed the view that an employee would not offer or negotiate terms of a mortgage loan if involvement of a loan officer also was necessary to finalize the loan terms or otherwise conclude the mortgage loan approval process. The Agencies believe that many of these situations discussed by the commenters would involve an offer or a negotiation of a loan. Thus the revised examples clarify that presenting a mortgage loan offer to a consumer for acceptance, either verbally or in writing, is offering or negotiating terms of a mortgage loan even if other individuals must complete the mortgage loan process or if only the rate approved by the Agency-regulated institution's loan approval mechanism function for a specific loan product is communicated without authority to negotiate the rate. Similarly, one commenter suggested that an employee does not offer or negotiate terms of a mortgage loan if the employee does not lock the rate. The Agencies do not agree and declined to address this particular activity in the general example of offering or negotiating terms of a mortgage loan.

The Agencies also have modified and added to the examples of activities that are not offering or negotiating terms of a mortgage loan. Some commenters noted that the S.A.F.E. Act excludes employees who are engaged in administrative and clerical activities. The Agencies have considered this exclusion in formulating the examples of mortgage loan origination. Specifically, with respect to offering and negotiating terms of a mortgage loan, the Agencies have added an example that an employee who communicates on behalf of a mortgage loan originator that a written offer has been sent to a consumer, without providing details of that offer, is not offering or negotiating a loan.

In addition, in response to commenters' requests for more detail, the Agencies have clarified that providing descriptions, in addition to explanations, in response to consumer queries regarding qualification for a specific mortgage loan product or product-related service does not constitute offering or negotiating terms of a mortgage loan. In response to the suggestion of another commenter, the Agencies have provided another new example, specifying that "offer or negotiate" does not include explaining or describing the steps or process that a consumer would need to take in order to obtain a loan offer, including qualifications or criteria that would need to be met without providing guidance specific to the consumer's circumstances.

Some commenters asked whether employees engaged solely in making underwriting decisions with respect to mortgage loans are offering terms of a mortgage loan. These employees, although they do not typically communicate directly with consumers, would appear to fall within the definition of taking an application. The Agencies have added, as an example of an activity that is not offering or negotiating terms of a mortgage loan, making an underwriting decision about whether the consumer qualifies for a loan. An employee engaged solely in this activity would not offer or negotiate terms of a loan, and would not, therefore, meet the two-prong test for acting as a loan originator.

The Agencies, as described previously, understand from many commenters that numerous employees of Agency-regulated institutions are engaged solely in modifying loans, such as those which result in reduced and sustainable payments for a borrower who is in default. The Agencies have provided, as a new example of an activity that is not taking an application, receiving information in connection with a modification to the terms of an existing loan to a borrower as part of the institution's loss mitigation efforts, when the borrower is reasonably likely to default. An employee engaged solely in this activity does not receive a residential mortgage loan application, and would not, therefore, meet the two-prong test for acting as a loan originator. The Agencies note that modifying the terms of an existing loan to a borrower as part of the institution's loss mitigation efforts generally would not constitute acting as a mortgage loan originator for purposes of the S.A.F.E. Act. In addition, one commenter requested that the Agencies clarify that an employee acts as a mortgage loan originator when the employee renews an existing loan at maturity, thereby replacing the old loan with a new loan. The Agencies agree with this commenter.

Finally, one commenter queried whether registration requirements apply to Agency-regulated institution employees who, in addition to a variety of customer service duties, only at times act as a mortgage loan originator and only with respect to a limited number of mortgage loan products. The Agencies note that an employee who meets the two-prong test is acting as a mortgage loan originator, even if that activity is not their primary job duty or the employee may only act as a mortgage loan originator for a limited number of products. As described previously, the Agencies have provided a *de minimis* exception to address employees who act as mortgage loan originators with respect to a small number of mortgage loans. In this light, the Agencies received comments that suggested that an employee would be engaged in offering the terms of a loan only if the employee's compensation was based on the number of loans closed or the employee's engagement in mortgage lending. The Agencies do not agree with this suggestion and have finalized the examples relating to compensation as proposed. Therefore, an employee offers or negotiates terms of a loan for compensation or gain even if the employee does not receive a referral fee or commission or other special compensation for the mortgage loan.

IV. Regulatory Analysis

A. Regulatory Flexibility Act

OCC: The Regulatory Flexibility Act (RFA) [1] requires Federal agencies to prepare and make available to the public a Final Regulatory Flexibility Analysis (FRFA) for a final rule, unless the agency certifies that the rule will not have a significant economic impact on a substantial number of small entities. *See* 5 U.S.C. 603–605. For purposes of the RFA, a "small entity" within the jurisdiction of the OCC is a national

[1] 5 U.S.C. 601–612.

bank or a Federal branch or agency with assets of $175 million or less (small national bank).[2] In the NPRM, the OCC certified, pursuant to section 605(b) of the RFA, that the proposal would not have a significant economic impact on a substantial number of small entities.[3] The OCC's certification was based on an estimated average total compliance cost of $18,800 per small national bank and the impact of compliance costs as a percentage of labor costs, as well as compliance costs as a percent of noninterest expenses. The OCC received one comment—from the Small Business Administration's Office of Advocacy (SBA Advocacy)—on the certification.

Based in part on this comment letter, the OCC has reevaluated the effect of this final rule on small national banks, and, for the reasons stated below, has determined that this rule will have a significant economic impact on a substantial number of small entities. Therefore, we have prepared the following FRFA in accordance with 5 U.S.C. 604.

1. Need for, and Objectives of, the Final Rule

The need for, and objectives of, this final rule are described in detail in the **SUPPLEMENTARY INFORMATION** section.

2. Significant Issues Raised by Public Comments

In the comment it submitted, SBA Advocacy expressed concern that the factual basis for the OCC's (and other Agencies') conclusion that the proposal would not have a significant economic impact on a substantial number of small entities may be insufficient, noting that the OCC's certification did not specify the assumptions used concerning labor costs or noninterest expenses. SBA Advocacy stated its concern that OCC's economic impact may be underestimated and sought clarification regarding the proposal's impact on the number of small national banks.[1]

In part as a result of this comment letter, the OCC conducted further analysis of the effect of its rule on the banking industry as a whole and on small banks in particular. The OCC also obtained additional information about the impact of the proposal on national banks. As a result of this information we have modified our initial conclusions about the economic effect of the rule on small national banks.

3. Description and Estimate of Small Entities Affected by the Final Rule

For purposes of OCC regulation, the final rule applies to national banks, Federal branches and agencies of foreign banks, their operating subsidiaries (collectively referred to as national banks), and their employees who act as mortgage loan originators.

OCC estimates that 623 national banks with employees originating loans secured by residential real estate are small entities based on the SBA's general principles of affiliation (13 CFR 121.103(a)) and the size threshold for a small national bank. The OCC believes the final rule will have a significant impact on approximately 10 percent of these small national banks (65 banks).[1] We classify the impact of total costs on a small national bank as significant if the total costs in a single year are greater than 5 percent of total salaries and benefits, or greater than 2.5 percent of total non-interest expense. Mean total costs per bank in the group of small banks where compliance costs are significant is approximately $25,000 per bank.[2]

4. Recordkeeping, Reporting, and Other Compliance Requirements

The final rule imposes requirements on both national banks and their employees who engage in the business of mortgage loan origination, regardless of the size of the national bank. Typical recordkeeping, administrative, computer technology and bank management skills will be needed to comply with all of the rule's requirements.

Reporting Requirements. Unless the *de minimis* exception applies, § 34.103(a) of the final rule requires a mortgage loan originator employed by a national bank to register with the Registry, maintain such registration, and obtain a unique identifier. Under § 34.103(b), a bank must require each mortgage loan originator employee to comply with these requirements. Section 34.103(d) describes the categories of information that an employee, or the employing bank on the employee's behalf, must submit to the Registry, along with the employee's attestation as to the correctness of the information supplied, and the employee's authorization to obtain further information and make public some of this information. This section also requires the submission of the mortgage loan originator's fingerprints to the Registry.

Section 34.103(e) specifies bank and employee information that a bank must submit to the Registry in connection with the initial registration of one or more mortgage loan originators. The bank must annually renew this information and update this information if necessary between renewals. Authorized bank representatives must attest to the correctness of this information and that such information will be updated on a timely basis.

Disclosure Requirements. Section 34.105(b) requires the mortgage loan originator to provide the unique identifier to a consumer: (i) Upon request; (2) before acting as a mortgage loan originator; and (3) through the originator's initial written communication with a consumer, if any, whether on paper or electronically.

Section 34.105(a) requires the bank to make the unique identifier(s) of its mortgage loan originator(s) available to consumers in a manner and method practicable to the bank.

Recordkeeping and Compliance Requirements.

Section 34.104 requires a bank that employs one or more mortgage loan originators to adopt and follow written policies and procedures designed to assure compliance with this final rule. These policies and procedures must be appropriate to the nature, size, complexity, and scope of their mortgage lending activities and will apply only to those employees acting within their scope of employment at the bank. At a minimum, these policies and procedures must establish a process for: (i) Identifying which employees are required to register, (ii) communicating the registration requirements to employees, (iii) complying with the rule's unique identifier requirements, (iv) confirming the adequacy and accuracy of employee registrations though comparisons with bank records, (v) monitoring employee compliance with the rule, (vi) independent compliance testing, (vii) taking

[2] 13 CFR 121.201.

[3] In addition to the OCC, the Board, the FDIC, the OTS, the NCUA, and the FCA also certified in the proposed rule that the proposal would not have a significant economic impact on a substantial number of small entities. *See* 74 FR at 27398–27399.

[1] A discussion of SBA Advocacy's comments on other provisions of the proposed rule, namely, the *de minimis* exception and the proposed 6-month initial compliance period, is contained in the **SUPPLEMENTARY INFORMATION** section of this final rule.

[1] The OCC estimated the impact on small banks both with and without employee turnover because it is the OCC's understanding that the turnover rate at small banks is significantly lower than the rate at large banks and there may be no turnover for several years in a row at some banks. However, even without employee turnover, the final rule appears to have a significant impact on a substantial number of small banks.

[2] The mean totals of the cost estimates (*i.e.,* the higher cost estimate and the lower cost estimate) for all (623) small banks impacted by the final rule are $32,000 and $27,000 respectively. The mean total cost per small bank in the group of small banks where costs are significant is approximately $26,000 under the higher cost estimate, and $23,000 under the lower cost estimate.

appropriate actions with respect to employees who fail to comply with the registration requirements, (viii) reviewing employee criminal history background checks received pursuant to this rule, and (ix) monitoring third party compliance with the S.A.F.E. Act.

5. Steps Taken To Address the Economic Impact on Small Entities

The final rule reflects the consideration given by the OCC, along with the other Agencies, to the impact that its requirements would have on small entities.

First, the Agencies have revised the rule's *de minimis* exception to reduce compliance burden. In the proposed rule, the Agencies established a *de minimis* exception that would have excepted from the registration requirements an employee of an Agency-regulated institution if, during the last 12 months: (1) The employee acted as a mortgage loan originator for 5 or fewer residential mortgage loans; and (2) the Agency-regulated institution employs mortgage loan originators who, while excepted from registration pursuant to this section, in the aggregate, acted as a mortgage loan originator in connection with 25 or fewer residential mortgage loans. Many commenters on this provision noted the complexity of the proposed exception. One commenter stated that the *de minimis* exception would not have any significant effect because its complexity would outweigh its benefits. Others noted that the proposed exception would be difficult for an institution to monitor and maintain. Still others said that the proposed *de minimis* exception would be fairer, and much easier to apply, if the threshold limitation applied only to the employee or to the institution, but not both. SBA Advocacy specifically commented that the proposed *de minimis* exception would make the rule unduly burdensome on small community banks. In response to these and other comments and upon further analysis, the Agencies removed the institution threshold from this *de minimis* exception. As a result, the final rule's *de minimis* exception only contains the individual threshold, as well as a prohibition on any Agency-regulated institution from engaging in any act or practice to evade the limits of the *de minimis* exception. This revised exception should simplify compliance and therefore impose the least burden overall for institutions, including small entities.

The Agencies also considered, pursuant to section 1507(c) of the S.A.F.E. Act (12 U.S.C. 5106(c)), applying the requirements of the rule only to institutions above a certain asset threshold, such as the threshold for Home Mortgage Disclosure Act reporting. However, the Agencies agreed that this would not further the consumer protection purposes of the S.A.F.E. Act [1] in that customers of smaller banks would not have the same information on mortgage loan originators as customers of larger institutions. In addition, we believed the exception should be structured so that employees of institutions of all sizes could qualify.

The OCC also has reviewed alternatives for small entity compliance, including eliminating the requirement for small banks to adopt and follow written policies and procedures addressing all of the elements described in the final rule. For example, under such an approach, a small bank's risk based compliance program might include only such procedures as are necessary to enable the bank to demonstrate compliance with the registration and renewal requirements of the S.A.F.E. Act. Although such an approach may have reduced the compliance cost per small bank, the OCC does not believe that it would best serve the interests of national banks or the OCC. Appropriate policies and procedures provide an institution and its employees with the expectations of the institution's board and include the specific implementing guidance that is applicable to the activities of that institution. Furthermore, such policies and procedures are necessary to enable examiners to evaluate the effectiveness of institutions' implementation of the S.A.F.E. Act requirements that apply to them. In reviewing this alternative, we determined that applying the policies and procedures requirement in the same way to all institutions, regardless of size, is necessary to ensure consistency in implementation and enforcement of the S.A.F.E. Act and is, therefore, the most appropriate way to ensure that the purposes of the S.A.F.E Act are met.

The OCC, and the other Agencies, also made changes to the final rule that reduce the impact that its requirements would have on all Agency-regulated financial institutions, including small entities. The final rule decreased the amount of information required for submission by a mortgage loan originator. Specifically, the final rule does not require submission of financial history information such as bankruptcies and liens; employment terminations; pending actions; and felonies unrelated to crimes of dishonesty. Furthermore, the Agencies declined to include loan modification activities in the final rule's definition of mortgage loan originator. Under the OCC's rule, Agency-regulated institution employees engaged solely in bona fide cost-free loss mitigation efforts which result in reduced and sustainable payments for the borrower generally would not meet the definition of "mortgage loan originator." This reduces the number of bank employees subject to the final rule's requirements.

Board: Pursuant to section 605(b) of the RFA, 5 U.S.C. 605(b), the regulatory flexibility analysis otherwise required under section 604 of the RFA is not required if the agency certifies that the rule will not have a significant economic impact on a substantial number of small entities and publishes its certification and a short, explanatory statement in the **Federal Register** along with its rule.

The final rule implements the S.A.F.E. Act's Federal registration requirements for mortgage loan originators. The S.A.F.E. Act states that the objectives of this registration include providing increased accountability and tracking of mortgage loan originators and providing consumers with easily accessible information at no charge regarding mortgage loan originators. The Board is not aware of other Federal rules which may duplicate, overlap, or conflict with the proposed rule.

The final rule applies to all banks that are members of the Federal Reserve System (other than national banks) and certain of their respective subsidiaries, branches and Agencies of foreign banks (other than Federal branches, Federal agencies, and insured State branches of foreign banks), and commercial lending companies owned or controlled by foreign banks.

Under the Board's final rule, employees of the above entities who act as residential mortgage loan originators must register with the Registry, obtain a unique identifier, and maintain this registration, consistent with the requirements of the S.A.F.E. Act. The above institutions must require their employees who act as residential mortgage loan originators to comply with the registration requirements and obtain a unique identifier. These institutions also must provide certain information to the Registry and must adopt and follow written policies and

[1] Among other things, the objectives of the S.A.F.E. Act include: Enhancing consumer protections and supporting anti-fraud measures; increasing accountability and tracking of loan originators; and providing consumers with easily accessible information at no charge regarding the employment history of, and publicly adjudicated disciplinary and enforcement actions against, loan originators. S.A.F.E. Act at section 1502 (12 U.S.C. 5101).

procedures designed to assure compliance with these requirements. The institutions and their employees must disclose the unique identifier of mortgage loan originators in compliance with the rule.

Under regulations issued by the Small Business Administration,[1] a small entity includes a banking organization with assets of $175 million or less (a small banking organization). As of December 31, 2008, there were approximately 433 State member banks that are small banking organizations. The Agencies proposed the *de minimis* exception in an effort to reduce compliance costs on small businesses.

The Board received comment from the Office of Advocacy of the U.S. Small Business Administration on its RFA analysis. This commenter expressed concern that the factual basis for the Board's (and other agencies') RFA analysis was insufficient and that the Board and other agencies may have underestimated the costs associated with the proposed rule. The commenter queried whether legal compliance costs and training and tracking costs should be estimated and included in the analysis. Specifically with respect to the Board's RFA analysis, the commenter recommended that the Board use revenue, rather than profits, in determining economic impact since revenue may be a more transparent indicator than profits.

The Board notes that legal compliance costs, tracking compliance, and training have been included in the burden analyses for the rule. The Board estimates compliance costs to be $7.6 million in the aggregate for the 433 small State member banks. As of December 31, 2008, these institutions had $2.4 billion in revenues in the aggregate. Therefore, compliance costs would be less than 1% of revenues.

The Board notes that it has adopted in the final rule alternatives to the proposed rule, which have reduced compliance costs of the rule. The final rule decreased the amount of information required for submission by a mortgage loan originator. For example, the final rule does not require submission of financial history information such as bankruptcies and liens; employment terminations; pending actions; and felonies unrelated to crimes of dishonesty. Furthermore, the Agencies declined to include loan modification activities in the definition of mortgage loan originator, after considering comments on this issue, including those regarding the burden and costs of compliance. Under the Board's rule, modifying the terms of an existing loan to a borrower as part of the institution's loss mitigation efforts would not constitute acting as a mortgage loan originator for purposes of the S.A.F.E. Act.

In addition, the final rule simplifies the *de minimis* exception to registration requirements of the rule, thereby decreasing compliance costs and increasing the number of employees who will qualify for the individual limits required under the *de minimis* exception. Under the proposed rule, even if an employee was within the individual limit on mortgage loan origination activity, the employee still could not utilize the exception unless the institution itself was within the aggregate limit on unregistered mortgage loan originators. The Board notes that it has taken a conservative approach to estimating the compliance impact of the revised *de minimis* exception, assuming that at least as many small entities would not incur registration-related expenses under the final rule as the proposed rule. Further, the Board notes that small institutions typically do not originate a significant volume of mortgage loans.

The Board has not adopted other significant alternatives to the proposed rule. For example, the final rule continues to include a mandate for Agency-regulated institutions to require their mortgage loan originator employees to meet registration requirements and adopt policies and procedures to assure compliance. These requirements remain in the final rule because the Board believes that these provisions are necessary to achieve the objectives of the statute and to assure compliance with the rule.

Therefore, pursuant to section 605(b) of the RFA, the Board hereby certifies that this proposal will not have a significant economic impact on a substantial number of small entities. Although a regulatory flexibility analysis is not needed, the Board has voluntarily provided an analysis.

FDIC: In accordance with the RFA, 5 U.S.C. 601–612, an agency must publish a final regulatory flexibility analysis with its final rule, unless the agency certifies that the rule will not have a significant economic impact on a substantial number of small entities (defined for purposes of the RFA to include banks with less than $175 million in assets). The FDIC hereby certifies that the final rule will not have a significant economic impact on a substantial number of small entities.

Approximately 3,116 FDIC-supervised banks are small entities. In the RFA analysis for the proposed rule, the FDIC determined that approximately 2,255 of those small entities would incur only those costs related to adopting and following appropriate policies and procedures, not registration-related expenses, because they originate 25 or fewer residential mortgage loans annually and therefore would not have qualified for the aggregate institution limit of the proposed rule's *de minimis* exception. Since the aggregate institution limit has been eliminated in the final rule, the exception will apply to a greater number of employees than under the proposed rule. However, because it is difficult to estimate how many more employees would be covered by the revised *de minimis* exception, a more conservative approach would be to assume that at least as many small entities would not incur registration-related expenses under the final rule as under the proposed rule (*i.e.,* 2,255 small entities). For those 2,255 small entities, the set up costs are estimated to be about 0.5% of total non-interest expense and annual costs are estimated to be about 0.2% of total non-interest expenses (based on a mean non-interest expense of $2.5 million reported by the 3,116 FDIC-supervised small entities for fourth quarter 2008).

Given the foregoing assumptions, only approximately 861 small entities supervised by the FDIC—about 28% of FDIC-supervised small entities—will be subject to all of the requirements of the final rule. For those 861 small entities, the estimated initial costs for complying with the final rule would represent, on average, approximately 0.7% of total non-interest expenses, and the annual compliance costs would represent, on average, approximately 0.3% of total non-interest expenses (based on the aforementioned mean non-interest expense of $2.5 million).

For the 861 FDIC supervised small entities that will be subject to all of the requirements of the final rule, the S.A.F.E. Act requirements will cost $17,395 for set up and $7,436 annually (based on an estimated 350 hours for set up, 113 hours for annual compliance, 11.435 mortgage loan originators per entity, and a weighted average labor cost of $49.70 per hour). For the 2,255 FDIC supervised small entities that will incur only those costs related to adopting and following appropriate policies and procedures, the S.A.F.E. Act requirements will cost $12,922 for set up (based on an estimated 260 labor hours and the aforementioned labor cost) and $4,473 annually (based on an estimated 90 labor hours and the aforementioned labor cost).

[1] *See* 13 CFR 121.201.

OTS: The RFA[1] requires Federal agencies to prepare and make available to the public a Final Regulatory Flexibility Analysis (FRFA) for a final rule, unless the agency certifies that the rule will not have a significant economic impact on a substantial number of small entities. *See* 5 U.S.C. 603–605. For purposes of the RFA and OTS-regulated entities, a "small entity" within the jurisdiction of the OTS is a savings association with assets of $175 million or less (small savings association). In the NPRM, the OTS certified, pursuant to section 605(b) of the RFA, that the regulatory flexibility analysis otherwise required under section 604 of the RFA was not required because the proposal would not have a significant economic impact on a substantial number of small entities.[1] The OTS's certification was based on an estimated average total compliance cost of $13,311 per small savings association and the impact of compliance costs as a percentage of labor costs, as well as compliance costs as a percent of noninterest expenses. The OTS received one comment—from the Small Business Administration's Office of Advocacy (SBA Advocacy)—on the certification.

Based in part on this comment letter, the OTS has reevaluated the effect of this final rule on small savings associations, and, based on the information provided below, has reaffirmed that this rule will not have a significant economic impact on a substantial number of small entities. Therefore, OTS is not required to prepare an FRFA under 5 U.S.C. 604. However, OTS believes that the initial analysis included in the proposed rule should be slightly modified, and therefore, we have included in the final rule a description of the economic effect on small savings associations and additional information addressing the final rule and the comment letter on the certification.

1. Description and Estimate of Small Entities Affected by the Final Rule

For purposes of the OTS regulation, the final rule applies to savings associations and their operating subsidiaries and their employees who act as mortgage loan originators. In determining the economic impact on small savings associations, OTS determined that 385 small savings associations would potentially be affected by the final rule. We estimate that 23 of these savings associations, or 6 percent, have no mortgage loan originator (MLO) employees, and therefore, will incur no costs under the final rule. The remaining 362 small savings associations can be expected to incur costs under the final rule. Specifically, OTS estimates the average cost of compliance for these 362 small savings associations to be $17,085. In order to determine whether the costs of compliance have a significant economic impact on this population of small savings associations, we compared each association's projected compliance costs to both its total annualized labor costs and to its total annualized noninterest expense. (Noninterest expense is typically used as a benchmark for "overhead" in financial firms.) If projected S.A.F.E. Act compliance costs exceeded 5 percent of a small saving association's total labor costs, or 2.5 percent of its noninterest expense, OTS considered the impact of compliance to be "significant." These benchmarks have been used in the past by OTS and other Federal financial regulatory agencies. OTS estimates that 32 small savings associations, or 8.3 percent of the small savings association population, will experience a significant economic impact associated with compliance using the benchmarks described above. The average cost of compliance for these 32 savings associations is projected to be $17,441. Pursuant to § 605(b) of the RFA, OTS therefore certifies that this final rule will not have a significant economic impact on a substantial number of small entities, and, accordingly, a FRFA is not required.

2. Need for, and Objectives of, the Final Rule

As described in the **SUPPLEMENTARY INFORMATION**, the objectives of this final rule are to implement the requirements of the S.A.F.E. Act. Specifically, the final rule implements:

- Section 1504 of the S.A.F.E. Act (12 U.S.C. 5103(a)), which provides that subject to the existence of a registration regime, an individual who is an employee of a depository institution may not engage in the business of a loan originator without first: (i) Obtaining and maintaining annually a registration as a registered loan originator, and, (ii) obtaining a unique identifier; and,
- Section 1507 of the S.A.F.E. Act (12 U.S.C. 5106), which requires the Agencies to: (i) Jointly develop and maintain a system for registering employees of a depository institution and of a subsidiary that is owned and controlled by a depository institution and regulated by an Agency as registered loan originators with the National Mortgage License System and Registry (Registry); and (ii) furnish certain information, or cause it to be furnished, to the Registry.

3. Significant Issues Raised by Public Comments

As indicated above, the OTS did not publish an IRFA with the proposed rule. We therefore did not receive any comments specifically directed at an analysis in an IRFA. However, in the comment the SBA Advocacy submitted, it expressed concern that the factual basis for the OTS's (and other Agencies') conclusion that the proposal would not have a significant economic impact on a substantial number of small entities may be insufficient, noting that the OTS's certification did not specify the assumptions used concerning labor costs or noninterest expenses. In addition, SBA Advocacy stated its concern that OTS's economic impact may be underestimated and sought clarification regarding the proposal's impact on the number of small savings associations.[1] SBA Advocacy recommended that the Agencies work with the industry to determine an accurate estimate of the economic impact of the rule on small entities and develop ways to minimize that burden. In part as a result of this comment letter and as noted above, the OTS conducted further analysis of the effect of our rule on the savings association industry as a whole and on small savings associations in particular.

4. Recordkeeping, Reporting, and Other Compliance Requirements

The final rule applies to savings associations, their operating subsidiaries (collectively referred to as savings associations), and their employees who act as mortgage loan originators. Typical recordkeeping, administrative, computer technology and savings association management skills will be needed to comply with all of the rule's requirements.

Reporting Requirements. Unless the *de minimis* exception applies, § 563.103(a) of the final rule requires a mortgage loan originator employed by a savings association to register with the Registry, maintain such registration, and obtain an unique identifier. Under § 563.103(b), an association must require each mortgage loan originator employee to comply with these

[1] 5 U.S.C. 601–612.

[1] In addition to the OTS, the Board, the OCC, the FDIC, the NCUA, and the FCA also certified in the proposed rule that the proposal would not have a significant economic impact on a substantial number of small entities. *See* 74 FR at 27398–27399.

[1] A discussion of SBA Advocacy's comments on other provisions of the proposed rule, namely, the *de minimis* exception and the proposed 6-month compliance period, is contained in the **SUPPLEMENTARY INFORMATION** section of this final rule.

requirements. Section 563.103(d) describes the categories of information that an employee, or the employing savings association on the employee's behalf, must submit to the Registry, along with the employee's attestation as to the correctness of the information supplied, and the employee's authorization to obtain further information and make public some of this information. This section also requires the submission of the mortgage loan originator's fingerprints to the Registry.

Section 563.103(e) specifies savings association and employee information that an association must submit to the Registry in connection with the initial registration of one or more mortgage loan originators. The savings association must annually renew this information and update this information if necessary between renewals. Authorized savings association representatives must attest to the correctness of this information and that such information will be updated on a timely basis.

Disclosure Requirements. Section 563.105(b) requires the mortgage loan originator to provide the unique identifier to a consumer: (i) Upon request; (2) before acting as a mortgage loan originator; and (3) through the originator's initial written communication with a consumer, if any, whether on paper or electronically.

Section 563.105(a) requires the savings association to make the unique identifiers of its mortgage loan originators available to consumers in a manner and method practicable to the association.

Recordkeeping and Compliance Requirements. Section 563.104 requires a savings association that employs one or more mortgage loan originators to adopt and follow written policies and procedures designed to assure compliance with this final rule. These policies and procedures must be appropriate to the nature, size, complexity, and scope of their mortgage lending activities and will apply only to those employees acting within their scope of employment at the savings association. At a minimum, these policies and procedures must establish a process for: (i) Identifying which employees are required to register, (ii) communicating the registration requirements to employees, (iii) complying with the rule's unique identifier requirements, (iv) confirming the adequacy and accuracy of employee registrations though comparisons with savings association records, (v) monitoring employee compliance with the rule, (vi) independent compliance testing, (vii) taking appropriate actions with respect to employees who fail to comply with the registration requirements, (viii) reviewing employee criminal history background checks received pursuant to this rule, and (ix) monitoring third party compliance with the S.A.F.E. Act.

5. Steps Taken To Address the Economic Impact on Small Entities

The final rule reflects the consideration given by the OTS, along with the other Agencies, to the impact that its requirements would have on small entities. First, the Agencies have revised the rule's *de minimis* exception to reduce compliance burden. In the proposed rule, the Agencies established a *de minimis* exception that would have excepted from the registration requirements an employee of an Agency-regulated institution if, during the last 12 months: (1) The employee acted as a mortgage loan originator for 5 or fewer residential mortgage loans and (2) the Agency-regulated institution employs mortgage loan originators who, while excepted from registration pursuant to this section, in the aggregate, acted as a mortgage loan originator in connection with 25 or fewer residential mortgage loans. Many commenters on this provision noted the complexity of the proposed exception. One commenter stated that the *de minimis* exception would not have any significant effect because its complexity would outweigh its benefits. Others noted that the proposed exception would be difficult for an institution to monitor and maintain. Still others said that the proposed *de minimis* exception would be fairer, and much easier to apply, if the threshold limitation applied only to the employee or to the institution, but not both. SBA Advocacy specifically commented that the proposed *de minimis* exception would make the rule unduly burdensome on small community institutions. In response to these and other comments and upon further analysis, the Agencies removed the institution threshold from this *de minimis* exception. As a result, the final rule's *de minimis* exception only contains the individual threshold, as well as a prohibition on any Agency-regulated institution from engaging in any act or practice to evade the limits of the *de minimis* exception. This revised exception should simplify compliance and therefore impose the least burden overall for institutions, including small entities.

The OTS also has reviewed alternatives for small entity compliance, including eliminating the requirement for small savings associations to adopt and follow written policies and procedures addressing all of the elements described in the final rule. For example, under such an approach, a small savings association's risk based compliance program might include only such procedures as are necessary to enable the association to demonstrate compliance with the registration and renewal requirements of the S.A.F.E. Act and the final rule. Although such an approach may have reduced the compliance cost per small savings association, the OTS does not believe that it would best serve the interests of savings associations or the OTS. Appropriate policies and procedures provide an institution and its employees with the expectations of the institution's board and include the specific implementing guidance that is applicable to the activities of that institution. Furthermore, such policies and procedures are necessary to enable examiners to evaluate the effectiveness of institutions' implementation of the S.A.F.E. Act requirements that apply to them. In reviewing this alternative, we determined that applying the policies and procedures requirement in the same way to all institutions, regardless of size, is necessary to ensure consistency in implementation and enforcement of the S.A.F.E. Act and is, therefore, the most appropriate way to ensure that the purposes of the S.A.F.E Act are met.

The OTS, and the other Agencies, also made changes to the final rule that reduce the impact that its requirements would have on all Agency-regulated financial institutions, including small entities. The final rule decreased the amount of information required for submission by a mortgage loan originator. Specifically, the final rule does not require submission of financial history information such as bankruptcies and liens; employment and terminations; pending actions; and felonies unrelated to crimes of dishonesty. Furthermore, the Agencies declined to include loan modification activities in the final rule's definition of mortgage loan originator. Under the OTS's rule, Agency-regulated institution employees engaged solely in bona fide cost-free loss mitigation efforts, which result in reduced and sustainable payments for the borrower generally would not meet the definition of "mortgage loan originator." This reduces the number of savings association employees subject to the final rule's requirements.

FCA: Pursuant to section 605(b) of the RFA (5 U.S.C. 601 *et seq.*) the FCA certifies that the final rule will not have a significant economic impact on a substantial number of small entities. Each of the banks in the Farm Credit

System, considered together with its affiliated associations, has assets and annual income in excess of the amounts that would qualify them as small entities.

The comment letter from the Office of Advocacy in the Small Business Administration (SBA) stated that the FCA did not provide any information about the potential impact of the rule on FCS institutions. The RFA requires each agency to certify that a rulemaking will not have a significant economic impact on a significant number of small entities. The FCA observes that the RFA definition of "small entity" derives from the SBA's definition of "small business concern," including size standards. According to section 3(a)(1) of the Small Business Act, as amended, a small business concern is independently owned and operated, and it is not dominant in its field of operation. Whether a business concern is "independently owned and operated" depends, in part, on its affiliation with other business entities. Generally, an affiliate is either controlled by, or has control over another entity. Businesses that are economically dependent on each other because of their ownership, management, and contractual relationships may be affiliates. FCS associations own and control their funding banks. Additionally, FCS associations borrow exclusively from their funding banks, and they pledge virtually all of their loans and other assets to these banks to secure their loans. For these reasons, the FCA has determined that the interrelated ownership, control, and contractual relationships are sufficient to treat FCS banks and associations as a single entity for the purposes of the RFA.

SBA regulations also establish size categories to determine whether entities that engage in "Credit Intermediation and Related Activities" are small business concerns. These regulations categorize "All Other Non-Depository Credit Intermediation" institutions as small entities if their annual receipts are $7 million or less. As affiliated entities, the combined annual receipts of each Farm Credit bank and its affiliated associations exceed $7 million. For this reason, FCS institutions do not qualify as small entities under the RFA.

NCUA: In accordance with the RFA, 5 U.S.C. 601–612, NCUA must publish a regulatory flexibility analysis with its final rule, unless NCUA certifies that the rule will not have a significant economic impact on a substantial number of small entities (defined for purposes of the RFA to include credit unions with less than $10 million in assets). Approximately 2,995 out of 7,554 Federally insured credit unions and 61 out of 156 non-Federally insured credit unions are small entities. NCUA hereby certifies that the final rule would not have a significant economic impact on a substantial number of these small entities.

The final rule will apply to all Federally insured credit unions, non-Federally insured credit unions located in States where the State supervisory authorities enter into and maintain MOUs with NCUA, and employees who act as mortgage originators for these credit unions. The final rule imposes no requirements on credit unions not originating residential mortgages. This accounts for 1,923 of the 2,995 small, Federally insured credit unions and 45 of the 61 small, non-Federally insured credit unions.

Under the final rule, all these credit unions, including small entities, originating any residential mortgages must have policies and procedures in place for mortgage loan origination registration. This currently includes only about 1,072 of the 2,995 small, Federally insured credit unions, and only about 16 of the 61 small, non-Federally insured credit unions. The policies and procedures must be appropriate to the nature, size, complexity, and scope of the credit unions' mortgage lending activities and will apply only to those employees acting within their scope of credit union employment.

Approximately 2,716 of the 2,995 small, Federally insured credit unions, and 15 of the 16 small, non-Federally insured credit unions, would qualify for the final rule's *de minimis* exception to the registration requirements for mortgage loan originators because they originate fewer than five or no residential mortgage loans. Those credit unions not originating mortgages have no obligations under this final rule. Those small credit unions and their employees originating between one and four mortgages per year are not subject to the final rule's registration requirements and, thus, drafting and implementing the policies and procedures will not be burdensome.

Accordingly, NCUA estimates only about 279 of the 2,995 small Federally insured credit unions, about 9.3% of them, and only one of the 61 small, non-Federally insured credit unions, about 1.6%, will be subject to the final rule's registration requirements and will establish policies and procedures for the registration.

Therefore, for all of the above reasons, NCUA concludes the final rule would not have a significant economic impact on a substantial number of small credit unions.

B. Paperwork Reduction Act

In accordance with the requirements of the Paperwork Reduction Act of 1995, the agencies may not conduct or sponsor, and respondents are not required to respond to, an information collection unless it displays a currently valid Office of Management and Budget (OMB) control number.

The information collection requirements contained in this joint final rule have been submitted by the OCC, FDIC, OTS, and NCUA to, and pre-approved by, OMB under section 3506 of the PRA and § 1320.11 of OMB's implementing regulations (5 CFR part 1320). The FCA collects information from Farm Credit System institutions, which are Federal instrumentalities, in the FCA's capacity as their safety and soundness regulator, and, therefore, OMB approval is not required for this collection. The Board reviewed the proposed rule under the authority delegated to the Board by the Office of Management and Budget. The final rule contains requirements subject to the PRA. The requirements are found in 12 CFR __.103(a)–(b), (d)–(e), __.104, and __.105.

No comments concerning PRA were received in response to the notice of proposed rulemaking. Therefore, the hourly burden estimates for respondents noted in the proposed rule have not changed. The agencies have an ongoing interest in your comments. They should be sent to [Agency] Desk Officer, [OMB Control No.], by mail to U.S. Office of Management and Budget, 725 17th Street, NW., 10235, Washington, DC 20503, or by fax to (202) 395–6974. Written comments should address:

(a) Whether the collection of information is necessary for the proper performance of the Federal banking agencies' functions, including whether the information has practical utility;

(b) The accuracy of the estimates of the burden of the information collection, including the validity of the methodology and assumptions used;

(c) Ways to enhance the quality, utility, and clarity of the information to be collected;

(d) Ways to minimize the burden of the information 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.

C. OCC Executive Order 12866 Determination

Executive Order 12866 requires each Federal agency to provide to the Administrator of OMB's Office of Information and Regulatory Affairs (OIRA) a Regulatory Impact Analysis for agency actions that are found to be "significant regulatory actions." "Significant regulatory actions" include, among other things, rulemakings that "have an annual effect on the economy of $100 million or more or adversely affect in a material way the economy, a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or State, local, or tribal governments or communities." [1] Regulatory actions that satisfy one or more of these criteria are referred to as "economically significant regulatory actions." In conducting this Regulatory Impact Analysis, Executive Order 12866 requires each Federal agency to provide to OIRA:

- The text of the draft regulatory action, together with a reasonably detailed description of the need for the regulatory action and an explanation of how the regulatory action will meet that need;
- An assessment of the potential costs and benefits of the regulatory action, including an explanation of the manner in which the regulatory action is consistent with a statutory mandate and, to the extent permitted by law, promotes the President's priorities and avoids undue interference with State, local, and Tribal governments in the exercise of their governmental functions;
- An assessment, including the underlying analysis, of benefits anticipated from the regulatory action (such as, but not limited to, the promotion of the efficient functioning of the economy and private markets, the enhancement of health and safety, the protection of the natural environment, and the elimination or reduction of discrimination or bias) together with, to the extent feasible, a quantification of those benefits;
- An assessment, including the underlying analysis, of costs anticipated from the regulatory action (such as, but not limited to, the direct cost both to the government in administering the regulation and to businesses and others in complying with the regulation, and any adverse effects on the efficient functioning of the economy, private markets (including productivity, employment, and competitiveness), health, safety, and the natural environment), together with, to the extent feasible, a quantification of those costs; and
- An assessment, including the underlying analysis, of costs and benefits of potentially effective and reasonably feasible alternatives to the planned regulation, identified by the agencies or the public (including improving the current regulation and reasonably viable nonregulatory actions), and an explanation why the planned regulatory action is preferable to the identified potential alternatives.

The OCC has concluded that the final rule exceeds the $100 million criterion and therefore is an economically significant regulatory action. As required by Executive Order 12866, the OCC prepared a Regulatory Impact Analysis, which was submitted to OIRA on January 8, 2010. The OCC's final set of revisions responding to OIRA comments was submitted on July 1, 2010. As discussed in more detail in the Regulatory Impact Analysis, the OCC determined that given the constraints imposed on the OCC by the S.A.F.E. Act, and based on the estimated mean cost, the rule was the least cost option available to the OCC. The OCC's Regulatory Impact Analysis in its entirety is available at *http://www.regulations.gov,* docket ID OCC–2010–0007.

D. OTS Executive Order 12866 Determination

Executive Order 12866 requires each Federal agency to provide the Administrator of OMB's OIRA a Regulatory Impact Analysis for agency actions that are found to be "significant regulatory actions." Significant regulatory actions include, among other things, rulemakings that "have an annual effect on the economy of $100 million or more or adversely affect in a material way the economy, a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or State, local, or Tribal governments or communities." [1] Regulatory actions that satisfy one or more of these criteria are referred to as "economically significant regulatory actions." In conducting this Regulatory Impact Analysis, Executive Order 12866 requires each Federal agency to provide to OIRA:

- The text of the draft regulatory action, together with a reasonably detailed description of the need for the regulatory action and an explanation of how the regulatory action will meet that need;
- An assessment of the potential costs and benefits of the regulatory action, including an explanation of the manner in which the regulatory action is consistent with a statutory mandate and, to the extent permitted by law, promotes the President's priorities and avoids undue interference with State, local, and Tribal governments in the exercise of their governmental functions;
- An assessment, including the underlying analysis, of benefits anticipated from the regulatory action (such as, but not limited to, the promotion of the efficient functioning of the economy and private markets, the enhancement of health and safety, the protection of the natural environment, and the elimination or reduction of discrimination or bias) together with, to the extent feasible, a quantification of those benefits;
- An assessment, including the underlying analysis, of costs anticipated from the regulatory action (such as, but not limited to, the direct cost both to the government in administering the regulation and to businesses and others in complying with the regulation, and any adverse effects on the efficient functioning of the economy, private markets (including productivity, employment, and competitiveness), health, safety, and the natural environment), together with, to the extent feasible, a quantification of those costs; and
- An assessment, including the underlying analysis, of costs and benefits of potentially effective and reasonably feasible alternatives to the planned regulation, identified by the agencies or the public (including improving the current regulation and reasonably viable nonregulatory actions), and an explanation why the planned regulatory action is preferable to the identified potential alternatives.

The OTS has determined that this final rule is not a significant regulatory action under Executive Order 12866. We have concluded that the changes made by this final rule will not have an

[1] Executive Order 12866 (September 30, 1993), 58 FR 51735 (October 4, 1993). For the complete text of the definition of "significant regulatory action," *see* E.O. 12866 at § 3(f). A "regulatory action" is "any substantive action by an agency (normally published in the **Federal Register**) that promulgates or is expected to lead to the promulgation of a final rule or regulation, including notices of inquiry, advance notices of proposed rulemaking, and notices of proposed rulemaking." E.O. 12866 at § 3(e).

[1] Executive Order 12866 (September 30, 1993), 58 FR 51735 (October 4, 1993). For the complete text of the definition of "significant regulatory action," *see* E.O. 12866 at § 3(f). A "regulatory action" is "any substantive action by an agency (normally published in the **Federal Register**) that promulgates or is expected to lead to the promulgation of a final rule or regulation, including notices of inquiry, advance notices of proposed rulemaking, and notices of proposed rulemaking." E.O. 12866 at § 3(e).

annual effect on the economy of $100 million or more. The OTS further concludes that this final rule does not meet any of the other standards for a significant regulatory action set forth in Executive Order 12866. As required by Executive Order 12866, the OTS prepared a Regulatory Impact Analysis, which was submitted to OIRA on March 9, 2010. The OTS's final revisions were submitted to OIRA on July 12, 2010. As discussed in more detail in the Regulatory Impact Analysis, the OTS determined that given the constraints imposed on the OTS by the S.A.F.E. Act, and based on the estimated cost, the rule was the least cost option available to the OTS. The OTS's Regulatory Impact Analysis in its entirety is available at *http://www.regulations.gov,* Docket No. OTS–2010–0021.

E. OCC and OTS Unfunded Mandates Reform Act of 1995 Determination

Section 202 of the Unfunded Mandates Reform Act of 1995 (2 U.S.C. 1532), requires the OCC and OTS to prepare a budgetary impact statement before promulgating a rule that 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 $133 million or more in any one year. However, this requirement does not apply to regulations that incorporate requirements specifically set forth in law. Because this proposed rule implements the S.A.F.E. Act, the OTS and OCC have not conducted an Unfunded Mandates Analysis for this rulemaking.[1]

F. OCC and OTS Executive Order 13132 Determination

E.O. 13132 sets forth certain "Fundamental Federalism Principles" and "Federalism Policymaking Criteria" that must be followed by the OCC and OTS in developing any regulation that has Federalism implications. A regulation has Federalism implications if it has "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." If a rule meets the test for Federalism implications, the executive order requires the agency, among other things, to prepare a Federalism summary impact statement for inclusion in the rule's **SUPPLEMENTARY INFORMATION** section and must consult with State and local officials about the rule. The OCC and OTS have determined that their respective portions of the final rule do not have a substantial direct effect on the States, on the connection between the national government and the States, or on the distribution of power and responsibilities among the various levels of government. Therefore, the final rule does not have any Federalism implications for purposes of Executive Order 13132.

G. NCUA Executive Order 13132 Determination

Executive Order 13132 encourages independent regulatory agencies to consider the impact of their actions on State and local interests. In adherence to fundamental Federalism principles, the NCUA, an independent regulatory agency as defined in 44 U.S.C. 3502(5) voluntarily complies with the Executive Order. The final rule applies to credit unions and would not have substantial direct effects on the States, on the connection between the national government and the States, or on the distribution of power and responsibilities among the various levels of government. The NCUA has determined that the final rule does not constitute a policy that has Federalism implications for purposes of the Executive Order.

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

The NCUA has determined that this final rule would not affect family well-being within the meaning of section 654 of the Treasury and General Government Appropriations Act, 1999, Public Law 105–277, 112 Stat. 2681 (1998).

I. NCUA: Small Business Regulatory Enforcement Fairness Act

The Small Business Regulatory Enforcement Fairness Act of 1996 (Pub. L. 104–121) (SBREFA) provides generally for congressional review of agency rules. A reporting requirement is triggered in instances where NCUA issues a final rule as defined by section 551 of the Administrative Procedure Act. 5 U.S.C. 551. NCUA does not believe this final rule is a "major rule" within the meaning of the relevant sections of SBREFA. NCUA has submitted the rule to the Office of Management and Budget (OMB) for its determination and OMB concurred that the rule is not a major rule.

List of Subjects

12 CFR Part 34

Mortgages, National banks, Reporting and recordkeeping requirements.

12 CFR Part 208

Accounting, Agriculture, Banks, banking, Confidential business information, Consumer protection, Crime, Currency, Insurance, Investments, Mortgages, Reporting and recordkeeping requirements, Securities.

12 CFR Part 211

Exports, Foreign banking, Holding companies, Investments, Reporting and recordkeeping requirements.

12 CFR Part 365

Banks, banking, Mortgages.

12 CFR Part 563

Accounting, Administrative practice and procedure, Advertising, Conflict of interests, Crime, Currency, Holding companies, Investments, Mortgages, Reporting and recordkeeping requirements, Savings associations, Securities, Surety bonds.

12 CFR Part 610

Banks, banking, Consumer protection, Loan programs—housing and community development, Mortgages, Reporting and recordkeeping requirements, Rural areas.

12 CFR Part 741

Bank deposit insurance, Credit unions, Reporting and recordkeeping requirements.

12 CFR Part 761

Credit unions, Mortgages, Reporting and recordkeeping requirements.

Office of the Comptroller of the Currency

12 CFR Chapter I

Authority and Issuance

■ For the reasons set forth in the preamble, chapter I of title 12 of the Code of Federal Regulations is amended as follows:

PART 34—REAL ESTATE LENDING AND APPRAISALS

■ 1. The authority citation for part 34 is revised to read as follows:

Authority: 12 U.S.C. 1 *et seq.,* 29, 93a, 371, 1701j–3, 1828(o), 3331 *et seq.,* and 5101 *et seq.*

■ 2. Add Subpart F to part 34 to read as follows:

[1] *See* 2 U.S.C. 1531.

Subpart F—Registration of Residential Mortgage Loan Originators

Sec.
34.101 Authority, purpose, and scope.
34.102 Definitions.
34.103 Registration of mortgage loan originators.
34.104 Policies and procedures.
34.105 Use of unique identifier.
Appendix A to Subpart F of Part 34—Examples of Mortgage Loan Originator Activities

Subpart F—Registration of Residential Mortgage Loan Originators

§ 34.101 Authority, purpose, and scope.

(a) *Authority.* This subpart is issued pursuant to the Secure and Fair Enforcement for Mortgage Licensing Act of 2008, title V of the Housing and Economic Recovery Act of 2008 (S.A.F.E. Act) (Pub. L. 110–289, 122 Stat. 2654, 12 U.S.C. 5101 *et seq.*).

(b) *Purpose.* This subpart implements the S.A.F.E. Act's Federal registration requirement for mortgage loan originators. The S.A.F.E. Act provides that the objectives of this registration include aggregating and improving the flow of information to and between regulators; providing increased accountability and tracking of mortgage loan originators; enhancing consumer protections; supporting anti-fraud measures; and providing consumers with easily accessible information at no charge regarding the employment history of, and publicly adjudicated disciplinary and enforcement actions against, mortgage loan originators.

(c) *Scope.* (1) *In general.* This subpart applies to national banks, Federal branches and agencies of foreign banks, their operating subsidiaries (collectively referred to in this subpart as national banks), and their employees who act as mortgage loan originators.

(2) *De minimis exception.* (i) This subpart and the requirements of 12 U.S.C. 5103(a)(1)(A) and (2) of the S.A.F.E. Act do not apply to any employee of a national bank who has never been registered or licensed through the Registry as a mortgage loan originator if during the past 12 months the employee acted as a mortgage loan originator for 5 or fewer residential mortgage loans.

(ii) Prior to engaging in mortgage loan origination activity that exceeds the exception limit in paragraph (c)(2)(i) of this section, a national bank employee must register with the Registry pursuant to this subpart.

(iii) *Evasion.* National banks are prohibited from engaging in any act or practice to evade the limits of the *de minimis* exception set forth in paragraph (c)(2)(i) of this section.

§ 34.102 Definitions.

For purposes of this subpart F, the following definitions apply:

(a) *Annual renewal period* means November 1 through December 31 of each year.

(b)(1) *Mortgage loan originator*[3] means an individual who:

(i) Takes a residential mortgage loan application; and

(ii) Offers or negotiates terms of a residential mortgage loan for compensation or gain.

(2) The term *mortgage loan originator* does not include:

(i) An individual who performs purely administrative or clerical tasks on behalf of an individual who is described in paragraph (b)(1) of this section;

(ii) An individual who only performs real estate brokerage activities (as defined in 12 U.S.C. 5102(3)(D)) and is licensed or registered as a real estate broker in accordance with applicable State law, unless the individual is compensated by a lender, a mortgage broker, or other mortgage loan originator or by any agent of such lender, mortgage broker, or other mortgage loan originator, and meets the definition of mortgage loan originator in paragraph (b)(1) of this section; or

(iii) An individual or entity solely involved in extensions of credit related to timeshare plans, as that term is defined in 11 U.S.C. 101(53D).

(3) *Administrative or clerical tasks* means the receipt, collection, and distribution of information common for the processing or underwriting of a loan in the residential mortgage industry and communication with a consumer to obtain information necessary for the processing or underwriting of a residential mortgage loan.

(c) *Nationwide Mortgage Licensing System and Registry* or *Registry* means the system developed and maintained by the Conference of State Bank Supervisors and the American Association of Residential Mortgage Regulators for the State licensing and registration of State-licensed mortgage loan originators and the registration of mortgage loan originators pursuant to 12 U.S.C. 5107.

(d) *Registered mortgage loan originator* or *registrant* means any individual who:

(1) Meets the definition of mortgage loan originator and is an employee of a national bank; and

(2) Is registered pursuant to this subpart with, and maintains a unique identifier through, the Registry.

(e) *Residential mortgage loan* means any loan primarily for personal, family, or household use that is secured by a mortgage, deed of trust, or other equivalent consensual security interest on a dwelling (as defined in section 103(v) of the Truth in Lending Act, 15 U.S.C. 1602(v)) or residential real estate upon which is constructed or intended to be constructed a dwelling, and includes refinancings, reverse mortgages, home equity lines of credit and other first and additional lien loans that meet the qualifications listed in this definition.

(f) *Unique identifier* means a number or other identifier that:

(1) Permanently identifies a registered mortgage loan originator;

(2) Is assigned by protocols established by the Nationwide Mortgage Licensing System and Registry, the Federal banking agencies, and the Farm Credit Administration to facilitate:

(i) Electronic tracking of mortgage loan originators; and

(ii) Uniform identification of, and public access to, the employment history of and the publicly adjudicated disciplinary and enforcement actions against mortgage loan originators; and

(3) Must not be used for purposes other than those set forth under the S.A.F.E. Act.

§ 34.103 Registration of mortgage loan originators.

(a) *Registration requirement*—(1) *Employee registration.* Each employee of a national bank who acts as a mortgage loan originator must register with the Registry, obtain a unique identifier, and maintain this registration in accordance with the requirements of this subpart. Any such employee who is not in compliance with the registration and unique identifier requirements set forth in this subpart is in violation of the S.A.F.E. Act and this subpart.

(2) *National bank requirement*—(i) *In general.* A national bank that employs one or more individuals who act as a residential mortgage loan originator must require each such employee to register with the Registry, maintain this registration, and obtain a unique identifier in accordance with the requirements of this subpart.

(ii) *Prohibition.* A national bank must not permit an employee of the bank who is subject to the registration requirements of this subpart to act as a mortgage loan originator for the bank unless such employee is registered with the Registry pursuant to this subpart.

[3] Appendix A of this subpart provides examples of activities that would, and would not, cause an employee to fall within this definition of mortgage loan originator.

(3) *Implementation period for initial registration.* An employee of a national bank who is a mortgage loan originator must complete an initial registration with the Registry pursuant to this subpart within 180 days from the date that the OCC provides in a public notice that the Registry is accepting registrations.

(4) *Employees previously registered or licensed through the Registry*—(i) *In general.* If an employee of a national bank was registered or licensed through, and obtained a unique identifier from, the Registry and has maintained this registration or license before the employee becomes subject to this subpart at this bank, then the registration requirements of the S.A.F.E. Act and this subpart are deemed to be met, provided that:

(A) The employment information in paragraphs (d)(1)(i)(C) and (d)(1)(ii) of this section is updated and the requirements of paragraph (d)(2) of this section are met;

(B) New fingerprints of the employee are submitted to the Registry for a background check, as required by paragraph (d)(1)(ix) of this section, unless the employee has fingerprints on file with the Registry that are less than 3 years old;

(C) The national bank information required in paragraphs (e)(1)(i) (to the extent the bank has not previously met these requirements) and (e)(2)(i) of this section is submitted to the Registry; and

(D) The registration is maintained pursuant to paragraphs (b) and (e)(1)(ii) of this section, as of the date that the employee becomes subject to this subpart.

(ii) *Rule for certain acquisitions, mergers, or reorganizations.* When registered or licensed mortgage loan originators become national bank employees as a result of an acquisition, merger, or reorganization, only the requirements of paragraphs (a)(4)(i)(A), (C), and (D) of this section must be met, and these requirements must be met within 60 days from the effective date of the acquisition, merger, or reorganization.

(b) *Maintaining registration.* (1) A mortgage loan originator who is registered with the Registry pursuant to paragraph (a) of this section must:

(i) Except as provided in paragraph (b)(3) of this section, renew the registration during the annual renewal period, confirming the responses set forth in paragraphs (d)(1)(i) through (viii) of this section remain accurate and complete, and updating this information, as appropriate; and

(ii) Update the registration within 30 days of any of the following events:

(A) A change in the name of the registrant;

(B) The registrant ceases to be an employee of the national bank; or

(C) The information required under paragraphs (d)(1)(iii) through (viii) of this section becomes inaccurate, incomplete, or out-of-date.

(2) A registered mortgage loan originator must maintain his or her registration, unless the individual is no longer engaged in the activity of a mortgage loan originator.

(3) The annual registration renewal requirement set forth in paragraph (b)(1) of this section does not apply to a registered mortgage loan originator who has completed his or her registration with the Registry pursuant to paragraph (a)(1) of this section less than 6 months prior to the end of the annual renewal period.

(c) *Effective dates*—(1) *Registration.* A registration pursuant to paragraph (a)(1) of this section is effective on the date the Registry transmits notification to the registrant that the registrant is registered.

(2) *Renewals or updates.* A renewal or update pursuant to paragraph (b) of this section is effective on the date the Registry transmits notification to the registrant that the registration has been renewed or updated.

(d) *Required employee information*—(1) *In general.* For purposes of the registration required by this section, a national bank must require each employee who is a mortgage loan originator to submit to the Registry, or must submit on behalf of the employee, the following categories of information, to the extent this information is collected by the Registry:

(i) Identifying information, including the employee's:

(A) Name and any other names used;

(B) Home address and contact information;

(C) Principal business location address and business contact information;

(D) Social security number;

(E) Gender; and

(F) Date and place of birth;

(ii) Financial services-related employment history for the 10 years prior to the date of registration or renewal, including the date the employee became an employee of the bank;

(iii) Convictions of any criminal offense involving dishonesty, breach of trust, or money laundering against the employee or organizations controlled by the employee, or agreements to enter into a pretrial diversion or similar program in connection with the prosecution for such offense(s);

(iv) Civil judicial actions against the employee in connection with financial services-related activities, dismissals with settlements, or judicial findings that the employee violated financial services-related statutes or regulations, except for actions dismissed without a settlement agreement;

(v) Actions or orders by a State or Federal regulatory agency or foreign financial regulatory authority that:

(A) Found the employee to have made a false statement or omission or been dishonest, unfair or unethical; to have been involved in a violation of a financial services-related regulation or statute; or to have been a cause of a financial services-related business having its authorization to do business denied, suspended, revoked, or restricted;

(B) Are entered against the employee in connection with a financial services-related activity;

(C) Denied, suspended, or revoked the employee's registration or license to engage in a financial services-related activity; disciplined the employee or otherwise by order prevented the employee from associating with a financial services-related business or restricted the employee's activities; or

(D) Barred the employee from association with an entity or its officers regulated by the agency or authority or from engaging in a financial services-related business;

(vi) Final orders issued by a State or Federal regulatory agency or foreign financial regulatory authority based on violations of any law or regulation that prohibits fraudulent, manipulative, or deceptive conduct;

(vii) Revocation or suspension of the employee's authorization to act as an attorney, accountant, or State or Federal contractor;

(viii) Customer-initiated financial services-related arbitration or civil action against the employee that required action, including settlements, or which resulted in a judgment; and

(ix) Fingerprints of the employee, in digital form if practicable, and any appropriate identifying information for submission to the Federal Bureau of Investigation and any governmental agency or entity authorized to receive such information in connection with a State and national criminal history background check; however, fingerprints provided to the Registry that are less than 3 years old may be used to satisfy this requirement.

(2) *Employee authorizations and attestation.* An employee registering as a mortgage loan originator or renewing or updating his or her registration under this subpart, and not the employing

national bank or other employees of the national bank, must:

(i) Authorize the Registry and the employing institution to obtain information related to sanctions or findings in any administrative, civil, or criminal action, to which the employee is a party, made by any governmental jurisdiction;

(ii) Attest to the correctness of all information required by paragraph (d) of this section, whether submitted by the employee or on behalf of the employee by the employing bank; and

(iii) Authorize the Registry to make available to the public information required by paragraphs (d)(1)(i)(A) and (C), and (d)(1)(ii) through (viii) of this section.

(3) *Submission of information.* A national bank may identify one or more employees of the bank who may submit the information required by paragraph (d)(1) of this section to the Registry on behalf of the bank's employees provided that this individual, and any employee delegated such authority, does not act as a mortgage loan originator, consistent with paragraph (e)(1)(i)(F) of this section. In addition, a national bank may submit to the Registry some or all of the information required by paragraphs (d)(1) and (e)(2) of this section for multiple employees in bulk through batch processing in a format to be specified by the Registry, to the extent such batch processing is made available by the Registry.

(e) *Required bank information.* A national bank must submit the following categories of information to the Registry:

(1) *Bank record.* (i) In connection with the registration of one or more mortgage loan originators:

(A) Name, main office address, and business contact information;

(B) Internal Revenue Service Employer Tax Identification Number (EIN);

(C) Research Statistics Supervision and Discount (RSSD) number, as issued by the Board of Governors of the Federal Reserve System;

(D) Identification of its primary Federal regulator;

(E) Name(s) and contact information of the individual(s) with authority to act as the bank's primary point of contact for the Registry;

(F) Name(s) and contact information of the individual(s) with authority to enter the information required by paragraphs (d)(1) and (e) of this section to the Registry and who may delegate this authority to other individuals. For the purpose of providing information required by paragraph (e) of this section, this individual and their delegates must not act as mortgage loan originators unless the bank has 10 or fewer full time or equivalent employees and is not a subsidiary; and

(G) If a subsidiary of a national bank, indication that it is a subsidiary and the RSSD number of the parent bank.

(ii) *Attestation.* The individual(s) identified in paragraphs (e)(1)(i)(E) and (F) of this section must comply with Registry protocols to verify their identity and must attest that they have the authority to enter data on behalf of the national bank, that the information provided to the Registry pursuant to this paragraph (e) is correct, and that the national bank will keep the information required by this paragraph (e) current and will file accurate supplementary information on a timely basis.

(iii) A national bank must update the information required by this paragraph (e) of this section within 30 days of the date that this information becomes inaccurate.

(iv) A national bank must renew the information required by paragraph (e) of this section on an annual basis.

(2) *Employee information.* In connection with the registration of each employee who acts as a mortgage loan originator:

(i) After the information required by paragraph (d) of this section has been submitted to the Registry, confirmation that it employs the registrant; and

(ii) Within 30 days of the date the registrant ceases to be an employee of the bank, notification that it no longer employs the registrant and the date the registrant ceased being an employee.

§ 34.104 Policies and procedures.

A national bank that employs one or more mortgage loan originators must adopt and follow written policies and procedures designed to assure compliance with this subpart. These policies and procedures must be appropriate to the nature, size, complexity, and scope of the mortgage lending activities of the bank, and apply only to those employees acting within the scope of their employment at the bank. At a minimum, these policies and procedures must:

(a) Establish a process for identifying which employees of the bank are required to be registered mortgage loan originators;

(b) Require that all employees of the national bank who are mortgage loan originators be informed of the registration requirements of the S.A.F.E. Act and this subpart and be instructed on how to comply with such requirements and procedures;

(c) Establish procedures to comply with the unique identifier requirements in § 34.105;

(d) Establish reasonable procedures for confirming the adequacy and accuracy of employee registrations, including updates and renewals, by comparisons with its own records;

(e) Establish reasonable procedures and tracking systems for monitoring compliance with registration and renewal requirements and procedures;

(f) Provide for independent testing for compliance with this subpart to be conducted at least annually by bank personnel or by an outside party;

(g) Provide for appropriate action in the case of any employee who fails to comply with the registration requirements of the S.A.F.E. Act, this subpart, or the bank's related policies and procedures, including prohibiting such employees from acting as mortgage loan originators or other appropriate disciplinary actions;

(h) Establish a process for reviewing employee criminal history background reports received pursuant to this subpart, taking appropriate action consistent with applicable Federal law, including section 19 of the Federal Deposit Insurance Act (12 U.S.C. 1829) and implementing regulations with respect to these reports, and maintaining records of these reports and actions taken with respect to applicable employees; and

(i) Establish procedures designed to ensure that any third party with which the bank has arrangements related to mortgage loan origination has policies and procedures to comply with the S.A.F.E. Act, including appropriate licensing and/or registration of individuals acting as mortgage loan originators.

§ 34.105 Use of unique identifier.

(a) The national bank shall make the unique identifier(s) of its registered mortgage loan originator(s) available to consumers in a manner and method practicable to the institution.

(b) A registered mortgage loan originator shall provide his or her unique identifier to a consumer:

(1) Upon request;

(2) Before acting as a mortgage loan originator; and

(3) Through the originator's initial written communication with a consumer, if any, whether on paper or electronically.

Appendix A to Subpart F of Part 34—Examples of Mortgage Loan Originator Activities

This Appendix provides examples to aid in the understanding of activities that would cause an employee of a national bank to fall within or outside the definition of mortgage loan originator. The examples in this

Appendix are not all inclusive. They illustrate only the issue described and do not illustrate any other issues that may arise under this subpart. For purposes of the examples below, the term "loan" refers to a residential mortgage loan.

(a) *Taking a loan application.* The following examples illustrate when an employee takes, or does not take, a loan application.

(1) Taking an application includes: receiving information provided in connection with a request for a loan to be used to determine whether the consumer qualifies for a loan, even if the employee:

(i) Has received the consumer's information indirectly in order to make an offer or negotiate a loan;

(ii) Is not responsible for verifying information;

(iii) Is inputting information into an online application or other automated system on behalf of the consumer; or

(iv) Is not engaged in approval of the loan, including determining whether the consumer qualifies for the loan.

(2) Taking an application does not include any of the following activities performed solely or in combination:

(i) Contacting a consumer to verify the information in the loan application by obtaining documentation, such as tax returns or payroll receipts;

(ii) Receiving a loan application through the mail and forwarding it, without review, to loan approval personnel;

(iii) Assisting a consumer who is filling out an application by clarifying what type of information is necessary for the application or otherwise explaining the qualifications or criteria necessary to obtain a loan product;

(iv) Describing the steps that a consumer would need to take to provide information to be used to determine whether the consumer qualifies for a loan or otherwise explaining the loan application process;

(v) In response to an inquiry regarding a prequalified offer that a consumer has received from a bank, collecting only basic identifying information about the consumer and forwarding the consumer to a mortgage loan originator; or

(vi) Receiving information in connection with a modification to the terms of an existing loan to a borrower as part of the bank's loss mitigation efforts when the borrower is reasonably likely to default.

(b) *Offering or negotiating terms of a loan.* The following examples are designed to illustrate when an employee offers or negotiates terms of a loan, and conversely, what does not constitute offering or negotiating terms of a loan.

(1) Offering or negotiating the terms of a loan includes:

(i) Presenting a loan offer to a consumer for acceptance, either verbally or in writing, including, but not limited to, providing a disclosure of the loan terms after application under the Truth in Lending Act, even if:

(A) Further verification of information is necessary;

(B) The offer is conditional;

(C) Other individuals must complete the loan process; or

(D) Only the rate approved by the bank's loan approval mechanism function for a specific loan product is communicated without authority to negotiate the rate.

(ii) Responding to a consumer's request for a lower rate or lower points on a pending loan application by presenting to the consumer a revised loan offer, either verbally or in writing, that includes a lower interest rate or lower points than the original offer.

(2) Offering or negotiating terms of a loan does not include solely or in combination:

(i) Providing general explanations or descriptions in response to consumer queries regarding qualification for a specific loan product, such as explaining loan terminology (*i.e.,* debt-to-income ratio); lending policies (*i.e.,* the loan-to-value ratio policy of the national bank); or product-related services;

(ii) In response to a consumer's request, informing a consumer of the loan rates that are publicly available, such as on the national bank's Web site, for specific types of loan products without communicating to the consumer whether qualifications are met for that loan product;

(iii) Collecting information about a consumer in order to provide the consumer with information on loan products for which the consumer generally may qualify, without presenting a specific loan offer to the consumer for acceptance, either verbally or in writing;

(iv) Arranging the loan closing or other aspects of the loan process, including communicating with a consumer about those arrangements, provided that communication with the consumer only verifies loan terms already offered or negotiated;

(v) Providing a consumer with information unrelated to loan terms, such as the best days of the month for scheduling loan closings at the bank;

(vi) Making an underwriting decision about whether the consumer qualifies for a loan;

(vii) Explaining or describing the steps or process that a consumer would need to take in order to obtain a loan offer, including qualifications or criteria that would need to be met without providing guidance specific to that consumer's circumstances; or

(viii) Communicating on behalf of a mortgage loan originator that a written offer, including disclosures provided pursuant to the Truth in Lending Act, has been sent to a consumer without providing any details of that offer.

(c) *Offering or negotiating a loan for compensation or gain.* The following examples illustrate when an employee does or does not offer or negotiate terms of a loan "for compensation or gain."

(1) Offering or negotiating terms of a loan for compensation or gain includes engaging in any of the activities in paragraph (b)(1) of this Appendix in the course of carrying out employment duties, even if the employee does not receive a referral fee or commission or other special compensation for the loan.

(2) Offering or negotiating terms of a loan for compensation or gain does not include engaging in a seller-financed transaction for the employee's personal property that does not involve the national bank.

Board of Governors of the Federal Reserve System

12 CFR Chapter II

Authority and Issuance

■ For the reasons set forth in the preamble, chapter II of title 12 of the Code of Federal Regulations is amended as follows:

PART 208—MEMBERSHIP OF STATE BANKING INSTITUTIONS IN THE FEDERAL RESERVE SYSTEM (REGULATION H)

■ 1. The authority citation for part 208 is revised to read as follows:

Authority: 12 U.S.C. 24, 36, 92a, 93a, 248(a), 248(c), 321–338a, 371d, 461, 481–486, 601, 611, 1814, 1816, 1820(d)(9), 1823(j), 1828(o), 1831, 1831o, 1831p–1, 1831r–1, 1831w, 1831x, 1835a, 1882, 2901–2907, 3105, 3106a(1), 3108(a), 3310, 3331–3351, and 3906–3909, 5101 *et seq.,* 15 U.S.C. 78b, 78l(b), 78l(g), 78l(i), 78o–4(c)(5), 78q, 78q–1, 78w, 1681s, 1681w, 6801 and 6805; 31 U.S.C. 5318, 42 U.S.C. 4012a, 4104a, 4104b, 4106, and 4128.

■ 2. Subpart I, consisting of §§ 208.100 and 208.101, is redesignated as Subpart J, consisting of §§ 208.110 and 208.111.

■ 3. New subpart I is added to read as follows:

Subpart I—Registration of Residential Mortgage Loan Originators

Sec.
208.101 Authority, purpose, and scope.
208.102 Definitions.
208.103 Registration of mortgage loan originators.
208.104 Policies and procedures.
208.105 Use of unique identifier.
Appendix A to Subpart I of Part 208—Examples of Mortgage Loan Originator Activities

Subpart I—Registration of Residential Mortgage Loan Originators

§ 208.101 Authority, purpose, and scope.

(a) *Authority.* This subpart is issued pursuant to the Secure and Fair Enforcement for Mortgage Licensing Act of 2008, title V of the Housing and Economic Recovery Act of 2008 (S.A.F.E. Act) (Pub. L. 110–289, 122 Stat. 2654, 12 U.S.C. 5101 *et seq.*), 12 U.S.C. 248(a), 3106a(1), and 3108(a).

(b) *Purpose.* This subpart implements the S.A.F.E. Act's Federal registration requirement for mortgage loan originators. The S.A.F.E. Act provides that the objectives of this registration include aggregating and improving the flow of information to and between regulators; providing increased accountability and tracking of mortgage loan originators; enhancing consumer protections; supporting anti-fraud measures; and providing consumers

with easily accessible information at no charge regarding the employment history of, and publicly adjudicated disciplinary and enforcement actions against, mortgage loan originators.

(c) *Scope.* (1) *In general.* This subpart applies to member banks of the Federal Reserve System (other than national banks); their respective subsidiaries that are not functionally regulated within the meaning of section 5(c)(5) of the Bank Holding Company Act, as amended (12 U.S.C. 1844(c)(5)); branches and agencies of foreign banks (other than Federal branches, Federal agencies and insured State branches of foreign banks); commercial lending companies owned or controlled by foreign banks (collectively referred to in this subpart as banks); and their employees who act as mortgage loan originators.

(2) *De minimis exception.* (i) This subpart and the requirements of 12 U.S.C. 5103(a)(1)(A) and (2) of the S.A.F.E. Act do not apply to any employee of a bank who has never been registered or licensed through the Registry as a mortgage loan originator if during the past 12 months the employee acted as a mortgage loan originator for 5 or fewer residential mortgage loans.

(ii) Prior to engaging in mortgage loan origination activity that exceeds the exception limit in paragraph (c)(2)(i) of this section, a bank employee must register with the Registry pursuant to this subpart.

(iii) *Evasion.* Banks are prohibited from engaging in any act or practice to evade the limits of the *de minimis* exception set forth in paragraph (c)(2)(i) of this section.

§ 208.102 Definitions.

For purposes of this subpart I, the following definitions apply:

(a) *Annual renewal period* means November 1 through December 31 of each year.

(b)(1) *Mortgage loan originator*[7] means an individual who:

(i) Takes a residential mortgage loan application; and

(ii) Offers or negotiates terms of a residential mortgage loan for compensation or gain.

(2) The term *mortgage loan originator* does not include:

(i) An individual who performs purely administrative or clerical tasks on behalf of an individual who is described in paragraph (b)(1) of this section;

(ii) An individual who only performs real estate brokerage activities (as defined in 12 U.S.C. 5102(3)(D)) and is licensed or registered as a real estate broker in accordance with applicable State law, unless the individual is compensated by a lender, a mortgage broker, or other mortgage loan originator or by any agent of such lender, mortgage broker, or other mortgage loan originator, and meets the definition of mortgage loan originator in paragraph (b)(1) of this section; or

(iii) An individual or entity solely involved in extensions of credit related to timeshare plans, as that term is defined in 11 U.S.C. 101(53D).

(3) *Administrative or clerical tasks* means the receipt, collection, and distribution of information common for the processing or underwriting of a loan in the residential mortgage industry and communication with a consumer to obtain information necessary for the processing or underwriting of a residential mortgage loan.

(c) *Nationwide Mortgage Licensing System and Registry* or *Registry* means the system developed and maintained by the Conference of State Bank Supervisors and the American Association of Residential Mortgage Regulators for the State licensing and registration of State-licensed mortgage loan originators and the registration of mortgage loan originators pursuant to 12 U.S.C. 5107.

(d) *Registered mortgage loan originator* or *registrant* means any individual who:

(1) Meets the definition of mortgage loan originator and is an employee of a bank; and

(2) Is registered pursuant to this subpart with, and maintains a unique identifier through, the Registry.

(e) *Residential mortgage loan* means any loan primarily for personal, family, or household use that is secured by a mortgage, deed of trust, or other equivalent consensual security interest on a dwelling (as defined in section 103(v) of the Truth in Lending Act, 15 U.S.C. 1602(v)) or residential real estate upon which is constructed or intended to be constructed a dwelling, and includes refinancings, reverse mortgages, home equity lines of credit and other first and additional lien loans that meet the qualifications listed in this definition.

(f) *Unique identifier* means a number or other identifier that:

(1) Permanently identifies a registered mortgage loan originator;

(2) Is assigned by protocols established by the Nationwide Mortgage Licensing System and Registry, the Federal banking agencies, and the Farm Credit Administration to facilitate:

(i) Electronic tracking of mortgage loan originators; and

(ii) Uniform identification of, and public access to, the employment history of and the publicly adjudicated disciplinary and enforcement actions against mortgage loan originators; and

(3) Must not be used for purposes other than those set forth under the S.A.F.E. Act.

§ 208.103 Registration of mortgage loan originators.

(a) *Registration requirement*—(1) *Employee registration.* Each employee of a bank who acts as a mortgage loan originator must register with the Registry, obtain a unique identifier, and maintain this registration in accordance with the requirements of this subpart. Any such employee who is not in compliance with the registration and unique identifier requirements set forth in this subpart is in violation of the S.A.F.E. Act and this subpart.

(2) *Bank requirement*—(i) *In general.* A bank that employs one or more individuals who act as a residential mortgage loan originator must require each such employee to register with the Registry, maintain this registration, and obtain a unique identifier in accordance with the requirements of this subpart.

(ii) *Prohibition.* A bank must not permit an employee of the bank who is subject to the registration requirements of this subpart to act as a mortgage loan originator for the bank unless such employee is registered with the Registry pursuant to this subpart.

(3) *Implementation period for initial registration.* An employee of a bank who is a mortgage loan originator must complete an initial registration with the Registry pursuant to this subpart within 180 days from the date that the Board provides in a public notice that the Registry is accepting registrations.

(4) *Employees previously registered or licensed through the Registry*—(i) *In general.* If an employee of a bank was registered or licensed through, and obtained a unique identifier from, the Registry and has maintained this registration or license before the employee becomes subject to this subpart at this bank, then the registration requirements of the S.A.F.E. Act and this subpart are deemed to be met, provided that:

(A) The employment information in paragraphs (d)(1)(i)(C) and (d)(1)(ii) of this section is updated and the requirements of paragraph (d)(2) of this section are met;

(B) New fingerprints of the employee are submitted to the Registry for a background check, as required by paragraph (d)(1)(ix) of this section,

[7] Appendix A of this subpart provides examples of activities that would, and would not, cause an employee to fall within this definition of mortgage loan originator.

unless the employee has fingerprints on file with the Registry that are less than 3 years old;

(C) The bank information required in paragraphs (e)(1)(i) (to the extent the bank has not previously met these requirements) and (e)(2)(i) of this section is submitted to the Registry; and

(D) The registration is maintained pursuant to paragraphs (b) and (e)(1)(ii) of this section, as of the date that the employee becomes subject to this subpart.

(ii) *Rule for certain acquisitions, mergers, or reorganizations.* When registered or licensed mortgage loan originators become bank employees as a result of an acquisition, merger, or reorganization, only the requirements of paragraphs (a)(4)(i)(A), (C), and (D) of this section must be met, and these requirements must be met within 60 days from the effective date of the acquisition, merger, or reorganization.

(b) *Maintaining registration.* (1) A mortgage loan originator who is registered with the Registry pursuant to paragraph (a) of this section must:

(i) Except as provided in paragraph (b)(3) of this section, renew the registration during the annual renewal period, confirming the responses set forth in paragraphs (d)(1)(i) through (viii) of this section remain accurate and complete, and updating this information, as appropriate; and

(ii) Update the registration within 30 days of any of the following events:

(A) A change in the name of the registrant;

(B) The registrant ceases to be an employee of the bank; or

(C) The information required under paragraphs (d)(1)(iii) through (viii) of this section becomes inaccurate, incomplete, or out-of-date.

(2) A registered mortgage loan originator must maintain his or her registration, unless the individual is no longer engaged in the activity of a mortgage loan originator.

(3) The annual registration renewal requirement set forth in paragraph (b)(1) of this section does not apply to a registered mortgage loan originator who has completed his or her registration with the Registry pursuant to paragraph (a)(1) of this section less than 6 months prior to the end of the annual renewal period.

(c) *Effective dates*—(1) *Registration.* A registration pursuant to paragraph (a)(1) of this section is effective on the date the Registry transmits notification to the registrant that the registrant is registered.

(2) *Renewals or updates.* A renewal or update pursuant to paragraph (b) of this section is effective on the date the Registry transmits notification to the registrant that the registration has been renewed or updated.

(d) *Required employee information*—(1) *In general.* For purposes of the registration required by this section, a bank must require each employee who is a mortgage loan originator to submit to the Registry, or must submit on behalf of the employee, the following categories of information, to the extent this information is collected by the Registry:

(i) Identifying information, including the employee's:

(A) Name and any other names used;

(B) Home address and contact information;

(C) Principal business location address and business contact information;

(D) Social security number;

(E) Gender; and

(F) Date and place of birth;

(ii) Financial services-related employment history for the 10 years prior to the date of registration or renewal, including the date the employee became an employee of the bank;

(iii) Convictions of any criminal offense involving dishonesty, breach of trust, or money laundering against the employee or organizations controlled by the employee, or agreements to enter into a pretrial diversion or similar program in connection with the prosecution for such offense(s);

(iv) Civil judicial actions against the employee in connection with financial services-related activities, dismissals with settlements, or judicial findings that the employee violated financial services-related statutes or regulations, except for actions dismissed without a settlement agreement;

(v) Actions or orders by a State or Federal regulatory agency or foreign financial regulatory authority that:

(A) Found the employee to have made a false statement or omission or been dishonest, unfair or unethical; to have been involved in a violation of a financial services-related regulation or statute; or to have been a cause of a financial services-related business having its authorization to do business denied, suspended, revoked, or restricted;

(B) Are entered against the employee in connection with a financial services-related activity;

(C) Denied, suspended, or revoked the employee's registration or license to engage in a financial services-related activity; disciplined the employee or otherwise by order prevented the employee from associating with a financial services-related business or restricted the employee's activities; or

(D) Barred the employee from association with an entity or its officers regulated by the agency or authority or from engaging in a financial services-related business;

(vi) Final orders issued by a State or Federal regulatory agency or foreign financial regulatory authority based on violations of any law or regulation that prohibits fraudulent, manipulative, or deceptive conduct;

(vii) Revocation or suspension of the employee's authorization to act as an attorney, accountant, or State or Federal contractor;

(viii) Customer-initiated financial services-related arbitration or civil action against the employee that required action, including settlements, or which resulted in a judgment; and

(ix) Fingerprints of the employee, in digital form if practicable, and any appropriate identifying information for submission to the Federal Bureau of Investigation and any governmental agency or entity authorized to receive such information in connection with a State and national criminal history background check; however, fingerprints provided to the Registry that are less than 3 years old may be used to satisfy this requirement.

(2) *Employee authorizations and attestation.* An employee registering as a mortgage loan originator or renewing or updating his or her registration under this subpart, and not the employing bank or other employees of the bank, must:

(i) Authorize the Registry and the employing institution to obtain information related to sanctions or findings in any administrative, civil, or criminal action, to which the employee is a party, made by any governmental jurisdiction;

(ii) Attest to the correctness of all information required by paragraph (d) of this section, whether submitted by the employee or on behalf of the employee by the employing bank; and

(iii) Authorize the Registry to make available to the public information required by paragraphs (d)(1)(i)(A) and (C), and (d)(1)(ii) through (viii) of this section.

(3) *Submission of information.* A bank may identify one or more employees of the bank who may submit the information required by paragraph (d)(1) of this section to the Registry on behalf of the bank's employees provided that this individual, and any employee delegated such authority, does not act as a mortgage loan originator, consistent with paragraph (e)(1)(i)(F) of this section. In addition, a bank may submit

to the Registry some or all of the information required by paragraphs (d)(1) and (e)(2) of this section for multiple employees in bulk through batch processing in a format to be specified by the Registry, to the extent such batch processing is made available by the Registry.

(e) *Required bank information.* A bank must submit the following categories of information to the Registry:

(1) *Bank record.* (i) In connection with the registration of one or more mortgage loan originators:

(A) Name, main office address, and business contact information;

(B) Internal Revenue Service Employer Tax Identification Number (EIN);

(C) Research Statistics Supervision and Discount (RSSD) number, as issued by the Board of Governors of the Federal Reserve System;

(D) Identification of its primary Federal regulator;

(E) Name(s) and contact information of the individual(s) with authority to act as the bank's primary point of contact for the Registry;

(F) Name(s) and contact information of the individual(s) with authority to enter the information required by paragraphs (d)(1) and (e) of this section to the Registry and who may delegate this authority to other individuals. For the purpose of providing information required by paragraph (e) of this section, this individual and their delegates must not act as mortgage loan originators unless the bank has 10 or fewer full time or equivalent employees and is not a subsidiary; and

(G) If a subsidiary of a bank, indication that it is a subsidiary and the RSSD number of the parent bank.

(ii) *Attestation.* The individual(s) identified in paragraphs (e)(1)(i)(E) and (F) of this section must comply with Registry protocols to verify their identity and must attest that they have the authority to enter data on behalf of the bank, that the information provided to the Registry pursuant to this paragraph (e) is correct, and that the bank will keep the information required by this paragraph (e) current and will file accurate supplementary information on a timely basis.

(iii) A bank must update the information required by this paragraph (e) of this section within 30 days of the date that this information becomes inaccurate.

(iv) A bank must renew the information required by paragraph (e) of this section on an annual basis.

(2) *Employee information.* In connection with the registration of each employee who acts as a mortgage loan originator:

(i) After the information required by paragraph (d) of this section has been submitted to the Registry, confirmation that it employs the registrant; and

(ii) Within 30 days of the date the registrant ceases to be an employee of the bank, notification that it no longer employs the registrant and the date the registrant ceased being an employee.

§ 208.104 Policies and procedures.

A bank that employs one or more mortgage loan originators must adopt and follow written policies and procedures designed to assure compliance with this subpart. These policies and procedures must be appropriate to the nature, size, complexity, and scope of the mortgage lending activities of the bank, and apply only to those employees acting within the scope of their employment at the bank. At a minimum, these policies and procedures must:

(a) Establish a process for identifying which employees of the bank are required to be registered mortgage loan originators;

(b) Require that all employees of the bank who are mortgage loan originators be informed of the registration requirements of the S.A.F.E. Act and this subpart and be instructed on how to comply with such requirements and procedures;

(c) Establish procedures to comply with the unique identifier requirements in § 208.105;

(d) Establish reasonable procedures for confirming the adequacy and accuracy of employee registrations, including updates and renewals, by comparisons with its own records;

(e) Establish reasonable procedures and tracking systems for monitoring compliance with registration and renewal requirements and procedures;

(f) Provide for independent testing for compliance with this subpart to be conducted at least annually by bank personnel or by an outside party;

(g) Provide for appropriate action in the case of any employee who fails to comply with the registration requirements of the S.A.F.E. Act, this subpart, or the bank's related policies and procedures, including prohibiting such employees from acting as mortgage loan originators or other appropriate disciplinary actions;

(h) Establish a process for reviewing employee criminal history background reports received pursuant to this subpart, taking appropriate action consistent with applicable Federal law, including section 19 of the Federal Deposit Insurance Act (12 U.S.C. 1829) and implementing regulations with respect to these reports, and maintaining records of these reports and actions taken with respect to applicable employees; and

(i) Establish procedures designed to ensure that any third party with which the bank has arrangements related to mortgage loan origination has policies and procedures to comply with the S.A.F.E. Act, including appropriate licensing and/or registration of individuals acting as mortgage loan originators.

§ 208.105 Use of unique identifier.

(a) The bank shall make the unique identifier(s) of its registered mortgage loan originator(s) available to consumers in a manner and method practicable to the institution.

(b) A registered mortgage loan originator shall provide his or her unique identifier to a consumer:

(1) Upon request;

(2) Before acting as a mortgage loan originator; and

(3) Through the originator's initial written communication with a consumer, if any, whether on paper or electronically.

Appendix A to Subpart I of Part 208—Examples of Mortgage Loan Originator Activities

This Appendix provides examples to aid in the understanding of activities that would cause an employee of a bank to fall within or outside the definition of mortgage loan originator. The examples in this Appendix are not all inclusive. They illustrate only the issue described and do not illustrate any other issues that may arise under this subpart. For purposes of the examples below, the term "loan" refers to a residential mortgage loan.

(a) *Taking a loan application.* The following examples illustrate when an employee takes, or does not take, a loan application.

(1) Taking an application includes: receiving information provided in connection with a request for a loan to be used to determine whether the consumer qualifies for a loan, even if the employee:

(i) Has received the consumer's information indirectly in order to make an offer or negotiate a loan;

(ii) Is not responsible for verifying information;

(iii) Is inputting information into an online application or other automated system on behalf of the consumer; or

(iv) Is not engaged in approval of the loan, including determining whether the consumer qualifies for the loan.

(2) Taking an application does not include any of the following activities performed solely or in combination:

(i) Contacting a consumer to verify the information in the loan application by obtaining documentation, such as tax returns or payroll receipts;

(ii) Receiving a loan application through the mail and forwarding it, without review, to loan approval personnel;

(iii) Assisting a consumer who is filling out an application by clarifying what type of information is necessary for the application or otherwise explaining the qualifications or criteria necessary to obtain a loan product;

(iv) Describing the steps that a consumer would need to take to provide information to be used to determine whether the consumer qualifies for a loan or otherwise explaining the loan application process;

(v) In response to an inquiry regarding a prequalified offer that a consumer has received from a bank, collecting only basic identifying information about the consumer and forwarding the consumer to a mortgage loan originator; or

(vi) Receiving information in connection with a modification to the terms of an existing loan to a borrower as part of the bank's loss mitigation efforts when the borrower is reasonably likely to default.

(b) *Offering or negotiating terms of a loan.* The following examples are designed to illustrate when an employee offers or negotiates terms of a loan, and conversely, what does not constitute offering or negotiating terms of a loan.

(1) Offering or negotiating the terms of a loan includes:

(i) Presenting a loan offer to a consumer for acceptance, either verbally or in writing, including, but not limited to, providing a disclosure of the loan terms after application under the Truth in Lending Act, even if:

(A) Further verification of information is necessary;

(B) The offer is conditional;

(C) Other individuals must complete the loan process; or

(D) Only the rate approved by the bank's loan approval mechanism function for a specific loan product is communicated without authority to negotiate the rate.

(ii) Responding to a consumer's request for a lower rate or lower points on a pending loan application by presenting to the consumer a revised loan offer, either verbally or in writing, that includes a lower interest rate or lower points than the original offer.

(2) Offering or negotiating terms of a loan does not include solely or in combination:

(i) Providing general explanations or descriptions in response to consumer queries regarding qualification for a specific loan product, such as explaining loan terminology (*i.e.,* debt-to-income ratio); lending policies (*i.e.,* the loan-to-value ratio policy of the bank); or product-related services;

(ii) In response to a consumer's request, informing a consumer of the loan rates that are publicly available, such as on the bank's Web site, for specific types of loan products without communicating to the consumer whether qualifications are met for that loan product;

(iii) Collecting information about a consumer in order to provide the consumer with information on loan products for which the consumer generally may qualify, without presenting a specific loan offer to the consumer for acceptance, either verbally or in writing;

(iv) Arranging the loan closing or other aspects of the loan process, including communicating with a consumer about those arrangements, provided that communication with the consumer only verifies loan terms already offered or negotiated;

(v) Providing a consumer with information unrelated to loan terms, such as the best days of the month for scheduling loan closings at the bank;

(vi) Making an underwriting decision about whether the consumer qualifies for a loan;

(vii) Explaining or describing the steps or process that a consumer would need to take in order to obtain a loan offer, including qualifications or criteria that would need to be met without providing guidance specific to that consumer's circumstances; or

(viii) Communicating on behalf of a mortgage loan originator that a written offer, including disclosures provided pursuant to the Truth in Lending Act, has been sent to a consumer without providing any details of that offer.

(c) *Offering or negotiating a loan for compensation or gain.* The following examples illustrate when an employee does or does not offer or negotiate terms of a loan "for compensation or gain."

(1) Offering or negotiating terms of a loan for compensation or gain includes engaging in any of the activities in paragraph (b)(1) of this Appendix in the course of carrying out employment duties, even if the employee does not receive a referral fee or commission or other special compensation for the loan.

(2) Offering or negotiating terms of a loan for compensation or gain does not include engaging in a seller-financed transaction for the employee's personal property that does not involve the bank.

■ 4. Newly designated § 208.111 is amended by redesignating footnotes 7 and 8 as footnotes 8 and 9, respectively, and by revising newly designated footnote 9 to read as follows:

§ 208.111 Obligations concerning institutional customers.

* * * * *

[9] *See* footnote 8 in paragraph (d) of this section.

PART 211—INTERNATIONAL BANKING OPERATIONS (REGULATION K)

■ 5. The authority citation for part 211 is revised to read as follows:

Authority: 12 U.S.C. 221 *et seq.,* 1818, 1835a, 1841 *et seq.,* 3101 *et seq.,* 3901 *et seq.,* and 5101 *et seq.;* 15 U.S.C. 1681s, 1681w, 6801 and 6805.

■ 6. Section 211.24 is amended by adding new paragraph (k) to read as follows:

§ 211.24 Approval of offices of foreign banks; procedures for applications; standards for approval; representative office activities and standards for approval; preservation of existing authority.

* * * * *

(k) *Registration of residential mortgage loan originators.* An uninsured State-licensed branch or agency of a foreign bank or commercial lending company owned or controlled by a foreign bank and any residential mortgage loan originator that it employs are subject to the requirements, including registration requirements, as applicable, of the Secure and Fair Enforcement for Mortgage Licensing Act (12 U.S.C. 5101 *et seq.*) and the Board's implementing regulation set forth in Regulation H at subpart I of part 208 of this chapter.

Federal Deposit Insurance Corporation

12 CFR Chapter III

Authority and Issuance

■ For the reasons set forth in the preamble, the Federal Deposit Insurance Corporation amends part 365 of chapter III of title 12 of the Code of Federal Regulations as follows:

PART 365—REAL ESTATE LENDING STANDARDS

■ 1. The authority citation for part 365 is revised to read as follows:

Authority: 12 U.S.C. 1828(o) and 5101 *et seq.*

■ 2. Sections 365.1 and 365.2 and Appendix A are placed under a new subpart A, and the heading for new subpart A is added to read as follows:

Subpart A—Real Estate Lending Standards

■ 3. Section 365.1 is amended by removing "part" and adding "subpart" in its place.

■ 4. Appendix A to Part 365 is redesignated as Appendix A to Subpart A of Part 365, and the heading is revised to read as follows:

Appendix A to Subpart A of Part 365—Interagency Guidelines for Real Estate Lending Policies

■ 5. New subpart B is added to read as follows:

Subpart B—Registration of Residential Mortgage Loan Originators

Sec.

365.101 Authority, purpose, and scope.
365.102 Definitions.
365.103 Registration of mortgage loan originators.
365.104 Policies and procedures.
365.105 Use of unique identifier.
Appendix A to Subpart B of Part 365—Examples of Mortgage Loan Originator Activities

Subpart B—Registration of Residential Mortgage Loan Originators

§ 365.101 Authority, purpose, and scope.

(a) *Authority.* This subpart is issued pursuant to the Secure and Fair Enforcement for Mortgage Licensing Act of 2008, title V of the Housing and Economic Recovery Act of 2008 (S.A.F.E. Act) (Pub. L. 110–289, 122 Stat. 2654, 12 U.S.C. 5101 *et seq.*).

(b) *Purpose.* This subpart implements the S.A.F.E. Act's Federal registration requirement for mortgage loan originators. The S.A.F.E. Act provides that the objectives of this registration include aggregating and improving the flow of information to and between regulators; providing increased accountability and tracking of mortgage loan originators; enhancing consumer protections; supporting anti-fraud measures; and providing consumers with easily accessible information at no charge regarding the employment history of, and publicly adjudicated disciplinary and enforcement actions against, mortgage loan originators.

(c) *Scope*—(1) *In general.* This subpart applies to insured State nonmember banks (including State-licensed insured branches of foreign banks), their subsidiaries (except brokers, dealers, persons providing insurance, investment companies, and investment advisers) (collectively referred to in this subpart as insured State nonmember banks), and employees of such banks or subsidiaries who act as mortgage loan originators.

(2) *De minimis exception.* (i) This subpart and the requirements of 12 U.S.C. 5103(a)(1)(A) and (2) of the S.A.F.E. Act do not apply to any employee of an insured State nonmember bank who has never been registered or licensed through the Registry as a mortgage loan originator if during the past 12 months the employee acted as a mortgage loan originator for 5 or fewer residential mortgage loans.

(ii) Prior to engaging in mortgage loan origination activity that exceeds the exception limit in paragraph (c)(2)(i) of this section, an insured State nonmember bank employee must register with the Registry pursuant to this subpart.

(iii) *Evasion.* Insured State nonmember banks are prohibited from engaging in any act or practice to evade the limits of the *de minimis* exception set forth in paragraph (c)(2)(i) of this section.

§ 365.102 Definitions.

For purposes of this subpart, the following definitions apply:

(a) *Annual renewal period* means November 1 through December 31 of each year.

(b)(1) *Mortgage loan originator* [1] means an individual who:

(i) Takes a residential mortgage loan application; and

(ii) Offers or negotiates terms of a residential mortgage loan for compensation or gain.

(2) The term *mortgage loan originator* does not include:

(i) An individual who performs purely administrative or clerical tasks on behalf of an individual who is described in paragraph (b)(1) of this section;

(ii) An individual who only performs real estate brokerage activities (as defined in 12 U.S.C. 5102(3)(D)) and is licensed or registered as a real estate broker in accordance with applicable State law, unless the individual is compensated by a lender, a mortgage broker, or other mortgage loan originator or by any agent of such lender, mortgage broker, or other mortgage loan originator, and meets the definition of mortgage loan originator in paragraph (b)(1) of this section; or

(iii) An individual or entity solely involved in extensions of credit related to timeshare plans, as that term is defined in 11 U.S.C. 101(53D).

(3) *Administrative or clerical tasks* means the receipt, collection, and distribution of information common for the processing or underwriting of a loan in the residential mortgage industry and communication with a consumer to obtain information necessary for the processing or underwriting of a residential mortgage loan.

(c) *Nationwide Mortgage Licensing System and Registry* or *Registry* means the system developed and maintained by the Conference of State Bank Supervisors and the American Association of Residential Mortgage Regulators for the State licensing and registration of State-licensed mortgage loan originators and the registration of mortgage loan originators pursuant to 12 U.S.C. 5107.

(d) *Registered mortgage loan originator* or *registrant* means any individual who:

(1) Meets the definition of mortgage loan originator and is an employee of an insured State nonmember bank; and

(2) Is registered pursuant to this subpart with, and maintains a unique identifier through, the Registry.

(e) *Residential mortgage loan* means any loan primarily for personal, family, or household use that is secured by a mortgage, deed of trust, or other equivalent consensual security interest on a dwelling (as defined in section 103(v) of the Truth in Lending Act, 15 U.S.C. 1602(v)) or residential real estate upon which is constructed or intended to be constructed a dwelling, and includes refinancings, reverse mortgages, home equity lines of credit and other first and additional lien loans that meet the qualifications listed in this definition.

(f) *Unique identifier* means a number or other identifier that:

(1) Permanently identifies a registered mortgage loan originator;

(2) Is assigned by protocols established by the Nationwide Mortgage Licensing System and Registry, the Federal banking agencies, and the Farm Credit Administration to facilitate:

(i) Electronic tracking of mortgage loan originators; and

(ii) Uniform identification of, and public access to, the employment history of and the publicly adjudicated disciplinary and enforcement actions against mortgage loan originators; and

(3) Must not be used for purposes other than those set forth under the S.A.F.E. Act.

§ 365.103 Registration of mortgage loan originators.

(a) *Registration requirement*—(1) *Employee registration.* Each employee of an insured State nonmember bank who acts as a mortgage loan originator must register with the Registry, obtain a unique identifier, and maintain this registration in accordance with the requirements of this subpart. Any such employee who is not in compliance with the registration and unique identifier requirements set forth in this subpart is in violation of the S.A.F.E. Act and this subpart.

(2) *Insured State nonmember bank requirement*—(i) *In general.* An insured State nonmember bank that employs one or more individuals who act as a residential mortgage loan originator must require each such employee to register with the Registry, maintain this registration, and obtain a unique identifier in accordance with the requirements of this subpart.

(ii) *Prohibition.* An insured State nonmember bank must not permit an employee of the bank who is subject to the registration requirements of this subpart to act as a mortgage loan originator for the bank unless such employee is registered with the Registry pursuant to this subpart.

(3) *Implementation period for initial registration.* An employee of an insured State nonmember bank who is a

[1] Appendix A of this subpart provides examples of activities that would, and would not, cause an employee to fall within this definition of mortgage loan originator.

mortgage loan originator must complete an initial registration with the Registry pursuant to this subpart within 180 days from the date that the FDIC provides in a public notice that the Registry is accepting registrations.

(4) *Employees previously registered or licensed through the Registry*—(i) *In general.* If an employee of an insured State nonmember bank was registered or licensed through, and obtained a unique identifier from, the Registry and has maintained this registration or license before the employee becomes subject to this subpart at this bank, then the registration requirements of the S.A.F.E. Act and this subpart are deemed to be met, provided that:

(A) The employment information in paragraphs (d)(1)(i)(C) and (d)(1)(ii) of this section is updated and the requirements of paragraph (d)(2) of this section are met;

(B) New fingerprints of the employee are submitted to the Registry for a background check, as required by paragraph (d)(1)(ix) of this section, unless the employee has fingerprints on file with the Registry that are less than 3 years old;

(C) The insured State nonmember bank information required in paragraphs (e)(1)(i) (to the extent the bank has not previously met these requirements) and (e)(2)(i) of this section is submitted to the Registry; and

(D) The registration is maintained pursuant to paragraphs (b) and (e)(1)(ii) of this section, as of the date that the employee becomes subject to this subpart.

(ii) *Rule for certain acquisitions, mergers, or reorganizations.* When registered or licensed mortgage loan originators become insured State nonmember bank employees as a result of an acquisition, merger, or reorganization, only the requirements of paragraphs (a)(4)(i)(A), (C), and (D) of this section must be met, and these requirements must be met within 60 days from the effective date of the acquisition, merger, or reorganization.

(b) *Maintaining registration.* (1) A mortgage loan originator who is registered with the Registry pursuant to paragraph (a) of this section must:

(i) Except as provided in paragraph (b)(3) of this section, renew the registration during the annual renewal period, confirming the responses set forth in paragraphs (d)(1)(i) through (viii) of this section remain accurate and complete, and updating this information, as appropriate; and

(ii) Update the registration within 30 days of any of the following events:

(A) A change in the name of the registrant;

(B) The registrant ceases to be an employee of the insured State nonmember bank; or

(C) The information required under paragraphs (d)(1)(iii) through (viii) of this section becomes inaccurate, incomplete, or out-of-date.

(2) A registered mortgage loan originator must maintain his or her registration, unless the individual is no longer engaged in the activity of a mortgage loan originator.

(3) The annual registration renewal requirement set forth in paragraph (b)(1) of this section does not apply to a registered mortgage loan originator who has completed his or her registration with the Registry pursuant to paragraph (a)(1) of this section less than 6 months prior to the end of the annual renewal period.

(c) *Effective dates*—(1) *Registration.* A registration pursuant to paragraph (a)(1) of this section is effective on the date the Registry transmits notification to the registrant that the registrant is registered.

(2) *Renewals or updates.* A renewal or update pursuant to paragraph (b) of this section is effective on the date the Registry transmits notification to the registrant that the registration has been renewed or updated.

(d) *Required employee information*—(1) *In general.* For purposes of the registration required by this section, an insured State nonmember bank must require each employee who is a mortgage loan originator to submit to the Registry, or must submit on behalf of the employee, the following categories of information to the extent this information is collected by the Registry:

(i) Identifying information, including the employee's:

(A) Name and any other names used;

(B) Home address and contact information;

(C) Principal business location address and business contact information;

(D) Social security number;

(E) Gender; and

(F) Date and place of birth;

(ii) Financial services-related employment history for the 10 years prior to the date of registration or renewal, including the date the employee became an employee of the bank;

(iii) Convictions of any criminal offense involving dishonesty, breach of trust, or money laundering against the employee or organizations controlled by the employee, or agreements to enter into a pretrial diversion or similar program in connection with the prosecution for such offense(s);

(iv) Civil judicial actions against the employee in connection with financial services-related activities, dismissals with settlements, or judicial findings that the employee violated financial services-related statutes or regulations, except for actions dismissed without a settlement agreement;

(v) Actions or orders by a State or Federal regulatory agency or foreign financial regulatory authority that:

(A) Found the employee to have made a false statement or omission or been dishonest, unfair or unethical; to have been involved in a violation of a financial services-related regulation or statute; or to have been a cause of a financial services-related business having its authorization to do business denied, suspended, revoked, or restricted;

(B) Are entered against the employee in connection with a financial services-related activity;

(C) Denied, suspended, or revoked the employee's registration or license to engage in a financial services-related activity; disciplined the employee or otherwise by order prevented the employee from associating with a financial services-related business or restricted the employee's activities; or

(D) Barred the employee from association with an entity or its officers regulated by the agency or authority or from engaging in a financial services-related business;

(vi) Final orders issued by a State or Federal regulatory agency or foreign financial regulatory authority based on violations of any law or regulation that prohibits fraudulent, manipulative, or deceptive conduct;

(vii) Revocation or suspension of the employee's authorization to act as an attorney, accountant, or State or Federal contractor;

(viii) Customer-initiated financial services-related arbitration or civil action against the employee that required action, including settlements, or which resulted in a judgment; and

(ix) Fingerprints of the employee, in digital form if practicable, and any appropriate identifying information for submission to the Federal Bureau of Investigation and any governmental agency or entity authorized to receive such information in connection with a State and national criminal history background check; however, fingerprints provided to the Registry that are less than 3 years old may be used to satisfy this requirement.

(2) *Employee authorizations and attestation.* An employee registering as a mortgage loan originator or renewing or updating his or her registration under this subpart, and not the employing

insured State nonmember bank or other employees of the insured State nonmember bank, must:

(i) Authorize the Registry and the employing institution to obtain information related to sanctions or findings in any administrative, civil, or criminal action, to which the employee is a party, made by any governmental jurisdiction;

(ii) Attest to the correctness of all information required by paragraph (d) of this section, whether submitted by the employee or on behalf of the employee by the employing bank; and

(iii) Authorize the Registry to make available to the public information required by paragraphs (d)(1)(i)(A) and (C), and (d)(1)(ii) through (viii) of this section.

(3) *Submission of information.* An insured State nonmember bank may identify one or more employees of the bank who may submit the information required by paragraph (d)(1) of this section to the Registry on behalf of the bank's employees provided that this individual, and any employee delegated such authority, does not act as a mortgage loan originator, consistent with paragraph (e)(1)(i)(F) of this section. In addition, an insured State nonmember bank may submit to the Registry some or all of the information required by paragraphs (d)(1) and (e)(2) of this section for multiple employees in bulk through batch processing in a format to be specified by the Registry, to the extent such batch processing is made available by the Registry.

(e) *Required bank information.* An insured State nonmember bank must submit the following categories of information to the Registry:

(1) *Bank record.* (i) In connection with the registration of one or more mortgage loan originators:

(A) Name, main office address, and business contact information;

(B) Internal Revenue Service Employer Tax Identification Number (EIN);

(C) Research Statistics Supervision and Discount (RSSD) number, as issued by the Board of Governors of the Federal Reserve System;

(D) Identification of its primary Federal regulator;

(E) Name(s) and contact information of the individual(s) with authority to act as the bank's primary point of contact for the Registry;

(F) Name(s) and contact information of the individual(s) with authority to enter the information required by paragraphs (d)(1) and (e) of this section to the Registry and who may delegate this authority to other individuals. For the purpose of providing information required by paragraph (e) of this section, this individual and their delegates must not act as mortgage loan originators unless the bank has 10 or fewer full time or equivalent employees and is not a subsidiary; and

(G) If a subsidiary of an insured State nonmember bank, indication that it is a subsidiary and the RSSD number of the parent bank.

(ii) *Attestation.* The individual(s) identified in paragraphs (e)(1)(i)(E) and (F) of this section must comply with Registry protocols to verify their identity and must attest that they have the authority to enter data on behalf of the insured State nonmember bank, that the information provided to the Registry pursuant to this paragraph (e) is correct, and that the insured State nonmember bank will keep the information required by this paragraph (e) current and will file accurate supplementary information on a timely basis.

(iii) An insured State nonmember bank must update the information required by this paragraph (e) of this section within 30 days of the date that this information becomes inaccurate.

(iv) An insured State nonmember bank must renew the information required by paragraph (e) of this section on an annual basis.

(2) *Employee information.* In connection with the registration of each employee who acts as a mortgage loan originator:

(i) After the information required by paragraph (d) of this section has been submitted to the Registry, confirmation that it employs the registrant; and

(ii) Within 30 days of the date the registrant ceases to be an employee of the bank, notification that it no longer employs the registrant and the date the registrant ceased being an employee.

§ 365.104 Policies and procedures.

An insured State nonmember bank that employs one or more mortgage loan originators must adopt and follow written policies and procedures designed to assure compliance with this subpart. These policies and procedures must be appropriate to the nature, size, complexity, and scope of the mortgage lending activities of the bank, and apply only to those employees acting within the scope of their employment at the bank. At a minimum, these policies and procedures must:

(a) Establish a process for identifying which employees of the bank are required to be registered mortgage loan originators;

(b) Require that all employees of the insured State nonmember bank who are mortgage loan originators be informed of the registration requirements of the S.A.F.E. Act and this subpart and be instructed on how to comply with such requirements and procedures;

(c) Establish procedures to comply with the unique identifier requirements in § 365.105;

(d) Establish reasonable procedures for confirming the adequacy and accuracy of employee registrations, including updates and renewals, by comparisons with its own records;

(e) Establish reasonable procedures and tracking systems for monitoring compliance with registration and renewal requirements and procedures;

(f) Provide for independent testing for compliance with this subpart to be conducted at least annually by bank personnel or by an outside party;

(g) Provide for appropriate action in the case of any employee who fails to comply with the registration requirements of the S.A.F.E. Act, this subpart, or the bank's related policies and procedures, including prohibiting such employees from acting as mortgage loan originators or other appropriate disciplinary actions;

(h) Establish a process for reviewing employee criminal history background reports received pursuant to this subpart, taking appropriate action consistent with applicable Federal law, including section 19 of the Federal Deposit Insurance Act (12 U.S.C. 1829) and implementing regulations with respect to these reports, and maintaining records of these reports and actions taken with respect to applicable employees; and

(i) Establish procedures designed to ensure that any third party with which the bank has arrangements related to mortgage loan origination has policies and procedures to comply with the S.A.F.E. Act, including appropriate licensing and/or registration of individuals acting as mortgage loan originators.

§ 365.105 Use of unique identifier.

(a) The insured State nonmember bank shall make the unique identifier(s) of its registered mortgage loan originator(s) available to consumers in a manner and method practicable to the institution.

(b) A registered mortgage loan originator shall provide his or her unique identifier to a consumer:

(1) Upon request;

(2) Before acting as a mortgage loan originator; and

(3) Through the originator's initial written communication with a consumer, if any, whether on paper or electronically.

Appendix A to Subpart B of Part 365—Examples of Mortgage Loan Originator Activities

This Appendix provides examples to aid in the understanding of activities that would cause an employee of an insured State nonmember bank to fall within or outside the definition of mortgage loan originator. The examples in this Appendix are not all inclusive. They illustrate only the issue described and do not illustrate any other issues that may arise under this subpart. For purposes of the examples below, the term "loan" refers to a residential mortgage loan.

(a) *Taking a loan application.* The following examples illustrate when an employee takes, or does not take, a loan application.

(1) Taking an application includes: receiving information provided in connection with a request for a loan to be used to determine whether the consumer qualifies for a loan, even if the employee:

(i) Has received the consumer's information indirectly in order to make an offer or negotiate a loan;

(ii) Is not responsible for verifying information;

(iii) Is inputting information into an online application or other automated system on behalf of the consumer; or

(iv) Is not engaged in approval of the loan, including determining whether the consumer qualifies for the loan.

(2) Taking an application does not include any of the following activities performed solely or in combination:

(i) Contacting a consumer to verify the information in the loan application by obtaining documentation, such as tax returns or payroll receipts;

(ii) Receiving a loan application through the mail and forwarding it, without review, to loan approval personnel;

(iii) Assisting a consumer who is filling out an application by clarifying what type of information is necessary for the application or otherwise explaining the qualifications or criteria necessary to obtain a loan product;

(iv) Describing the steps that a consumer would need to take to provide information to be used to determine whether the consumer qualifies for a loan or otherwise explaining the loan application process;

(v) In response to an inquiry regarding a prequalified offer that a consumer has received from a bank, collecting only basic identifying information about the consumer and forwarding the consumer to a mortgage loan originator; or

(vi) Receiving information in connection with a modification to the terms of an existing loan to a borrower as part of the bank's loss mitigation efforts when the borrower is reasonably likely to default.

(b) *Offering or negotiating terms of a loan.* The following examples are designed to illustrate when an employee offers or negotiates terms of a loan, and conversely, what does not constitute offering or negotiating terms of a loan.

(1) Offering or negotiating the terms of a loan includes:

(i) Presenting a loan offer to a consumer for acceptance, either verbally or in writing, including, but not limited to, providing a disclosure of the loan terms after application under the Truth in Lending Act, even if:

(A) Further verification of information is necessary;

(B) The offer is conditional;

(C) Other individuals must complete the loan process; or

(D) Only the rate approved by the bank's loan approval mechanism function for a specific loan product is communicated without authority to negotiate the rate.

(ii) Responding to a consumer's request for a lower rate or lower points on a pending loan application by presenting to the consumer a revised loan offer, either verbally or in writing, that includes a lower interest rate or lower points than the original offer.

(2) Offering or negotiating terms of a loan does not include solely or in combination:

(i) Providing general explanations or descriptions in response to consumer queries regarding qualification for a specific loan product, such as explaining loan terminology (*i.e.,* debt-to-income ratio); lending policies (*i.e.,* the loan-to-value ratio policy of the insured State nonmember bank); or product-related services;

(ii) In response to a consumer's request, informing a consumer of the loan rates that are publicly available, such as on the insured State nonmember bank's Web site, for specific types of loan products without communicating to the consumer whether qualifications are met for that loan product;

(iii) Collecting information about a consumer in order to provide the consumer with information on loan products for which the consumer generally may qualify, without presenting a specific loan offer to the consumer for acceptance, either verbally or in writing;

(iv) Arranging the loan closing or other aspects of the loan process, including communicating with a consumer about those arrangements, provided that communication with the consumer only verifies loan terms already offered or negotiated;

(v) Providing a consumer with information unrelated to loan terms, such as the best days of the month for scheduling loan closings at the bank;

(vi) Making an underwriting decision about whether the consumer qualifies for a loan;

(vii) Explaining or describing the steps or process that a consumer would need to take in order to obtain a loan offer, including qualifications or criteria that would need to be met without providing guidance specific to that consumer's circumstances; or

(viii) Communicating on behalf of a mortgage loan originator that a written offer, including disclosures provided pursuant to the Truth in Lending Act, has been sent to a consumer without providing any details of that offer.

(c) *Offering or negotiating a loan for compensation or gain.* The following examples illustrate when an employee does or does not offer or negotiate terms of a loan "for compensation or gain."

(1) Offering or negotiating terms of a loan for compensation or gain includes engaging in any of the activities in paragraph (b)(1) of this Appendix in the course of carrying out employment duties, even if the employee does not receive a referral fee or commission or other special compensation for the loan.

(2) Offering or negotiating terms of a loan for compensation or gain does not include engaging in a seller-financed transaction for the employee's personal property that does not involve the insured State nonmember bank.

Office of Thrift Supervision

12 CFR Chapter V

Authority and Issuance

■ For the reasons set forth in the preamble, chapter V of title 12 of the Code of Federal Regulations is amended as follows:

PART 563—SAVINGS ASSOCIATIONS—OPERATIONS

■ 1. The authority citation for part 563 is revised to read as follows:

Authority: 12 U.S.C. 375b, 1462, 1462a, 1463, 1464, 1467a, 1468, 1817, 1820, 1828, 1831o, 3806, 5101 *et seq.;* 31 U.S.C. 5318; 42 U.S.C. 4106.

■ 3. Add Subpart D to part 563 to read as follows:

Subpart D—Registration of Residential Mortgage Loan Originators

Sec.
563.101 Authority, purpose, and scope.
563.102 Definitions.
563.103 Registration of mortgage loan originators.
563.104 Policies and procedures.
563.105 Use of unique identifier.
Appendix A to Subpart D of Part 563—Examples of Mortgage Loan Originator Activities

Subpart D—Registration of Residential Mortgage Loan Originators

§ 563.101 Authority, purpose, and scope.

(a) *Authority.* This subpart is issued pursuant to the Secure and Fair Enforcement for Mortgage Licensing Act of 2008, title V of the Housing and Economic Recovery Act of 2008 (S.A.F.E. Act) (Pub. L. 110–289, 122 Stat. 2654, 12 U.S.C. 5101 *et seq.*).

(b) *Purpose.* This subpart implements the S.A.F.E. Act's Federal registration requirement for mortgage loan originators. The S.A.F.E. Act provides that the objectives of this registration include aggregating and improving the flow of information to and between regulators; providing increased accountability and tracking of mortgage loan originators; enhancing consumer protections; supporting anti-fraud measures; and providing consumers with easily accessible information at no charge regarding the employment history of, and publicly adjudicated disciplinary and enforcement actions against, mortgage loan originators.

(c) *Scope*—(1) *In general.* This subpart applies to savings associations, their operating subsidiaries (collectively referred to in this subpart as savings associations), and their employees who act as mortgage loan originators.

(2) *De minimis exception.* (i) This subpart and the requirements of 12 U.S.C. 5103(a)(1)(A) and (2) of the S.A.F.E. Act do not apply to any employee of a savings association who has never been registered or licensed through the Registry as a mortgage loan originator if during the past 12 months the employee acted as a mortgage loan originator for 5 or fewer residential mortgage loans.

(ii) Prior to engaging in mortgage loan origination activity that exceeds the exception limit in paragraph (c)(2)(i) of this section, a savings association employee must register with the Registry pursuant to this subpart.

(iii) *Evasion.* Savings associations are prohibited from engaging in any act or practice to evade the limits of the *de minimis* exception set forth in paragraph (c)(2)(i) of this section.

§ 563.102 Definitions.

For purposes of this subpart D, the following definitions apply:

(a) *Annual renewal period* means November 1 through December 31 of each year.

(b)(1) *Mortgage loan originator*[1] means an individual who:

(i) Takes a residential mortgage loan application; and

(ii) Offers or negotiates terms of a residential mortgage loan for compensation or gain.

(2) The term *mortgage loan originator* does not include:

(i) An individual who performs purely administrative or clerical tasks on behalf of an individual who is described in paragraph (b)(1) of this section;

(ii) An individual who only performs real estate brokerage activities (as defined in 12 U.S.C. 5102(3)(D)) and is licensed or registered as a real estate broker in accordance with applicable State law, unless the individual is compensated by a lender, a mortgage broker, or other mortgage loan originator or by any agent of such lender, mortgage broker, or other mortgage loan originator, and meets the definition of mortgage loan originator in paragraph (b)(1) of this section; or

(iii) An individual or entity solely involved in extensions of credit related to timeshare plans, as that term is defined in 11 U.S.C. 101(53D).

(3) *Administrative or clerical tasks* means the receipt, collection, and distribution of information common for the processing or underwriting of a loan in the residential mortgage industry and communication with a consumer to obtain information necessary for the processing or underwriting of a residential mortgage loan.

(c) *Nationwide Mortgage Licensing System and Registry* or *Registry* means the system developed and maintained by the Conference of State Bank Supervisors and the American Association of Residential Mortgage Regulators for the State licensing and registration of State-licensed mortgage loan originators and the registration of mortgage loan originators pursuant to 12 U.S.C. 5107.

(d) *Registered mortgage loan originator* or *registrant* means any individual who:

(1) Meets the definition of mortgage loan originator and is an employee of a savings association; and

(2) Is registered pursuant to this subpart with, and maintains a unique identifier through, the Registry.

(e) *Residential mortgage loan* means any loan primarily for personal, family, or household use that is secured by a mortgage, deed of trust, or other equivalent consensual security interest on a dwelling (as defined in section 103(v) of the Truth in Lending Act, 15 U.S.C. 1602(v)) or residential real estate upon which is constructed or intended to be constructed a dwelling, and includes refinancings, reverse mortgages, home equity lines of credit and other first and additional lien loans that meet the qualifications listed in this definition.

(f) *Unique identifier* means a number or other identifier that:

(1) Permanently identifies a registered mortgage loan originator;

(2) Is assigned by protocols established by the Nationwide Mortgage Licensing System and Registry, the Federal banking agencies, and the Farm Credit Administration to facilitate:

(i) Electronic tracking of mortgage loan originators; and

(ii) Uniform identification of, and public access to, the employment history of and the publicly adjudicated disciplinary and enforcement actions against mortgage loan originators; and

(3) Must not be used for purposes other than those set forth under the S.A.F.E. Act.

§ 563.103 Registration of mortgage loan originators.

(a) *Registration requirement*—(1) *Employee registration.* Each employee of a savings association who acts as a mortgage loan originator must register with the Registry, obtain a unique identifier, and maintain this registration in accordance with the requirements of this subpart. Any such employee who is not in compliance with the registration and unique identifier requirements set forth in this subpart is in violation of the S.A.F.E. Act and this subpart.

(2) *Savings association requirement*—(i) *In general.* A savings association that employs one or more individuals who act as a residential mortgage loan originator must require each such employee to register with the Registry, maintain this registration, and obtain a unique identifier in accordance with the requirements of this subpart.

(ii) *Prohibition.* A savings association must not permit an employee of the association who is subject to the registration requirements of this subpart to act as a mortgage loan originator for the association unless such employee is registered with the Registry pursuant to this subpart.

(3) *Implementation period for initial registration.* An employee of a savings association who is a mortgage loan originator must complete an initial registration with the Registry pursuant to this subpart within 180 days from the date that the OTS provides in a public notice that the Registry is accepting registrations.

(4) *Employees previously registered or licensed through the Registry*—(i) *In general.* If an employee of a savings association was registered or licensed through, and obtained a unique identifier from, the Registry and has maintained this registration or license before the employee of the association becomes subject to this subpart at this association, then the registration requirements of the S.A.F.E. Act and this subpart are deemed to be met, provided that:

(A) The employment information in paragraphs (d)(1)(i)(C) and (d)(1)(ii) of this section is updated and the requirements of paragraph (d)(2) of this section are met;

(B) New fingerprints of the employee are submitted to the Registry for a background check, as required by paragraph (d)(1)(ix) of this section, unless the employee has fingerprints on file with the Registry that are less than 3 years old;

(C) The savings association information required in paragraphs (e)(1)(i) (to the extent the association has not previously met these requirements) and (e)(2)(i) of this section is submitted to the Registry; and

(D) The registration is maintained pursuant to paragraphs (b) and (e)(1)(ii)

[1] Appendix A of this subpart provides examples of activities that would, and would not, cause an employee to fall within this definition of mortgage loan originator.

of this section, as of the date that the employee becomes subject to this subpart.

(ii) *Rule for certain acquisitions, mergers, or reorganizations.* When registered or licensed mortgage loan originators become savings association employees as a result of an acquisition, merger, or reorganization, only the requirements of paragraphs (a)(4)(i)(A), (C), and (D) of this section must be met, and these requirements must be met within 60 days from the effective date of the acquisition, merger, or reorganization.

(b) *Maintaining registration.* (1) A mortgage loan originator who is registered with the Registry pursuant to paragraph (a) of this section must:

(i) Except as provided in paragraph (b)(3) of this section, renew the registration during the annual renewal period, confirming the responses set forth in paragraphs (d)(1)(i) through (viii) of this section remain accurate and complete, and updating this information, as appropriate; and

(ii) Update the registration within 30 days of any of the following events:

(A) A change in the name of the registrant;

(B) The registrant ceases to be an employee of the savings association; or

(C) The information required under paragraphs (d)(1)(iii) through (viii) of this section becomes inaccurate, incomplete, or out-of-date.

(2) A registered mortgage loan originator must maintain his or her registration, unless the individual is no longer engaged in the activity of a mortgage loan originator.

(3) The annual registration renewal requirement set forth in paragraph (b)(1) of this section does not apply to a registered mortgage loan originator who has completed his or her registration with the Registry pursuant to paragraph (a)(1) of this section less than 6 months prior to the end of the annual renewal period.

(c) *Effective dates*—(1) *Registration.* A registration pursuant to paragraph (a)(1) of this section is effective on the date the Registry transmits notification to the registrant that the registrant is registered.

(2) *Renewals or updates.* A renewal or update pursuant to paragraph (b) of this section is effective on the date the Registry transmits notification to the registrant that the registration has been renewed or updated.

(d) *Required employee information*—(1) *In general.* For purposes of the registration required by this section, a savings association must require each employee who is a mortgage loan originator to submit to the Registry, or must submit on behalf of the employee, the following categories of information, to the extent this information is collected by the Registry:

(i) Identifying information, including the employee's:

(A) Name and any other names used;

(B) Home address and contact information;

(C) Principal business location address and business contact information;

(D) Social security number;

(E) Gender; and

(F) Date and place of birth;

(ii) Financial services-related employment history for the 10 years prior to the date of registration or renewal, including the date the employee became an employee of the savings association;

(iii) Convictions of any criminal offense involving dishonesty, breach of trust, or money laundering against the employee or organizations controlled by the employee, or agreements to enter into a pretrial diversion or similar program in connection with the prosecution for such offense(s);

(iv) Civil judicial actions against the employee in connection with financial services-related activities, dismissals with settlements, or judicial findings that the employee violated financial services-related statutes or regulations, except for actions dismissed without a settlement agreement;

(v) Actions or orders by a State or Federal regulatory agency or foreign financial regulatory authority that:

(A) Found the employee to have made a false statement or omission or been dishonest, unfair or unethical; to have been involved in a violation of a financial services-related regulation or statute; or to have been a cause of a financial services-related business having its authorization to do business denied, suspended, revoked, or restricted;

(B) Are entered against the employee in connection with a financial services-related activity;

(C) Denied, suspended, or revoked the employee's registration or license to engage in a financial services-related activity; disciplined the employee or otherwise by order prevented the employee from associating with a financial services-related business or restricted the employee's activities; or

(D) Barred the employee from association with an entity or its officers regulated by the agency or authority or from engaging in a financial services-related business;

(vi) Final orders issued by a State or Federal regulatory agency or foreign financial regulatory authority based on violations of any law or regulation that prohibits fraudulent, manipulative, or deceptive conduct;

(vii) Revocation or suspension of the employee's authorization to act as an attorney, accountant, or State or Federal contractor;

(viii) Customer-initiated financial services-related arbitration or civil action against the employee that required action, including settlements, or which resulted in a judgment; and

(ix) Fingerprints of the employee, in digital form if practicable, and any appropriate identifying information for submission to the Federal Bureau of Investigation and any governmental agency or entity authorized to receive such information in connection with a State and national criminal history background check; however, fingerprints provided to the Registry that are less than 3 years old may be used to satisfy this requirement.

(2) *Employee authorizations and attestation.* An employee registering as a mortgage loan originator or renewing or updating his or her registration under this subpart, and not the employing savings association or other employees of the savings association, must:

(i) Authorize the Registry and the employing institution to obtain information related to sanctions or findings in any administrative, civil, or criminal action, to which the employee is a party, made by any governmental jurisdiction;

(ii) Attest to the correctness of all information required by paragraph (d) of this section, whether submitted by the employee or on behalf of the employee by the employing savings association; and

(iii) Authorize the Registry to make available to the public information required by paragraphs (d)(1)(i)(A) and (C), and (d)(1)(ii) through (viii) of this section.

(3) *Submission of information.* A savings association may identify one or more employees of the association who may submit the information required by paragraph (d)(1) of this section to the Registry on behalf of the association's employees provided that this individual, and any employee delegated such authority, does not act as a mortgage loan originator, consistent with paragraph (e)(1)(i)(F) of this section. In addition, a savings association may submit to the Registry some or all of the information required by paragraphs (d)(1) and (e)(2) of this section for multiple employees in bulk through batch processing in a format to be specified by the Registry, to the extent such batch processing is made available by the Registry.

(e) *Required savings association information.* A savings association must submit the following categories of information to the Registry:

(1) *Savings association record.* (i) In connection with the registration of one or more mortgage loan originators:

(A) Name, main office address, and business contact information;

(B) Internal Revenue Service Employer Tax Identification Number (EIN);

(C) Research Statistics Supervision and Discount (RSSD) number, as issued by the Board of Governors of the Federal Reserve System;

(D) Identification of its primary Federal regulator;

(E) Name(s) and contact information of the individual(s) with authority to act as the savings association's primary point of contact for the Registry;

(F) Name(s) and contact information of the individual(s) with authority to enter the information required by paragraphs (d)(1) and (e) of this section to the Registry and who may delegate this authority to other individuals. For the purpose of providing information required by paragraph (e) of this section, this individual and their delegates must not act as mortgage loan originators unless the savings association has 10 or fewer full time or equivalent employees and is not a subsidiary; and

(G) If a subsidiary of a savings association, indication that it is a subsidiary and the RSSD number of the parent association.

(ii) *Attestation.* The individual(s) identified in paragraphs (e)(1)(i)(E) and (F) of this section must comply with Registry protocols to verify their identity and must attest that they have the authority to enter data on behalf of the savings association, that the information provided to the Registry pursuant to this paragraph (e) is correct, and that the savings association will keep the information required by this paragraph (e) current and will file accurate supplementary information on a timely basis.

(iii) A savings association must update the information required by this paragraph (e) of this section within 30 days of the date that this information becomes inaccurate.

(iv) A savings association must renew the information required by paragraph (e) of this section on an annual basis.

(2) *Employee information.* In connection with the registration of each employee who acts as a mortgage loan originator:

(i) After the information required by paragraph (d) of this section has been submitted to the Registry, confirmation that it employs the registrant; and

(ii) Within 30 days of the date the registrant ceases to be an employee of the savings association, notification that it no longer employs the registrant and the date the registrant ceased being an employee.

§ 563.104 Policies and procedures.

A savings association that employs one or more mortgage loan originators must adopt and follow written policies and procedures designed to assure compliance with this subpart. These policies and procedures must be appropriate to the nature, size, complexity, and scope of the mortgage lending activities of the savings association, and apply only to those employees acting within the scope of their employment at the association. At a minimum, these policies and procedures must:

(a) Establish a process for identifying which employees of the savings association are required to be registered mortgage loan originators;

(b) Require that all employees of the savings association who are mortgage loan originators be informed of the registration requirements of the S.A.F.E. Act and this subpart and be instructed on how to comply with such requirements and procedures;

(c) Establish procedures to comply with the unique identifier requirements in § 563.105;

(d) Establish reasonable procedures for confirming the adequacy and accuracy of employee registrations, including updates and renewals, by comparisons with its own records;

(e) Establish reasonable procedures and tracking systems for monitoring compliance with registration and renewal requirements and procedures;

(f) Provide for independent testing for compliance with this subpart to be conducted at least annually by savings association personnel or by an outside party;

(g) Provide for appropriate action in the case of any employee who fails to comply with the registration requirements of the S.A.F.E. Act, this subpart, or the savings association's related policies and procedures, including prohibiting such employees from acting as mortgage loan originators or other appropriate disciplinary actions;

(h) Establish a process for reviewing employee criminal history background reports received pursuant to this subpart, taking appropriate action consistent with applicable Federal law, including section 19 of the Federal Deposit Insurance Act (12 U.S.C. 1829) and implementing regulations with respect to these reports, and maintaining records of these reports and actions taken with respect to applicable employees; and

(i) Establish procedures designed to ensure that any third party with which the savings association has arrangements related to mortgage loan origination has policies and procedures to comply with the S.A.F.E. Act, including appropriate licensing and/or registration of individuals acting as mortgage loan originators.

§ 563.105 Use of unique identifier.

(a) The savings association shall make the unique identifier(s) of its registered mortgage loan originator(s) available to consumers in a manner and method practicable to the institution.

(b) A registered mortgage loan originator shall provide his or her unique identifier to a consumer:

(1) Upon request;

(2) Before acting as a mortgage loan originator; and

(3) Through the originator's initial written communication with a consumer, if any, whether on paper or electronically.

Appendix A to Subpart D of Part 563—Examples of Mortgage Loan Originator Activities

This Appendix provides examples to aid in the understanding of activities that would cause an employee of a savings association to fall within or outside the definition of mortgage loan originator. The examples in this Appendix are not all inclusive. They illustrate only the issue described and do not illustrate any other issues that may arise under this subpart. For purposes of the examples below, the term "loan" refers to a residential mortgage loan.

(a) *Taking a loan application.* The following examples illustrate when an employee takes, or does not take, a loan application.

(1) Taking an application includes: receiving information provided in connection with a request for a loan to be used to determine whether the consumer qualifies for a loan, even if the employee:

(i) Has received the consumer's information indirectly in order to make an offer or negotiate a loan;

(ii) Is not responsible for verifying information;

(iii) Is inputting information into an online application or other automated system on behalf of the consumer; or

(iv) Is not engaged in approval of the loan, including determining whether the consumer qualifies for the loan.

(2) Taking an application does not include any of the following activities performed solely or in combination:

(i) Contacting a consumer to verify the information in the loan application by obtaining documentation, such as tax returns or payroll receipts;

(ii) Receiving a loan application through the mail and forwarding it, without review, to loan approval personnel;

(iii) Assisting a consumer who is filling out an application by clarifying what type of information is necessary for the application or otherwise explaining the qualifications or criteria necessary to obtain a loan product;

(iv) Describing the steps that a consumer would need to take to provide information to be used to determine whether the consumer qualifies for a loan or otherwise explaining the loan application process;

(v) In response to an inquiry regarding a prequalified offer that a consumer has received from a savings association, collecting only basic identifying information about the consumer and forwarding the consumer to a mortgage loan originator; or

(vi) Receiving information in connection with a modification to the terms of an existing loan to a borrower as part of the savings association's loss mitigation efforts when the borrower is reasonably likely to default.

(b) *Offering or negotiating terms of a loan.* The following examples are designed to illustrate when an employee offers or negotiates terms of a loan, and conversely, what does not constitute offering or negotiating terms of a loan.

(1) Offering or negotiating the terms of a loan includes:

(i) Presenting a loan offer to a consumer for acceptance, either verbally or in writing, including, but not limited to, providing a disclosure of the loan terms after application under the Truth in Lending Act, even if:

(A) Further verification of information is necessary;

(B) The offer is conditional;

(C) Other individuals must complete the loan process; or

(D) Only the rate approved by the savings association's loan approval mechanism function for a specific loan product is communicated without authority to negotiate the rate.

(ii) Responding to a consumer's request for a lower rate or lower points on a pending loan application by presenting to the consumer a revised loan offer, either verbally or in writing, that includes a lower interest rate or lower points than the original offer.

(2) Offering or negotiating terms of a loan does not include solely or in combination:

(i) Providing general explanations or descriptions in response to consumer queries regarding qualification for a specific loan product, such as explaining loan terminology (*i.e.,* debt-to-income ratio); lending policies (*i.e.,* the loan-to-value ratio policy of the savings association); or product-related services;

(ii) In response to a consumer's request, informing a consumer of the loan rates that are publicly available, such as on the savings association's Web site, for specific types of loan products without communicating to the consumer whether qualifications are met for that loan product;

(iii) Collecting information about a consumer in order to provide the consumer with information on loan products for which the consumer generally may qualify, without presenting a specific loan offer to the consumer for acceptance, either verbally or in writing;

(iv) Arranging the loan closing or other aspects of the loan process, including communicating with a consumer about those arrangements, provided that communication with the consumer only verifies loan terms already offered or negotiated;

(v) Providing a consumer with information unrelated to loan terms, such as the best days of the month for scheduling loan closings at the savings association;

(vi) Making an underwriting decision about whether the consumer qualifies for a loan;

(vii) Explaining or describing the steps or process that a consumer would need to take in order to obtain a loan offer, including qualifications or criteria that would need to be met without providing guidance specific to that consumer's circumstances; or

(viii) Communicating on behalf of a mortgage loan originator that a written offer, including disclosures provided pursuant to the Truth in Lending Act, has been sent to a consumer without providing any details of that offer.

(c) *Offering or negotiating a loan for compensation or gain.* The following examples illustrate when an employee does or does not offer or negotiate terms of a loan "for compensation or gain."

(1) Offering or negotiating terms of a loan for compensation or gain includes engaging in any of the activities in paragraph (b)(1) of this Appendix in the course of carrying out employment duties, even if the employee does not receive a referral fee or commission or other special compensation for the loan.

(2) Offering or negotiating terms of a loan for compensation or gain does not include engaging in a seller-financed transaction for the employee's personal property that does not involve the savings association.

Farm Credit Administration

12 CFR Chapter VI

Authority and Issuance

■ For the reasons set forth in the preamble, chapter VI of title 12 of the Code of Federal Regulations is amended by adding a new part 610 to read as follows:

PART 610—REGISTRATION OF MORTGAGE LOAN ORIGINATORS

Sec.
610.101 Authority, purpose, and scope.
610.102 Definitions.
610.103 Registration of mortgage loan originators.
610.104 Policies and procedures.
610.105 Use of unique identifier.
Appendix A to Part 610—Examples of Mortgage Loan Originator Activities

Authority: Secs. 1.5, 1.7, 1.9, 1.10, 1.11, 1.13, 2.2, 2.4, 2.12, 5.9, 5.17, 7.2, 7.6, 7.8 of the Farm Credit Act (12 U.S.C. 2013, 2015, 2017, 2018, 2019, 2021, 2073, 2075, 2093, 2243, 2252, 2279a–2, 2279b, 2279c–10); and secs. 1501 *et seq.* of Pub. L. 110–289, 122 Stat. 2654.

§ 610.101 Authority, purpose, and scope.

(a) *Authority.* This part is issued pursuant to the Secure and Fair Enforcement for Mortgage Licensing Act of 2008, title V of the Housing and Economic Recovery Act of 2008 (S.A.F.E. Act) (Pub. L. 110–289, 122 Stat. 2654, 12 U.S.C. 5101 *et seq.*).

(b) *Purpose.* This part implements the S.A.F.E. Act's Federal registration requirement for mortgage loan originators. The S.A.F.E. Act provides that the objectives of this registration include aggregating and improving the flow of information to and between regulators; providing increased accountability and tracking of mortgage loan originators; enhancing consumer protections; supporting anti-fraud measures; and providing consumers with easily accessible information at no charge regarding the employment history of, and publicly adjudicated disciplinary and enforcement actions against, mortgage loan originators.

(c) *Scope*—(1) *In general.* This part applies to any Farm Credit System lending institution that actually originates residential mortgage loans pursuant to its authority under sections 1.9(3), 1.11, or 2.4(a) and (b) of the Farm Credit Act of 1971, as amended, and their employees who act as mortgage loan originators.

(2) *De minimis exception.*

(i) This part and the requirements of 12 U.S.C. 5103(a)(1)(A) and (2) of the S.A.F.E. Act do not apply to any employee of a Farm Credit System institution who has never been registered or licensed through the Registry as a mortgage loan originator if during the past 12 months the employee acted as a mortgage loan originator for 5 or fewer residential mortgage loans.

(ii) Prior to engaging in mortgage loan origination activity that exceeds the exception limit in paragraph (c)(2)(i) of this section, a Farm Credit System institution employee must register with the Registry pursuant to this part.

(iii) *Evasion.* Farm Credit System institutions are prohibited from engaging in any act or practice to evade the limits of the *de minimis* exception set forth in paragraph (c)(2)(i) of this section.

§ 610.102 Definitions.

For purposes of this part, the following definitions apply:

(a) *Annual renewal period* means November 1 through December 31 of each year.

(b)(1) *Mortgage loan originator* [1] means an individual who:

(i) Takes a residential mortgage loan application; and

[1] Appendix A of this part provides examples of activities that would, and would not, cause an employee to fall within this definition of mortgage loan originator.

(ii) Offers or negotiates terms of a residential mortgage loan for compensation or gain.

(2) The term *mortgage loan originator* does not include:

(i) An individual who performs purely administrative or clerical tasks on behalf of an individual who is described in paragraph (b)(1) of this section;

(ii) An individual who only performs real estate brokerage activities (as defined in 12 U.S.C. 5102(3)(D)) and is licensed or registered as a real estate broker in accordance with applicable State law, unless the individual is compensated by a lender, a mortgage broker, or other mortgage loan originator or by any agent of such lender, mortgage broker, or other mortgage loan originator, and meets the definition of mortgage loan originator in paragraph (b)(1) of this section; or

(iii) An individual or entity solely involved in extensions of credit related to timeshare plans, as that term is defined in 11 U.S.C. 101(53D).

(3) *Administrative or clerical tasks* means the receipt, collection, and distribution of information common for the processing or underwriting of a loan in the residential mortgage industry and communication with a consumer to obtain information necessary for the processing or underwriting of a residential mortgage loan.

(c) *Nationwide Mortgage Licensing System and Registry* or *Registry* means the system developed and maintained by the Conference of State Bank Supervisors and the American Association of Residential Mortgage Regulators for the State licensing and registration of State-licensed mortgage loan originators and the registration of mortgage loan originators pursuant to 12 U.S.C. 5107.

(d) *Registered mortgage loan originator* or *registrant* means any individual who:

(1) Meets the definition of mortgage loan originator and is an employee of a Farm Credit System institution; and

(2) Is registered pursuant to this part with, and maintains a unique identifier through, the Registry.

(e) *Residential mortgage loan* means any loan primarily for personal, family, or household use that is secured by a mortgage, deed of trust, or other equivalent consensual security interest on a dwelling (as defined in section 103(v) of the Truth in Lending Act, 15 U.S.C. 1602(v)) or residential real estate upon which is constructed or intended to be constructed a dwelling, and includes refinancings, reverse mortgages, home equity lines of credit and other first and additional lien loans that meet the qualifications listed in this definition. This definition does not amend or supersede § 613.3030(c) of this chapter.

(f) *Unique identifier* means a number or other identifier that:

(1) Permanently identifies a registered mortgage loan originator;

(2) Is assigned by protocols established by the Nationwide Mortgage Licensing System and Registry, the Federal banking agencies, and the Farm Credit Administration to facilitate:

(i) Electronic tracking of mortgage loan originators; and

(ii) Uniform identification of, and public access to, the employment history of and the publicly adjudicated disciplinary and enforcement actions against mortgage loan originators; and

(3) Must not be used for purposes other than those set forth under the S.A.F.E. Act.

§ 610.103 Registration of mortgage loan originators.

(a) *Registration requirement*—(1) *Employee registration.* Each employee of a Farm Credit System institution who acts as a mortgage loan originator must register with the Registry, obtain a unique identifier, and maintain this registration in accordance with the requirements of this part. Any such employee who is not in compliance with the registration and unique identifier requirements set forth in this part is in violation of the S.A.F.E. Act and this part.

(2) *Farm Credit System institution requirement*—(i) *In general.* A Farm Credit System institution that employs one or more individuals who act as a residential mortgage loan originator must require each such employee to register with the Registry, maintain this registration, and obtain a unique identifier in accordance with the requirements of this part.

(ii) *Prohibition.* A Farm Credit System institution must not permit an employee who is subject to the registration requirements of this part to act as a mortgage loan originator for the Farm Credit System institution unless such employee is registered with the Registry pursuant to this part.

(3) *Implementation period for initial registration.* An employee of a Farm Credit System institution who is a mortgage loan originator must complete an initial registration with the Registry pursuant to this part within 180 days from the date that the Farm Credit Administration provides in a public notice that the Registry is accepting registrations.

(4) *Employees previously registered or licensed through the Registry*—(i) *In general.* If an employee of a Farm Credit System institution was registered or licensed through, and obtained a unique identifier from, the Registry and has maintained this registration or license before the employee becomes subject to this part at this Farm Credit System institution, then the registration requirements of the S.A.F.E. Act and this part are deemed to be met, provided that:

(A) The employment information in paragraphs (d)(1)(i)(C) and (d)(1)(ii) of this section is updated and the requirements of paragraph (d)(2) of this section are met;

(B) New fingerprints of the employee are submitted to the Registry for a background check, as required by paragraph (d)(1)(ix) of this section, unless the employee has fingerprints on file with the Registry that are less than 3 years old;

(C) The Farm Credit System institution information required in paragraphs (e)(1)(i) (to the extent the Farm Credit System institution has not previously met these requirements) and (e)(2)(i) of this section is submitted to the Registry; and

(D) The registration is maintained pursuant to paragraphs (b) and (e)(1)(ii) of this section, as of the date that the employee becomes subject to this part.

(ii) *Rule for certain acquisitions, mergers, or reorganizations.* When registered or licensed mortgage loan originators become employees of another Farm Credit System institution as a result of a consolidation, merger, or reorganization, only the requirements of paragraphs (a)(4)(i)(A), (C), and (D) of this section must be met, and these requirements must be met within 60 days from the effective date of the consolidation, merger, or reorganization.

(b) *Maintaining registration.*

(1) A mortgage loan originator who is registered with the Registry pursuant to paragraph (a) of this section must:

(i) Except as provided in paragraph (b)(3) of this section, renew the registration during the annual renewal period, confirming the responses set forth in paragraphs (d)(1)(i) through (viii) of this section remain accurate and complete, and updating this information, as appropriate; and

(ii) Update the registration within 30 days of any of the following events:

(A) A change in the name of the registrant;

(B) The registrant ceases to be an employee of the Farm Credit System institution; or

(C) The information required under paragraphs (d)(1)(iii) through (viii) of this section becomes inaccurate, incomplete, or out-of-date.

(2) A registered mortgage loan originator must maintain his or her registration, unless the individual is no longer engaged in the activity of a mortgage loan originator.

(3) The annual registration renewal requirement set forth in paragraph (b)(1) of this section does not apply to a registered mortgage loan originator who has completed his or her registration with the Registry pursuant to paragraph (a)(1) of this section less than 6 months prior to the end of the annual renewal period.

(c) *Effective dates*—(1) *Registration.* A registration pursuant to paragraph (a)(1) of this section is effective on the date the Registry transmits notification to the registrant that the registrant is registered.

(2) *Renewals or updates.* A renewal or update pursuant to paragraph (b) of this section is effective on the date the Registry transmits notification to the registrant that the registration has been renewed or updated.

(d) *Required employee information*—(1) *In general.* For purposes of the registration required by this section, a Farm Credit System institution must require each employee who is a mortgage loan originator to submit to the Registry, or must submit on behalf of the employee, the following categories of information, to the extent this information is collected by the Registry:

(i) Identifying information, including the employee's:

(A) Name and any other names used;

(B) Home address and contact information;

(C) Principal business location address and business contact information;

(D) Social security number;

(E) Gender; and

(F) Date and place of birth;

(ii) Financial services-related employment history for the 10 years prior to the date of registration or renewal, including the date the employee became an employee of the Farm Credit System institution;

(iii) Convictions of any criminal offense involving dishonesty, breach of trust, or money laundering against the employee or organizations controlled by the employee, or agreements to enter into a pretrial diversion or similar program in connection with the prosecution for such offense(s);

(iv) Civil judicial actions against the employee in connection with financial services-related activities, dismissals with settlements, or judicial findings that the employee violated financial services-related statutes or regulations, except for actions dismissed without a settlement agreement;

(v) Actions or orders by a State or Federal regulatory agency or foreign financial regulatory authority that:

(A) Found the employee to have made a false statement or omission or been dishonest, unfair or unethical; to have been involved in a violation of a financial services-related regulation or statute; or to have been a cause of a financial services-related business having its authorization to do business denied, suspended, revoked, or restricted;

(B) Are entered against the employee in connection with a financial services-related activity;

(C) Denied, suspended, or revoked the employee's registration or license to engage in a financial services-related activity; disciplined the employee or otherwise by order prevented the employee from associating with a financial services-related business or restricted the employee's activities; or

(D) Barred the employee from association with an entity or its officers regulated by the agency or authority or from engaging in a financial services-related business;

(vi) Final orders issued by a State or Federal regulatory agency or foreign financial regulatory authority based on violations of any law or regulation that prohibits fraudulent, manipulative, or deceptive conduct;

(vii) Revocation or suspension of the employee's authorization to act as an attorney, accountant, or State or Federal contractor;

(viii) Customer-initiated financial services-related arbitration or civil action against the employee that required action, including settlements, or which resulted in a judgment; and

(ix) Fingerprints of the employee, in digital form if practicable, and any appropriate identifying information for submission to the Federal Bureau of Investigation and any governmental agency or entity authorized to receive such information in connection with a State and national criminal history background check; however, fingerprints provided to the Registry that are less than 3 years old may be used to satisfy this requirement.

(2) *Employee authorizations and attestation.* An employee registering as a mortgage loan originator or renewing or updating his or her registration under this part, and not the employing Farm Credit System institution or other employees of the Farm Credit System institution, must:

(i) Authorize the Registry and the employing institution to obtain information related to sanctions or findings in any administrative, civil, or criminal action, to which the employee is a party, made by any governmental jurisdiction;

(ii) Attest to the correctness of all information required by paragraph (d) of this section, whether submitted by the employee or on behalf of the employee by the employing Farm Credit System institution; and

(iii) Authorize the Registry to make available to the public information required by paragraphs (d)(1)(i)(A) and (C), and (d)(1)(ii) through (viii) of this section.

(3) *Submission of information.* A Farm Credit System institution may identify one or more employees of the Farm Credit System institution who may submit the information required by paragraph (d)(1) of this section to the Registry on behalf of the Farm Credit System institution's employees provided that this individual, and any employee delegated such authority, does not act as a mortgage loan originator, consistent with paragraph (e)(1)(i)(F) of this section. In addition, a Farm Credit System institution may submit to the Registry some or all of the information required by paragraphs (d)(1) and (e)(2) of this section for multiple employees in bulk through batch processing in a format to be specified by the Registry, to the extent such batch processing is made available by the Registry.

(e) *Required Farm Credit System institution information.* A Farm Credit System institution must submit the following categories of information to the Registry:

(1) *Farm Credit System institution record.*

(i) In connection with the registration of one or more mortgage loan originators:

(A) Name, main office address, and business contact information;

(B) Internal Revenue Service Employer Tax Identification Number (EIN);

(C) Research Statistics Supervision and Discount (RSSD) number, as issued by the Board of Governors of the Federal Reserve System;

(D) Identification of its primary Federal regulator;

(E) Name(s) and contact information of the individual(s) with authority to act as the Farm Credit System institution's primary point of contact for the Registry;

(F) Name(s) and contact information of the individual(s) with authority to enter the information required by paragraphs (d)(1) and (e) of this section to the Registry and who may delegate this authority to other individuals. For

the purpose of providing information required by paragraph (e) of this section, this individual and their delegates must not act as mortgage loan originators unless the Farm Credit System institution has 10 or fewer full time or equivalent employees and is not a subsidiary; and

(G) If an operating subsidiary of an agricultural credit association, indication that it is a subsidiary and the RSSD number of the parent agricultural credit association.

(ii) *Attestation.* The individual(s) identified in paragraphs (e)(1)(i)(E) and (F) of this section must comply with Registry protocols to verify their identity and must attest that they have the authority to enter data on behalf of the Farm Credit System institution, that the information provided to the Registry pursuant to this paragraph (e) is correct, and that the Farm Credit System institution will keep the information required by this paragraph (e) current and will file accurate supplementary information on a timely basis.

(iii) A Farm Credit System institution must update the information required by this paragraph (e) of this section within 30 days of the date that this information becomes inaccurate.

(iv) A Farm Credit System institution must renew the information required by paragraph (e) of this section on an annual basis.

(2) *Employee information.* In connection with the registration of each employee who acts as a mortgage loan originator:

(i) After the information required by paragraph (d) of this section has been submitted to the Registry, confirmation that it employs the registrant; and

(ii) Within 30 days of the date the registrant ceases to be an employee of the Farm Credit System institution, notification that it no longer employs the registrant and the date the registrant ceased being an employee.

§ 610.104 Policies and procedures.

A Farm Credit System institution that employs one or more mortgage loan originators must adopt and follow written policies and procedures designed to assure compliance with this part. These policies and procedures must be appropriate to the nature, size, complexity, and scope of the mortgage lending activities of the Farm Credit System institution, and apply only to those employees acting within the scope of their employment at the Farm Credit System institution. At a minimum, these policies and procedures must:

(a) Establish a process for identifying which employees of the Farm Credit System institution are required to be registered mortgage loan originators;

(b) Require that all employees of the Farm Credit System institution who are mortgage loan originators be informed of the registration requirements of the S.A.F.E. Act and this part and be instructed on how to comply with such requirements and procedures;

(c) Establish procedures to comply with the unique identifier requirements in § 610.105;

(d) Establish reasonable procedures for confirming the adequacy and accuracy of employee registrations, including updates and renewals, by comparisons with its own records;

(e) Establish reasonable procedures and tracking systems for monitoring compliance with registration and renewal requirements and procedures;

(f) Provide for independent testing for compliance with this part to be conducted at least annually by Farm Credit System institution personnel or by an outside party;

(g) Provide for appropriate action in the case of any employee who fails to comply with the registration requirements of the S.A.F.E. Act, this part, or the Farm Credit System institution's related policies and procedures, including prohibiting such employees from acting as mortgage loan originators or other appropriate disciplinary actions;

(h) Establish a process for reviewing employee criminal history background reports received pursuant to this part, taking appropriate action consistent with applicable Federal law, including section 5.65(d) of the Farm Credit Act of 1971, as amended, 12 U.S.C. 2277a–14(d) and implementing regulations with respect to these reports, and maintaining records of these reports and actions taken with respect to applicable employees; and

(i) Establish procedures designed to ensure that any third party with which the Farm Credit System institution has arrangements related to mortgage loan origination has policies and procedures to comply with the S.A.F.E. Act, including appropriate licensing and/or registration of individuals acting as mortgage loan originators.

§ 610.105 Use of unique identifier.

(a) The Farm Credit System institution shall make the unique identifier(s) of its registered mortgage loan originator(s) available to consumers in a manner and method practicable to the institution.

(b) A registered mortgage loan originator shall provide his or her unique identifier to a consumer:

(1) Upon request;

(2) Before acting as a mortgage loan originator; and

(3) Through the originator's initial written communication with a consumer, if any, whether on paper or electronically.

Appendix A to Part 610—Examples of Mortgage Loan Originator Activities

This Appendix provides examples to aid in the understanding of activities that would cause an employee of a Farm Credit System institution to fall within or outside the definition of mortgage loan originator. The examples in this Appendix are not all inclusive. They illustrate only the issue described and do not illustrate any other issues that may arise under this part. For purposes of the examples below, the term "loan" refers to a residential mortgage loan.

(a) *Taking a loan application.* The following examples illustrate when an employee takes, or does not take, a loan application.

(1) Taking an application includes: receiving information provided in connection with a request for a loan to be used to determine whether the consumer qualifies for a loan, even if the employee:

(i) Has received the consumer's information indirectly in order to make an offer or negotiate a loan;

(ii) Is not responsible for verifying information;

(iii) Is inputting information into an online application or other automated system on behalf of the consumer; or

(iv) Is not engaged in approval of the loan, including determining whether the consumer qualifies for the loan.

(2) Taking an application does not include any of the following activities performed solely or in combination:

(i) Contacting a consumer to verify the information in the loan application by obtaining documentation, such as tax returns or payroll receipts;

(ii) Receiving a loan application through the mail and forwarding it, without review, to loan approval personnel;

(iii) Assisting a consumer who is filling out an application by clarifying what type of information is necessary for the application or otherwise explaining the qualifications or criteria necessary to obtain a loan product;

(iv) Describing the steps that a consumer would need to take to provide information to be used to determine whether the consumer qualifies for a loan or otherwise explaining the loan application process;

(v) In response to an inquiry regarding a prequalified offer that a consumer has received from a Farm Credit System institution, collecting only basic identifying information about the consumer and forwarding the consumer to a mortgage loan originator; or

(vi) Receiving information in connection with a modification to the terms of an existing loan to a borrower as part of the Farm Credit System institution's loss mitigation efforts when the borrower is reasonably likely to default.

(b) *Offering or negotiating terms of a loan.* The following examples are designed to

illustrate when an employee offers or negotiates terms of a loan, and conversely, what does not constitute offering or negotiating terms of a loan.

(1) Offering or negotiating the terms of a loan includes:

(i) Presenting a loan offer to a consumer for acceptance, either verbally or in writing, including, but not limited to, providing a disclosure of the loan terms after application under the Truth in Lending Act, even if:

(A) Further verification of information is necessary;

(B) The offer is conditional;

(C) Other individuals must complete the loan process; or

(D) Only the rate approved by the Farm Credit System institution's loan approval mechanism function for a specific loan product is communicated without authority to negotiate the rate.

(ii) Responding to a consumer's request for a lower rate or lower points on a pending loan application by presenting to the consumer a revised loan offer, either verbally or in writing, that includes a lower interest rate or lower points than the original offer.

(2) Offering or negotiating terms of a loan does not include solely or in combination:

(i) Providing general explanations or descriptions in response to consumer queries regarding qualification for a specific loan product, such as explaining loan terminology (*i.e.,* debt-to-income ratio); lending policies (*i.e.,* the loan-to-value ratio policy of the Farm Credit System institution); or product-related services;

(ii) In response to a consumer's request, informing a consumer of the loan rates that are publicly available, such as on the Farm Credit System institution's Web site, for specific types of loan products without communicating to the consumer whether qualifications are met for that loan product;

(iii) Collecting information about a consumer in order to provide the consumer with information on loan products for which the consumer generally may qualify, without presenting a specific loan offer to the consumer for acceptance, either verbally or in writing;

(iv) Arranging the loan closing or other aspects of the loan process, including communicating with a consumer about those arrangements, provided that communication with the consumer only verifies loan terms already offered or negotiated;

(v) Providing a consumer with information unrelated to loan terms, such as the best days of the month for scheduling loan closings at the Farm Credit System institution;

(vi) Making an underwriting decision about whether the consumer qualifies for a loan;

(vii) Explaining or describing the steps or process that a consumer would need to take in order to obtain a loan offer, including qualifications or criteria that would need to be met without providing guidance specific to that consumer's circumstances; or

(viii) Communicating on behalf of a mortgage loan originator that a written offer, including disclosures provided pursuant to the Truth in Lending Act, has been sent to a consumer without providing any details of that offer.

(c) *Offering or negotiating a loan for compensation or gain.* The following examples illustrate when an employee does or does not offer or negotiate terms of a loan "for compensation or gain."

(1) Offering or negotiating terms of a loan for compensation or gain includes engaging in any of the activities in paragraph (b)(1) of this Appendix in the course of carrying out employment duties, even if the employee does not receive a referral fee or commission or other special compensation for the loan.

(2) Offering or negotiating terms of a loan for compensation or gain does not include engaging in a seller-financed transaction for the employee's personal property that does not involve the Farm Credit System institution.

National Credit Union Administration

12 CFR Chapter VII

Authority and Issuance

■ For the reasons stated in the preamble, the National Credit Union Administration amends chapter VII of title 12 of the Code of Federal Regulations as follows:

PART 741—REQUIREMENTS FOR INSURANCE

■ 1. The authority citation for part 741 continues to read as follows:

Authority: 12 U.S.C. 1757, 1766, 1781–1790, and 1790d.

■ 2. Add a new § 741.223 to subpart B to read as follows:

§ 741.223 Registration of residential mortgage loan originators.

Any credit union which is insured pursuant to Title II of the Act must adhere to the requirements stated in part 761 of this chapter.

■ 3. Add a new part 761 to subchapter A to read as follows:

PART 761—REGISTRATION OF RESIDENTIAL MORTGAGE LOAN ORIGINATORS

Sec.

761.101 Authority, purpose, and scope.
761.102 Definitions.
761.103 Registration of mortgage loan originators.
761.104 Policies and procedures.
761.105 Use of unique identifier.
Appendix A to Part 761—Examples of Mortgage Loan Originator Activities.

Authority: 12 U.S.C. 1751 *et seq.* and 5101 *et seq.*

PART 761—REGISTRATION OF RESIDENTIAL MORTGAGE LOAN ORIGINATORS

§ 761.101 Authority, purpose, and scope.

(a) *Authority.* This part is issued pursuant to the Secure and Fair Enforcement for Mortgage Licensing Act of 2008, title V of the Housing and Economic Recovery Act of 2008 (S.A.F.E. Act) (Pub. L. 110–289, 122 Stat. 2654, 12 U.S.C. 5101 *et seq.*).

(b) *Purpose.* This part implements the S.A.F.E. Act's Federal registration requirement for mortgage loan originators. The S.A.F.E. Act provides that the objectives of this registration include aggregating and improving the flow of information to and between regulators; providing increased accountability and tracking of mortgage loan originators; enhancing member protections; reducing fraud in the residential mortgage loan origination process; and providing members with easily accessible information at no charge regarding the employment history of, and publicly adjudicated disciplinary and enforcement actions against, mortgage loan originators.

(c) *Scope*—(1) *In general.* This part applies to any Federally insured credit union and its employees, including volunteers, who act as mortgage loan originators. This part also applies to non-Federally insured credit unions and their employees, including volunteers, who act as mortgage loan originators, subject to the conditions in paragraph (c)(3) of this section.

(2) *Exception.* (i) This part and the requirements of 12 U.S.C. 5104(a)(1)(A) and (2) of the S.A.F.E. Act do not apply to any employee of a credit union who has never been registered or licensed through the Registry as a mortgage loan originator if during the past 12 months the employee acted as a mortgage loan originator for 5 or fewer residential mortgage loans.

(ii) Prior to engaging in mortgage loan origination activity that exceeds the exception limit in paragraph (c)(2)(i) of this section, a credit union employee must register with the Registry pursuant to this part.

(iii) *Evasion.* Credit unions are prohibited from engaging in any act or practice to evade the limits of the *de minimis* exception set forth in paragraph (c)(2)(i) of this section.

(3) *For non-Federally insured credit unions.* Non-Federally insured credit unions and their employees who are mortgage loan originators may register under this rule only if:

(i) The appropriate State supervisory authorities where non-Federally insured credit unions are located enter into a Memorandum of Understanding (MOU) with the National Credit Union Administration on or before the date NCUA provides in a public notice that the Registry is accepting initial registrations.

(ii) The MOU may require non-Federally insured credit unions to pay various fees related to oversight costs and registration costs for the non-

Federally insured credit unions' mortgage loan originators.

(iii) Any Nationwide Mortgage Licensing System and Registry listing of a non-Federally insured credit union and its employees must contain a clear and conspicuous statement that the non-Federally insured credit union is not insured by the National Credit Union Share Insurance Fund.

(iv) If any State supervisory authority where non-Federally insured credit unions are located fails to enter into or maintain an agreement with the National Credit Union Administration for this registration process and oversight, the non-Federally insured credit unions and their employees in that State cannot register or maintain registration under the Federal system. They instead must use the appropriate State licensing and registration system, or if the State does not have such a system, the licensing and registration system established by the Department of Housing and Urban Department (HUD) for mortgage loan originators and their employees.

§ 761.102 Definitions.

For purposes of this part, the following definitions apply:

(a) *Annual renewal period* means November 1 through December 31 of each year.

(b)(1) *Mortgage loan originator*[1] means an individual who:

(i) Takes a residential mortgage loan application; and

(ii) Offers or negotiates terms of a residential mortgage loan for compensation or gain.

(2) The term *mortgage loan originator* does not include:

(i) An individual who performs purely administrative or clerical tasks on behalf of an individual who is described in paragraph (b)(1) of this section;

(ii) An individual who only performs real estate brokerage activities (as defined in 12 U.S.C. 5102(3)(D)) and is licensed or registered as a real estate broker in accordance with applicable State law, unless the individual is compensated by a lender, a mortgage broker, or other mortgage loan originator or by any agent of such lender, mortgage broker, or other mortgage loan originator, and meets the definition of mortgage loan originator in paragraph (b)(1) of this section; or

(iii) An individual or entity solely involved in extensions of credit related to timeshare plans, as that term is defined in 11 U.S.C. 101(53D).

(3) *Administrative or clerical tasks* means the receipt, collection, and distribution of information common for the processing or underwriting of a loan in the residential mortgage industry and communication with a member to obtain information necessary for the processing or underwriting of a residential mortgage loan.

(c) *Nationwide Mortgage Licensing System and Registry* or *Registry* means the system developed and maintained by the Conference of State Bank Supervisors and the American Association of Residential Mortgage Regulators for the State licensing and registration of State-licensed mortgage loan originators and the registration of mortgage loan originators pursuant to 12 U.S.C. 5107.

(d) *Registered mortgage loan originator* or *registrant* means any individual who:

(1) Meets the definition of mortgage loan originator and is an employee of a credit union; and

(2) Is registered pursuant to this part with, and maintains a unique identifier through, the Registry.

(e) *Residential mortgage loan* means any loan primarily for personal, family, or household use that is secured by a mortgage, deed of trust, or other equivalent consensual security interest on a dwelling (as defined in section 103(v) of the Truth in Lending Act, 15 U.S.C. 1602(v)) or residential real estate upon which is constructed or intended to be constructed a dwelling, and includes refinancings, reverse mortgages, home equity lines of credit and other first and additional lien loans that meet the qualifications listed in this definition.

(f) *Unique identifier* means a number or other identifier that:

(1) Permanently identifies a registered mortgage loan originator;

(2) Is assigned by protocols established by the Nationwide Mortgage Licensing System and Registry, the Federal banking agencies, and the Farm Credit Administration to facilitate:

(i) Electronic tracking of mortgage loan originators; and

(ii) Uniform identification of, and public access to, the employment history of and the publicly adjudicated disciplinary and enforcement actions against mortgage loan originators; and

(3) Must not be used for purposes other than those set forth under the S.A.F.E. Act.

§ 761.103 Registration of mortgage loan originators.

(a) *Registration requirement*—(1) *Employee registration.* Each employee of a credit union who acts as a mortgage loan originator must register with the Registry, obtain a unique identifier, and maintain this registration in accordance with the requirements of this part. Any such employee who is not in compliance with the registration and unique identifier requirements set forth in this part is in violation of the S.A.F.E. Act and this part.

(2) *Credit union requirement*—(i) *In general.* A credit union that employs one or more individuals who act as a residential mortgage loan originator must require each employee who is a mortgage loan originator to register with the Registry, maintain this registration, and obtain a unique identifier in accordance with the requirements of this part.

(ii) *Prohibition.* A credit union must not permit an employee of the credit union who is subject to the registration requirements of this part to act as a mortgage loan originator for the credit union unless such employee is registered with the Registry pursuant to this part.

(3) *Implementation period for initial registration.* An employee of a credit union who is a mortgage loan originator must complete an initial registration with the Registry pursuant to this part within 180 days from the date that the NCUA provides in a public notice that the Registry is accepting registrations.

(4) *Employees previously registered or licensed through the Registry*—(i) *In general.* If an employee of a credit union was registered or licensed through, and obtained a unique identifier from, the Registry and has maintained this registration or license before the employee becomes subject to this part at this credit union, then the registration requirements of the S.A.F.E. Act and this part are deemed to be met, provided that:

(A) The employment information in paragraphs (d)(1)(i)(C) and (d)(1)(ii) of this section is updated and the requirements of paragraph (d)(2) of this section are met;

(B) New fingerprints of the employee are submitted to the Registry for a background check, as required by paragraph (d)(1)(ix) of this section, unless the employee has fingerprints on file with the Registry that are less than 3 years old;

(C) The credit union information required in paragraphs (e)(1)(i) (to the extent the credit union has not previously met these requirements) and (e)(2)(i) of this section is submitted to the Registry; and

(D) The registration is maintained pursuant to paragraphs (b) and (e)(1)(ii) of this section, as of the date that the

[1] Appendix A of this part provides examples of activities that would, and would not, cause an employee to fall within the definition of mortgage loan originator.

employee is employed by the credit union.

(ii) *Rule for certain acquisitions, mergers, or reorganizations.* When registered or licensed mortgage loan originators become credit union employees as a result of an acquisition, merger, or reorganization, the requirements of paragraphs (a)(4)(i)(A), (C), and (D) of this section must be met within 60 days from the effective date of the acquisition, merger, or reorganization.

(b) *Maintaining registration.* (1) A mortgage loan originator who is registered with the Registry pursuant to paragraph (a) of this section must:

(i) Except as provided in paragraph (b)(3) of this section, renew the registration during the annual renewal period, confirming the responses set forth in paragraphs (d)(1)(i) through (viii) of this section remain accurate and complete, and updating this information, as appropriate; and

(ii) Update the registration within 30 days of any of the following events:

(A) A change in the name of the registrant;

(B) The registrant ceases to be an employee of the credit union; or

(C) The information required under paragraphs (d)(1)(iii) through (viii) of this section becomes inaccurate, incomplete, or out-of-date.

(2) A registered mortgage loan originator must maintain his or her registration, unless the individual is no longer engaged in the activity of a mortgage loan originator.

(3) The annual registration renewal requirement set forth in paragraph (b)(1) of this section does not apply to a registered mortgage loan originator who has completed his or her registration with the Registry pursuant to paragraph (a)(1) of this section less than 6 months prior to the end of the annual renewal period.

(c) *Effective dates*—(1) *Registration.* A registration pursuant to paragraph (a)(1) of this section is effective on the date the Registry transmits notification to the registrant that the registrant is registered.

(2) *Renewals or updates.* A renewal or update pursuant to paragraph (b) of this section is effective on the date the Registry transmits notification to the registrant that the registration has been renewed or updated.

(d) *Required employee information*—(1) *In general.* For purposes of the registration required by this section, a credit union must require each employee who is a mortgage loan originator to submit to the Registry, or must submit on behalf of the employee, the following categories of information, to the extent this information is collected by the Registry:

(i) Identifying information, including the employee's:

(A) Name and any other names used;

(B) Home address and contact information;

(C) Principal business location address and business contact information;

(D) Social security number;

(E) Gender; and

(F) Date and place of birth;

(ii) Financial services-related employment history for the 10 years prior to the date of registration or renewal, including the date the employee became an employee of the credit union;

(iii) Convictions of any criminal offense involving dishonesty, breach of trust, or money laundering against the employee or organizations controlled by the employee, or agreements to enter into a pretrial diversion or similar program in connection with the prosecution for such offense(s);

(iv) Civil judicial actions against the employee in connection with financial services-related activities, dismissals with settlements, or judicial findings that the employee violated financial services-related statutes or regulations, except for actions dismissed without a settlement agreement;

(v) Actions or orders by a State or Federal regulatory agency or foreign financial regulatory authority that:

(A) Found the employee to have made a false statement or omission or been dishonest, unfair or unethical; to have been involved in a violation of a financial services-related regulation or statute; or to have been a cause of a financial services-related business having its authorization to do business denied, suspended, revoked, or restricted;

(B) Are entered against the employee in connection with a financial services-related activity;

(C) Denied, suspended, or revoked the employee's registration or license to engage in a financial services-related activity; disciplined the employee or otherwise by order prevented the employee from associating with a financial services-related business or restricted the employee's activities; or

(D) Barred the employee from association with an entity or its officers regulated by the agency or authority or from engaging in a financial services-related business;

(vi) Final orders issued by a State or Federal regulatory agency or foreign financial regulatory authority based on violations of any law or regulation that prohibits fraudulent, manipulative, or deceptive conduct;

(vii) Revocation or suspension of the employee's authorization to act as an attorney, accountant, or State or Federal contractor;

(viii) Customer-initiated financial services-related arbitration or civil action against the employee that required action, including settlements, or which resulted in a judgment; and

(ix) Fingerprints of the employee, in digital form if practicable, and any appropriate identifying information for submission to the Federal Bureau of Investigation and any governmental agency or entity authorized to receive such information in connection with a State and national criminal history background check; however, fingerprints provided to the Registry that are less than 3 years old may be used to satisfy this requirement.

(2) *Employee authorization and attestation.* An employee registering as a mortgage loan originator or renewing or updating his or her registration under this part, and not the employing credit union or other employees of the credit union, must:

(i) Authorize the Registry and the employing institution to obtain information related to sanctions or findings in any administrative, civil, or criminal action, to which the employee is a party, made by any governmental jurisdiction;

(ii) Attest to the correctness of all information required by paragraph (d) of this section, whether submitted by the employee or on behalf of the employee by the employing credit union; and

(iii) Authorize the Registry to make available to the public information required by paragraphs (d)(1)(i)(A) and (C), and (d)(1)(ii) through (viii) of this section.

(3) *Submission of information.* A credit union may identify one or more employees of the credit union who may submit the information required by paragraph (d)(1) of this section to the Registry on behalf of the credit union's employees provided that this individual, and any employee delegated such authority, does not act as a mortgage loan originator, consistent with (e)(1)(i)(F) of this section. In addition, a credit union may submit to the Registry some or all of the information required by paragraphs (d)(1) and (e)(2) of this section for multiple employees in bulk through batch processing in a format to be specified by the Registry, to the extent such batch processing is made available by the Registry.

(e) *Required credit union information.* A credit union must submit the following categories of information to the Registry:

(1) *Credit union record.* (i) In connection with the registration of one or more mortgage loan originators:

(A) Name, main office address, and business contact information;

(B) Internal Revenue Service Employer Tax Identification Number (EIN);

(C) Research Statistics Supervision and Discount (RSSD) number, as issued by the Board of Governors of the Federal Reserve System;

(D) Identification of its primary Federal regulator;

(E) Name(s) and contact information of the individual(s) with authority to act as the credit union's primary point of contact for the Registry;

(F) Name(s) and contact information of the individual(s) with authority to enter the information required by paragraphs (d)(1) and (e) of this section to the Registry and who may delegate this authority to other individuals. For the purpose of providing information required by paragraph (e) of this section, this individual and their delegates must not act as mortgage loan originators unless the credit union has 10 or fewer full time or equivalent employees.

(ii) *Attestation.* The individual(s) identified in paragraphs (e)(1)(i)(E) and (F) of this section must comply with Registry protocols to verify their identity and must attest that they have the authority to enter data on behalf of the credit union, that the information provided to the Registry pursuant to this paragraph (e) is correct, and that the credit union will keep the information required by this paragraph (e) current and will file accurate supplementary information on a timely basis.

(iii) A credit union must update the information required by this paragraph (e) of this section within 30 days of the date that this information becomes inaccurate.

(iv) A credit union must renew the information required by paragraph (e) of this section on an annual basis.

(2) *Employee information.* In connection with the registration of each employee who acts as a mortgage loan originator:

(i) After the information required by paragraph (d) of this section has been submitted to the Registry, confirmation that it employs the registrant; and

(ii) Within 30 days of the date the registrant ceases to be an employee of the credit union, notification that it no longer employs the registrant and the date the registrant ceased being an employee.

§ 761.104 Policies and procedures.

A credit union that employs one or more mortgage loan originators must adopt and follow written policies and procedures designed to assure compliance with this part. These policies and procedures must be appropriate to the nature, size, complexity, and scope of the mortgage lending activities of the credit union, and apply only to those employees acting within the scope of their employment at the credit union. At a minimum, these policies and procedures must:

(a) Establish a process for identifying which employees of the credit union are required to be registered mortgage loan originators;

(b) Require that all employees of the credit union who are mortgage loan originators be informed of the registration requirements of the S.A.F.E. Act and this part and be instructed on how to comply with such requirements and procedures;

(c) Establish procedures to comply with the unique identifier requirements in § 761.105;

(d) Establish reasonable procedures for confirming the adequacy and accuracy of employee registrations, including updates and renewals, by comparisons with its own records;

(e) Establish reasonable procedures and tracking systems for monitoring compliance with registration and renewal requirements and procedures;

(f) Provide for independent testing for compliance with this part to be conducted at least annually by credit union personnel or by an outside party;

(g) Provide for appropriate action in the case of any employee who fails to comply with the registration requirements of the S.A.F.E. Act, this part, or the credit union's related policies and procedures, including prohibiting such employees from acting as mortgage loan originators or other appropriate disciplinary actions;

(h) Establish a process for reviewing employee criminal history background reports received pursuant to this part, taking appropriate action consistent with applicable Federal law, including section 206 of the Federal Credit Union Act (12 U.S.C. 1786(i)) and implementing regulations with respect to these reports, and maintaining records of these reports and actions taken with respect to applicable employees; and

(i) Establish procedures designed to ensure that any third party with which the credit union has arrangements related to mortgage loan origination has policies and procedures to comply with the S.A.F.E. Act, including appropriate licensing and/or registration of individuals acting as mortgage loan originators.

§ 761.105 Use of unique identifier.

(a) The credit union shall make the unique identifier(s) of its registered mortgage loan originator(s) available to members in a manner and method practicable to the credit union.

(b) A registered mortgage loan originator shall provide his or her unique identifier to a member:

(1) Upon request;

(2) Before acting as a mortgage loan originator; and

(3) Through the originator's initial written communication with a member, if any, whether on paper or electronically.

Appendix A to Part 761—Examples of Mortgage Loan Originator Activities

This Appendix provides examples to aid in the understanding of activities that would cause an employee of a credit union to fall within or outside the definition of mortgage loan originator. The examples in this Appendix are not all inclusive. They illustrate only the issue described and do not illustrate any other issues that may arise under this part. For the purposes of the examples below, the term "loan" refers to a residential mortgage loan.

(a) *Taking a loan application.* The following examples illustrate when an employee takes, or does not take, a loan application.

(1) Taking an application includes: receiving information provided in connection with a request for a loan to be used to determine whether the member qualifies for a loan, even if the employee:

(i) Has received the member's information indirectly in order to make an offer or negotiate a loan;

(ii) Is not responsible for further verification of information;

(iii) Is inputting information into an online application or other automated system on behalf of the member; or

(iv) Is not engaged in approval of the loan, including determining whether the member qualifies for the loan.

(2) Taking an application does not include any of the following activities performed solely or in combination:

(i) Contacting a member to verify the information in the loan application by obtaining documentation, such as tax returns or payroll receipts;

(ii) Receiving a loan application through the mail and forwarding it, without review, to loan approval personnel;

(iii) Assisting a member who is filling out an application by clarifying what type of information is necessary for the application or otherwise explaining the qualifications or criteria necessary to obtain a loan product;

(iv) Describing the steps that a member would need to take to provide information to be used to determine whether the member qualifies for a loan or otherwise explaining the loan application process;

(v) In response to an inquiry regarding a prequalified offer that a member has received from a credit union, collecting only basic identifying information about the member

and forwarding the member to a loan originator; or

(vi) Receiving information in connection with a modification to the terms of an existing loan to a borrower as part of the credit union's loss mitigation efforts when the borrower is reasonably likely to default.

(b) *Offering or negotiating terms of a loan.* The following examples are designed to illustrate when an employee offers or negotiates terms of a loan, and conversely, what does not constitute offering or negotiating terms of a loan.

(1) Offering or negotiating the terms of a loan includes:

(i) Presenting a loan offer to a member for acceptance, either verbally or in writing, including, but not limited to, providing a disclosure of the loan terms after application under the Truth in Lending Act, even if:

(A) Further verification of information is necessary;

(B) The offer is conditional;

(C) Other individuals must complete the loan process; or

(D) Only the rate approved by the credit union's loan approval mechanism function for a specific loan product is communicated without authority to negotiate the rate.

(ii) Responding to a member's request for a lower rate or lower points on a pending loan application by presenting to the member a revised loan offer, either verbally or in writing, that includes a lower interest rate or lower points than the original offer.

(2) Offering or negotiating terms of a loan does not include solely or in combination:

(i) Providing general explanations or descriptions in response to member queries regarding qualification for a specific loan product, such as explaining loan terminology (*i.e.,* debt-to-income ratio); lending policies (*i.e.,* the loan-to-value ratio policy of the credit union); or product-related services;

(ii) In response to a member's request, informing a member of the loan rates that are publicly available, such as on the credit union's Web site, for specific types of loan products without communicating to the member whether qualifications are met for that loan product;

(iii) Collecting information about a member in order to provide the member with information on loan products for which the member generally may qualify, without presenting a specific loan offer to the member for acceptance, either verbally or in writing;

(iv) Arranging the loan closing or other aspects of the loan process, including communicating with a member about those arrangements, provided that communication with the member only verifies loan terms already offered or negotiated;

(v) Providing a member with information unrelated to loan terms, such as the best days of the month for scheduling loan closings at the credit union;

(vi) Making an underwriting decision about whether the member qualifies for a loan;

(vii) Explaining or describing the steps or process that a member would need to take in order to obtain a loan offer, including qualifications or criteria that would need to be met without providing guidance specific to that member's circumstances; or

(viii) Communicating on behalf of a mortgage loan originator that a written offer, including disclosures provided pursuant to the Truth in Lending Act, has been sent to a member without providing any details of that offer.

(c) *Offering or negotiating a loan for compensation or gain.* The following examples illustrate when an employee does or does not offer or negotiate terms of a loan "for compensation or gain."

(1) Offering or negotiating terms of a loan for compensation or gain includes engaging in any of the activities in paragraph (b)(1) of this Appendix in the course of carrying out employment duties, even if the employee does not receive a referral fee or commission or other special compensation for the loan.

(2) Offering or negotiating terms of a loan for compensation or gain does not include engaging in a seller-financed transaction for the employee's personal property that does not involve the credit union.

Dated: December 23, 2009.

John C. Dugan,

Comptroller of the Currency.

By order of the Board of Governors of the Federal Reserve System, July 13, 2010.

Jennifer J. Johnson,

Secretary of the Board.

By order of the Board of Directors.

Dated at Washington, DC the 14th day of July, 2010.

Robert E. Feldman,

Executive Secretary,

Federal Deposit Insurance Corporation.

Dated: May 12, 2010.

By the Office of Thrift Supervision.

John E. Bowman,

Acting Director.

Dated: April 15, 2010.

Roland E. Smith,

Secretary, Farm Credit Administration Board.

Dated: April 10, 2010.

Mary F. Rupp,

Secretary to the Board, National Credit Union Administration.

Editorial Note: This document was received in the Office of the Federal Register on July 20, 2010.

[FR Doc. 2010–18148 Filed 7–27–10; 8:45 am]

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