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WHEN: Tuesday, February 22, 2011
9 a.m.–12:30 p.m.

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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.

DEPARTMENT OF AGRICULTURE

Animal and Plant Health Inspection Service

7 CFR Part 301

[Docket No. APHIS–2009–0098]

Emerald Ash Borer; Addition of Quarantined Areas in Kentucky, Michigan, Minnesota, New York, Pennsylvania, West Virginia, and Wisconsin

AGENCY: Animal and Plant Health Inspection Service, USDA.

ACTION: Affirmation of interim rule as final rule.

SUMMARY: We are adopting as a final rule, without change, an interim rule that amended the emerald ash borer regulations by adding portions of Kentucky, Michigan, Minnesota, New York, Pennsylvania, Wisconsin, and the entire State of West Virginia to the list of quarantined areas. This interim rule, which restricted the interstate movement of regulated articles from those areas, was necessary to prevent the artificial spread of the emerald ash borer to noninfested areas of the United States.

DATES: Effective on February 2, 2011, we are adopting as final the interim rule published at 75 FR 29189 on May 25, 2010.

FOR FURTHER INFORMATION CONTACT: Mr. Paul Chaloux, Emergency and Domestic Programs, PPQ, APHIS, 4700 River Road Unit 134, Riverdale, MD 20737–1231; (301) 734–0917.

SUPPLEMENTARY INFORMATION:

Background

The emerald ash borer (EAB) (*Agrilus planipennis*) is a destructive wood-boring insect that attacks ash trees (*Fraxinus* spp., including green ash, white ash, black ash, and several horticultural varieties of ash). The insect, which is indigenous to Asia and known to occur in China, Korea, Japan, Mongolia, the Russian Far East, Taiwan, and Canada, eventually kills healthy ash trees after it bores beneath their bark and disrupts their vascular tissues.

Although EAB adults have been known to fly as much as one-half mile from one tree to the next, the pest can also spread when infested nursery trees, logs, or firewood are transported from one region to the next. Ash trees are valuable to the commercial timber industry and are commonly planted in urban areas.

In an interim rule [1] effective and published in the **Federal Register** on May 25, 2010 (75 FR 29189–29191, Docket No. APHIS–2009–0098), we amended the EAB regulations in 7 CFR part 301 by adding areas in Kentucky, Michigan, Minnesota, New York, Pennsylvania, Wisconsin, and the entire state of West Virginia to the list of quarantined areas.

Comments on the interim rule were required to be received on or before July 26, 2010. We did not receive any comments. Therefore, for the reasons given in the interim rule, we are adopting the interim rule as a final rule without change.

This action also affirms the information contained in the interim rule concerning Executive Orders 12866, 12372, and 12988, and the Paperwork Reduction Act.

Further, for this action, the Office of Management and Budget has waived its review under Executive Order 12866.

Regulatory Flexibility Act

This action affirms an interim rule that amended the EAB regulations to expand the quarantine area to include an additional 21 counties in Kentucky, 3 counties in Michigan, 2 counties in Minnesota, 2 counties in New York, 5 counties in Pennsylvania, 5 counties in Wisconsin, and the entire State of West Virginia. Prior to this regulation, one county in Minnesota, six counties in Pennsylvania, six counties in Wisconsin, and one county in West Virginia were under quarantine. The interim rule helped to protect uninfested areas from further spread of EAB.

In accordance with 5 U.S.C. 604, we have performed a final regulatory flexibility analysis, which is summarized below, regarding the economic effects of this rule on small entities. Copies of the full analysis are available on the Regulations.gov Web site (see footnote 1 in this document for a link to Regulations.gov) or by contacting the person listed under **FOR FURTHER INFORMATION CONTACT**.

If left unregulated, the spread of EAB could negatively impact several industries including nurseries, timber operations, and landscaping. These potential economic impacts would likely be much greater than government program costs and any additional costs incurred from the expansion of the quarantine area. While some firms may have been negatively affected by the interim rule, those effects will be limited to those firms that ship regulated products interstate or from quarantined areas to areas that are not under quarantine. Such firms will be required to obtain a certificate or limited permit from an APHIS inspector in order to comply with the regulation or enter into a compliance agreement with APHIS for the inspection and certification of the articles to be moved. Additional restrictions on movement during adult fly season (roughly May through September) may result in additional impacts on entities in some quarantined counties. Limited information was available on the extent to which firms in the potentially affected industries deal in ash products.

List of Subjects in 7 CFR Part 301

Agricultural commodities, Plant diseases and pests, Quarantine, Reporting and recordkeeping requirements, Transportation.

PART 301—DOMESTIC QUARANTINE NOTICES

■ Accordingly, we are adopting as final, without change, the interim rule that amended 7 CFR part 301 and that was published at 75 FR 29189 on May 25, 2010.

Done in Washington, DC, this 27th day of January 2011.

Kevin Shea,

Acting Administrator, Animal and Plant Health Inspection Service.

[FR Doc. 2011–2234 Filed 2–1–11; 8:45 am]

BILLING CODE 3410–34–P

[1] To view the interim rule, go to *http://www.regulations.gov/fdmspublic/component/main?main=DocketDetail&d=APHIS-2009-0098.*

SMALL BUSINESS ADMINISTRATION

13 CFR Parts 121, 124, 125, 126, and 134

RIN 3245–AF65

Small Business, Small Disadvantaged Business, HUBZone, and Service-Disabled Veteran-Owned Business Status Protest and Appeal Regulations.

AGENCY: U.S. Small Business Administration.

ACTION: Final rule.

SUMMARY: The U.S. Small Business Administration (SBA or Agency) is amending its regulations to clarify the effect, across all small business programs, of initial and appeal eligibility decisions on the procurement in question; increase the amount of time that SBA has to render formal size determinations; require that SBA's Office of Hearings and Appeals (OHA) issue a size appeal decision within 60 calendar days of the close of the record, if possible; increase the amount of time that SBA has to file North American Industry Classification System (NAICS) code appeals; alter the NAICS code appeal procedures to comply with a Federal Court decision; clarify that contracting officers must reflect final agency eligibility decisions in Federal procurement databases and goaling statistics; and make other changes to size status protest and appeal rules.

DATES: *Effective date:* March 4, 2011. *Applicability date*: The amendments to 13 CFR 121.402(b), 121.404(a), and 121.407 apply to solicitations issued on or after March 4, 2011.

FOR FURTHER INFORMATION CONTACT: Jon Haitsuka, Program Analyst, Office of Size Standards, Office of Government Contracting, (202) 401–1420 or *jon.haitsuka@sba.gov.*

SUPPLEMENTARY INFORMATION: On March 1, 2010, SBA published a proposed rule in the **Federal Register** (75 FR 9129) to clarify the effect, across all small business programs, of initial and appeal eligibility decisions on the procurement in question; increase the amount of time that SBA has to render formal size determinations; require that SBA's OHA issue a size appeal decision within 60 calendar days of the close of the record, if possible; increase the amount of time that SBA has to file NAICS code appeals; alter the NAICS code appeal procedures to comply with a Federal Court decision; clarify that contracting officers must reflect final agency eligibility decisions in Federal procurement databases and goaling statistics; clarify how a contracting officer assigns a NAICS code and size standard to a multiple award procurement; and make other changes to status protest and appeal rules.

SBA received comments from four individuals or entities in response to the proposed rule. The comments, as well as SBA's response to them, are discussed below. For a section-by-section analysis of the revised Parts 121, 124, 125, 126, and 134, see the supplementary information published as part of the proposed rule (75 FR 9129).

Analysis of Comments Received

SBA received three supportive comments concerning its proposed removal of the second sentence of paragraph 121.404(a), which required recertification if a procuring agency modifies a solicitation to such an extent that original offers are no longer responsive. All three commenters maintained that it is unfair to disqualify a firm from consideration after the firm has spent a great deal of time and resources pursuing a contract opportunity that it was eligible for at the time of its initial offer including price. The commenters also noted that the current rule reduces competition by eliminating offerors, which is not necessarily in the best interests of the procuring agency. As we explained in the proposed rule, if a requirement changes so much that it is essentially new, the agency should cancel the solicitation and issue a new solicitation and open the competition up to all eligible offerors. In that case, size will be determined as of the date of the initial offer including price in response to the new solicitation. Consequently, SBA has adopted its proposed rule.

Two commenters supported SBA's proposed amendment of § 121.407 to address the assignment of NAICS codes and corresponding size standards to task or delivery order contracts with contract line item numbers (CLINs) for divergent goods and services. One commenter found the proposed rule confusing and suggested requiring NAICS codes and size standards for orders with a value above $500,000. On September 27, 2010, Congress enacted the Small Business Jobs Act of 2010, Pub. L. No. 111–240, 124 Stat. 2504 (Jobs Act), which contained several provisions addressing small business contracting in the context of multiple award contracts. Consequently, we have decided to address the issue of assignment of NAICS codes and size standards to multiple award contracts when we address all of the statutory provisions of the Jobs Act that pertain to multiple award contracts, to ensure that multiple award small business contracting is addressed in a holistic manner.

Several commenters supported SBA's proposed amendment of § 121.1009 to allow itself more time to decide size protests. One commenter suggested that SBA use calendar days instead of business days. SBA has historically used business days to measure timeframes concerning protest filing and processing. Consequently, SBA has retained business days to measure status protest determination timeframes, and has not adopted the commenter's suggestion.

Several commenters supported SBA's proposed amendment of §§ 121.1009, 124.1013, 125.27, 126.803, and 134.504 to address the effect of status determinations on the procurement in question. However, two commenters did not support the provision which addresses situations where a contracting officer withholds award, SBA finds the protested concern to be eligible, the procuring agency then awards to that concern, and the initial determination is subsequently overturned on appeal. In that circumstance, the contracting officer may take some action based on the appellate decision, but is not required to do so. One commenter also noted the possibility that a firm found to be ineligible as a result of a formal size determination could successfully challenge the decision on appeal, yet not be awarded the contract. Both of these outcomes are consistent with the regulatory framework which has been in place for many years. The existing framework provides contracting officers with an incentive to withhold award until SBA renders a formal size determination. If SBA issues a formal size determination finding an apparent successful offeror to be small, the agency may proceed with award, even if an appeal is filed. Similarly, if SBA finds an apparent successful offeror to be other than small, the agency may proceed with award to another offeror, even if an appeal is filed. Size appeals can take several months or more to resolve, and agencies typically cannot delay their procurements for months and await an appeal decision. Consequently, SBA has never required contracting officers to apply appellate decisions to the procurement in question when the contracting officer waited for SBA's formal size determination and awarded to a concern based on SBA's formal size determination. If in all cases the contracting officer was required to take some action based on an appellate decision, regardless of whether the contracting officer withheld award and

waited for SBA's formal size determination, contracting officers would likely award before SBA issues a formal size determination, which could result in an increase in the number of ineligible firms performing the base terms of set-aside contracts. Similarly, if SBA issues a formal size determination finding the apparent successful offeror to be other than small and the contracting officer awards to another concern, it would be costly for the Government to have to terminate the award to an eligible concern based on an appellate decision finding the initial successful offeror to be eligible. Thus, SBA is adopting the proposed rule without modification.

One commenter supported SBA's proposed amendment of § 134.316 to require OHA to issue a NAICS code appeal decision within 15 calendar days of the close of the record. However, after further internal review and discussion SBA decided to remove the NAICS code appeal decision deadline. OHA prioritizes NAICS code appeals and issues decisions as soon as practicable, because of the time sensitive nature of such an appeal.

One commenter objected to SBA's proposed amendment of § 134.304 to allow SBA to file a NAICS code appeal at any time before offers are due. The commenter recommended that SBA be allowed to file a NAICS code appeal up to 15 calendar days before offers are due. However, the commenter's proposal would extend the deadline for an SBA NAICS code appeal by only five days in many cases, since offers are often due 30 days after issuance of a solicitation and SBA currently must file a NAICS code appeal within 10 calendar days of issuance of a solicitation. As SBA stated in the preamble of the proposed rule, SBA often does not find out about egregious NAICS codes and/or size standard designations until well after the solicitation has been issued. SBA anticipates that it will file relatively few NAICS code and size standard appeals, but needs to be able to intervene to stop clear-cut abuses. Thus, SBA is adopting the proposed rule without modification.

One commenter suggested that SBA should require firms to recertify their size prior to award and on an annual basis. The commenter suggested that procuring agencies should not exercise any option with a firm that is other than small. This comment is beyond the scope of this rule. SBA considered these issues when it issued its recertification rule (71 FR 66434), and believes requiring such action could seriously disrupt the procurement process and result in unacceptable costs for procuring agencies and contractors. SBA notes that recertification is required in all cases where there is an acquisition, merger or novation and, for long-term contracts, prior to the sixth year and prior to each option thereafter (see § 121.404(g)).

Compliance With Executive Orders 12866, 12988, 13132, the Paperwork Reduction Act (44 U.S.C. Ch. 35), and the Regulatory Flexibility Act (5 U.S.C. 601–612), Executive Order 12866

The Office of Management and Budget (OMB) has determined that this final rule is a significant regulatory action for purposes of Executive Order 12866. Accordingly, the next section contains SBA's Regulatory Impact Analysis. This is not a major rule, however, under the Congressional Review Act, 5 U.S.C. 800.

Regulatory Impact Analysis

1. *Is there a need for the regulatory action?*

SBA's mission is to aid and assist small businesses through a variety of financial, procurement, business development, and advocacy programs. To effectively assist the intended beneficiaries of these programs, SBA must establish distinct definitions of which businesses are deemed small businesses. The Small Business Act (15 U.S.C. 632(a)) delegates the responsibility for establishing small business definitions to SBA's Administrator. This act also provides SBA with the authority to determine which businesses are small businesses concerns (15 U.S.C. 637(b)(1)(G)(6)). The supplementary information section of the proposed and final rule explains SBA's reasons for revising the size protest and appeal timeframes and application of final decisions on size and other small business status determinations. SBA believes that these changes are needed to provide clarity to procuring agencies and contractors.

2. *What are the potential benefits and costs of this regulatory action?*

SBA believes that more realistic timeframes for filing and rendering decisions on size protest and NAICS code appeal cases will improve the functioning of the size protest and size determination processes. Small businesses will have a sufficient time in which to raise size and NAICS classification issues and SBA will have more time, if needed, to prepare thorough decisions.

The final provisions may have cost implications associated with delays to the contracting process. Contracting officers may have to wait an additional five business days in some cases before SBA renders a size determination. However, contracting officers are already generally required to withhold award for 15 days for a Historically Underutilized Business Zone (HUBZone), Small Disadvantaged Business (SDB), or Service-Disabled Veteran-Owned (SDVO) status protest. SBA believes that the potential costs associated with delays in the contracting process are relatively minor and are significantly outweighed by the benefits to the integrity of small business procurement programs and the intended beneficiaries.

3. *What are the alternatives to this final rule?*

SBA considered as an alternative completing size determinations within 10 business days of receiving all requested information from the protested concern. Although this would also achieve the objective of this final rule, it would create uncertainty as to when a size determination would actually be rendered. If the necessary information requested of a business is received within the three-day period requested by SBA, a size determination will be completed within 13 days. However, if the protested concern submits incomplete information, the size determination period will vary depending on the circumstances. SBA believes a 15-day period is sufficient in most cases and provides a degree of certainty to contracting officers. It also reinforces the importance of promptly providing information to SBA.

Executive Order 12988

For purposes of Executive Order 12988, SBA has drafted this final rule, to the extent practicable, in accordance with the standards set forth in section 3(a) and 3(b)(2) of that Order, to minimize litigation, eliminate ambiguity, and reduce burden. This rule has no preemptive or retroactive effect.

Executive Order 13132

This rule does not have federalism implications as defined in Executive Order 13132. It will not have substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various layers of government, as specified in the order. As such, it does not warrant the preparation of a Federalism Assessment.

Paperwork Reduction Act

For the purpose of the Paperwork Reduction Act, 44 U.S.C. Ch. 35, SBA has determined that this final rule will not impose new reporting requirements nor will require new recordkeeping requirements.

Regulatory Flexibility Act

SBA has determined that this final rule could have a significant economic impact on a substantial number of small entities within the meaning of the Regulatory Flexibility Act (RFA), 5 U.S.C. 601–612. Therefore, SBA has prepared a Final Regulatory Flexibility Act (FRFA) analysis addressing this final rule.

FRFA

When preparing a Regulatory Flexibility Analysis, an agency shall address all of the following: the need for, and objectives of, the rule; the estimated number of small entities to which the rule may apply; the projected reporting, recordkeeping and other compliance requirements; steps taken to minimize the significant economic impact on small entities. This FRFA considers these points and the impact this final rule may have on small entities.

a. Need for, and Objectives of, the Rule

Under the Small Business Act, SBA is authorized to determine the size of a business entity. 15 U.S.C. 632. SBA's standards and definitions relating to formal size determinations and NAICS code designation for small business concerns are set forth in 13 CFR part 121. The rules for procedures governing cases before OHA are set forth in 13 CFR part 134.

SBA's regulations currently provide that SBA will issue a formal size determination within 10 working days of its receipt of a size protest, "if possible." 13 CFR 121.1009(e). The FAR currently provides that a contracting officer should withhold award for 10 business days after SBA's receipt of a size protest, after which time the contracting officer may proceed with award if "further delay would be disadvantageous to the Government." FAR 19.302(h)(2). The FAR further provides that a contracting officer need not withhold award if he or she determines in writing that award must be made to protect the public interest. FAR 19.302(h)(1).

After SBA receives a size protest it notifies the protested concern, and the protested concern is provided three business days to respond to the protest. Thus, SBA generally has only five business days to draft a formal size determination. In some cases, protested concerns ask for additional time to submit the requested information. In other cases, the information submitted by the protested concern leads the size specialist to request additional information. Size specialists typically have to sift through voluminous documentation before reaching a decision.

Current regulations provide SBA with 15 business days to decide socio-economic status protests, such as HUBZone, SDB and SDVO. 13 CFR 124.1013(a), 125.27(d), 126.803(b). Increasing the amount of time SBA has to make a size determination will allow size specialists adequate time to perform a thorough review and prepare a carefully constructed determination. Increasing the amount of time SBA has to render a formal size determination will also make SBA's regulations consistent and coherent across programs.

SBA's regulations currently do not address the amount of time OHA has to render a decision in connection with a size or NAICS code appeal. SBA is amending its regulations to require OHA to issue size appeal decisions within 60 business days of the close of the record, if possible, and render NAICS code appeal decision as soon as practicable.

The final rule will require the contracting officer to update Federal procurement databases to reflect final agency status determinations.

b. Estimate of the Number of Small Entities to Which the Rule May Apply

The RFA directs agencies to provide a description of and, where feasible, an estimate of the number of entities that may be affected by the final rule. The RFA defines "small entity" to include "small businesses," "small organizations," and "small governmental jurisdictions." SBA's programs do not apply to "small organizations" or "small governmental jurisdictions" because they are non-profit or governmental entities and do not qualify as "business concerns" within the meaning of SBA's regulations. SBA's programs apply only to for-profit business concerns. Therefore, this final rule (like the regulation currently in effect) will not impact small organizations or small governmental jurisdictions.

The final rule will have no direct negative impact on any small business concern, since it is aimed at preventing other than small concerns from receiving or performing contracts set aside for small business concerns. The final rule will indirectly benefit small business concerns by preventing awards to ineligible concerns, or shortening the length of time other than small concerns perform small business set-aside contracts. SBA maintains an internal database of all size protest processed by the agency and the following table was constructed to illustrate the number of protest processed in the last five fiscal years.

Size protests	FY 2005	FY 2006	FY 2007	FY 2008	FY 2009
Total Determinations Requested	459	593	451	493	488
Cases Dismissed	122	139	131	104	146
Determined Small Business	190	219	193	200	207
Determined Other Than Small	115	163	119	115	128
Cases in Process/Other Determinations	32	72	8	74	7

There are more than 330,000 concerns listed as small business concerns in the Dynamic Small Business Search of the Central Contractor Registration database. Based on data for fiscal years 2005–2009, SBA processes an average of nearly 500 size protests each fiscal year, resulting in 41 percent being determined to be small and 26 percent determined to be other than small. The rest are dismissed on procedural grounds. Thus, the number of concerns affected by this rule, regardless of size, will be approximately 330 per year, as compared to 330,000 small business concerns that are active in the Federal Government marketplace. The number of protests in other small business programs is significantly less than the numbers of size protests received.

c. Projected Reporting, Recordkeeping and Other Compliance Requirements

This final rule would not impose any new information collection requirement on small businesses. This final rule will require contracting officers to update Federal procurement databases to reflect final agency status decisions. Contracting officers should currently be updating these databases, and this rule will make it clear that this must be done.

d. Steps Taken to Minimize the Significant Economic Impact on Small Entities

This final rule should not result in a significant economic impact on small entities. This final rule will extend the timeframe SBA has for determining size of an entity resulting from a size protest. The addition of the five business days will allow SBA more time to adequately review the documentation needed to render a decision and will make SBA's regulations consistent across programs. The timeframe imposed on OHA for rendering decision resulting from appeals should minimize the economic impact on small entities by providing a decision in a timely manner.

e. Conclusion

Based on the foregoing, SBA has determined that this final rule will not have a significant impact on a substantial number of small entities with the meaning of the RFA.

List of Subjects in 13 CFR Parts 121, 124, 125, 126, and 134

Administrative practice and procedure, Government procurement, Government property, Grant programs—business, Loan programs—business, Individuals with disabilities, Reporting and recordkeeping requirements, Small businesses.

For the reasons stated in the preamble, SBA amends parts 121, 124, 125, 126, and 134 of title 13 of the Code of Federal Regulations as follows:

PART 121—SMALL BUSINESS SIZE REGULATIONS

■ 1. The authority citation for part 121 continues to read as follows:

Authority: 15 U.S.C. 632, 634(b)(6), 636(b), 637(a), 644, 662(5) and 694a; Public Law 105–135, sec. 401 *et seq.,* 111 Stat. 2592.

Subpart A—Size Eligibility Provisions and Standards

§ 121.402 [Amended]

■ 2. Amend § 121.402(b) by removing the third sentence.

§ 121.404 [Amended]

■ 3. Amend § 121.404(a) by removing the second sentence.

■ 4. Amend § 121.1009 by revising paragraphs (a), (g)(1), (g)(2), (g)(3), and (h) to read as follows:

§ 121.1009 What are the procedures for making the size determination?

(a) *Time frame for making size determination.* (1) After receipt of a protest or a request for a formal size determination, the SBA Area Office will issue a formal size determination within 15 business days, if possible.

(2) The contracting officer may award a contract after receipt of a protest if the contracting officer determines in writing that an award must be made to protect the public interest. Notwithstanding such a determination, the provisions of paragraph (g) of this section apply to the procurement in question.

(3) If SBA does not issue its determination within 15 business days (or request an extension that is granted), the contracting officer may award the contract if he or she determines in writing that there is an immediate need to award the contract and that waiting until SBA makes its determination will be disadvantageous to the Government. Notwithstanding such a determination, the provisions of paragraph (g) of this section apply to the procurement in question.

* * * * *

(g) * * *

(1) A contracting officer may award a contract to a protested concern after the SBA Area Office has determined either that the protested concern is an eligible small business or has dismissed all protests against it. If OHA subsequently overturns the Area Office's determination or dismissal, the contracting officer may apply the OHA decision to the procurement in question.

(2) A contracting officer shall not award a contract to a protested concern that the Area Office has determined is not an eligible small business for the procurement in question.

(i) If a contracting officer receives such a determination after contract award, and no OHA appeal has been filed, the contracting officer shall terminate the award.

(ii) If a timely OHA appeal is filed after contract award, the contracting officer must consider whether performance can be suspended until an appellate decision is rendered.

(iii) If OHA affirms the size determination finding the protested concern ineligible, the contracting officer shall either terminate the contract or not exercise the next option.

(3) The contracting officer must update the Federal Procurement Data System and other procurement reporting databases to reflect the final agency size decision (the formal size determination if no appeal is filed or the appellate decision).

* * * * *

(h) *Limited reopening of size determinations.* SBA may, in its sole discretion, reopen a formal size determination to correct an error or mistake, provided it is within the appeal period and no appeal has been filed with OHA. Once the agency has issued a final decision (either a formal size determination that is not timely appealed or an appellate decision), SBA cannot re-open the size determination.

■ 5. Amend § 121.1101 by revising paragraph (b) to read as follows:

§ 121.1101 Are formal size determinations subject to appeal?

* * * * *

(b) OHA will review all timely appeals of size determinations.

■ 6. Amend § 121.1103 as follows:

■ a. Revise the section heading;

■ b. In paragraph (a), add a new sentence after the first sentence and before the second sentence;

■ c. Revise paragraph (b)(1);

■ d. Remove paragraphs (b)(4), and (b)(5); and

■ e. Add new paragraph (c).

§ 121.1103 What are the procedures for appealing a NAICS code or size standard designation?

(a) * * * A NAICS code appeal may include an appeal involving the applicable size standard, such as where more than one size standard corresponds to the selected NAICS code or there is a question as to the size standard in effect at the time the solicitation was issued or amended.

* * *

(b) * * *

(1) An appeal from a contracting officer's NAICS code or size standard designation must be served and filed within 10 business days after the issuance of the solicitation or amendment affecting the NAICS code or size standard. However, SBA may file a NAICS code appeal at any time before offers are due. OHA will summarily dismiss an untimely NAICS code appeal.

* * * * *

(c) *Procedure after a NAICS code appeal is filed and served.*

(1) Upon receipt of the service copy of a NAICS code appeal, the contracting officer shall:

(i) Stay the solicitation;

(ii) Advise the public, by amendment to the solicitation or other method, of the existence of the NAICS code appeal and the procedures and deadline for interested parties to file and serve arguments concerning the appeal;

(iii) Send a copy of (or an electronic link to) the entire solicitation, including amendments, to OHA;

(iv) File and serve any response to the appeal prior to the close of the record; and

(v) Inform OHA of any amendments, actions or developments concerning the procurement in question.

(2) Upon receipt of a NAICS code appeal, OHA shall:

(i) Notify the appellant, the contracting officer, the SBA and any other known party of the date OHA received the appeal and the date the record will close; and

(ii) Conduct the appeal in accordance with part 134 of this chapter.

(3) Any interested party may file and serve its response to the NAICS code appeal.

PART 124—8(a) BUSINESS DEVELOPMENT/SMALL DISADVANTAGED BUSINESS STATUS DETERMINATIONS

■ 7. The authority citation for part 124 continues to read as follows:

Authority: 15 U.S.C. 634(b)(6), 636(j), 637(a), 637(d) and Pub. L. 99–661, Pub. L. 100–656, sec. 1207, Pub. L. 100–656, Pub. L. 101–37, Pub. L. 101–574, and 42 U.S.C. 9815.

Subpart B—Eligibility, Certification, and Protests Relating to Federal Small Disadvantaged Business Programs

■ 8. Amend § 124.1013 as follows:

■ a. Remove the second sentence in paragraph (a);

■ b. Revise paragraph (b);

■ c. Revise paragraph (d)(1);

■ d. Revise paragraphs (h)(1) and (h)(2); and

■ e. Add new paragraphs (h)(3) and (h)(4).

§ 124.1013 How does SBA make disadvantaged status determinations in considering an SDB protest?

* * * * *

(b) *Award of contract.* (1) The contracting officer may award a contract after receipt of a protest if the contracting officer determines in writing that an award must be made to protect the public interest. Notwithstanding such a determination, the provisions of paragraph (h) of this section apply to the procurement in question.

(2) If SBA does not issue its determination within 15 business days (or request an extension that is granted), the contracting officer may award the contract if he or she determines in writing that there is an immediate need to award the contract and that waiting until SBA makes its determination will be disadvantageous to the Government, Notwithstanding such a determination, the provisions of paragraph (h) of this section apply to the procurement in question.

* * * * *

(d) * * *

(1) Except with respect to a concern which is a current Participant in SBA's 8(a) BD program and is authorized under § 124.1013(b)(3) to submit an affidavit concerning its disadvantaged status, the disadvantaged status determination will be based on the protest record, including reasonable inferences therefrom, as supplied by the protested concern, SBA or others.

* * * * *

(h) * * *

(1) A contracting officer may award a contract to a protested concern after the DC/SDBCE has determined either that the protested concern is an eligible SDB or has dismissed all protests against it. If the AA/GCBD subsequently overturns the initial determination or dismissal, the contracting officer may apply the appeal decision to the procurement in question.

(2) A contracting officer shall not award a contract to a protested concern that the DC/SDBCE has determined is not an eligible SDB for the procurement in question.

(i) If a contracting officer receives such a determination after contract award, and no appeal has been filed, the contracting officer shall terminate the award.

(ii) If a timely appeal is filed after contract award, the contracting officer must consider whether performance can be suspended until an appellate decision is rendered.

(iii) If the AA/GCBD affirms the initial determination finding that the protested concern ineligible, the contracting officer shall either terminate the contract or not exercise the next option.

(3) The contracting officer must update the Federal Procurement Data System and other procurement reporting databases to reflect the final agency SDB decision (the decision of the AA/SDBCE if no appeal is filed or the decision of the AA/GCBD).

(4) A concern found to be ineligible is precluded from applying for SDB certification for 12 months from the date of the final agency decision (whether by the DC/SDBCE, without an appeal, or by the AA/GCBD on appeal). A concern found to be ineligible is also precluded from representing itself as an SDB for a subcontract unless it overcomes the reasons for the protest (*e.g.,* it changes its ownership to satisfy the definition of an SDB set forth in § 124.1002).

§ 124.1014 [Amended]

■ 9. Amend § 124.1014 by removing paragraph (f) and redesignating paragraphs (g) through (i) as paragraphs (f) through (h), respectively.

PART 125—GOVERNMENT CONTRACTING PROGRAMS

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

Authority: 15 U.S.C. 632(p), (q); 634(b)(6); 637; 644 and 657(f).

Subpart D—Protests Concerning SDVO SBCs

■ 11. Amend § 125.27 by revising paragraphs (e) and (g) to read as follows:

§ 125.27 How will SBA process an SDVO protest?

* * * * *

(e) *Award of contract.* (1) The contracting officer may award a contract after receipt of a protest if the contracting officer determines in writing that an award must be made to protect the public interest. Notwithstanding such a determination, the provisions of paragraph (g) of this section apply to the procurement in question.

(2) If SBA does not issue its determination within 15 business days (or request an extension that is granted), the contracting officer may award the contract if he or she determines in writing that there is an immediate need to award the contract and that waiting until SBA makes its determination will be disadvantageous to the Government. Notwithstanding such a determination, the provisions of paragraph (g) of this section apply to the procurement in question.

* * * * *

(g) *Effect of determination.* (1) A contracting officer may award a contract to a protested concern after the Director, Office of Government Contracting (D/GC) has determined either that the protested concern is an eligible SDVO or has dismissed all protests against it. If OHA subsequently overturns the D/GC's determination or dismissal, the contracting officer may apply the OHA decision to the procurement in question.

(2) A contracting officer shall not award a contract to a protested concern that the D/GC has determined is not an eligible SDVO for the procurement in question.

(i) If a contracting officer receives such a determination after contract award, and no OHA appeal has been filed, the contracting officer shall terminate the award.

(ii) If a timely OHA appeal is filed after award, the contracting officer must consider whether performance can be suspended until an appellate decision is rendered.

(iii) If OHA affirms the D/GC's determination finding the protested concern ineligible, the contracting

officer shall either terminate the contract or not exercise the next option.

(3) The contracting officer must update the Federal Procurement Data System and other procurement reporting databases to reflect the final agency decision (the D/GC's decision if no appeal is filed or OHA's decision).

(4) A concern found to be ineligible may not submit an offer as an SDVO SBC on a future procurement unless it demonstrates to SBA's satisfaction that it has overcome the reasons for the protest (*e.g.,* it changes its ownership to satisfy the definition of an SDVO SBC set forth in § 125.8) and SBA issues a decision to this effect.

■ 12. Revise § 125.28 to read as follows:

§ 125.28 What are the procedures for appealing an SDVO status protest?

The protested concern, the protester, or the contracting officer may file an appeal of an SDVO status protest determination with OHA in accordance with part 134 of this chapter.

PART 126—HUBZONE PROGRAM

■ 13. The authority citation for part 126 continues to read as follows:

Authority: 15 U.S.C. 632(a), 632(j), 632(p), and 657a.

Subpart H—Protests

■ 14. Amend § 126.803 by revising paragraphs (b)(2) and (b)(3), redesignating paragraph (d) as paragraph (d)(1), and adding new paragraphs (d)(2), (d)(3), (d)(4) and (d)(5) to read as follows:

§ 126.803 How will SBA process a HUBZone status protest?

* * * * *

(b) * * *

(2) The contracting officer may award a contract after receipt of a protest if the contracting officer determines in writing that an award must be made to protect the public interest. Notwithstanding such a determination, the provisions of paragraph (d) of this section apply to the procurement in question.

(3) If SBA does not issue its determination within 15 business days (or request an extension that is granted), the contracting officer may award the contract if he or she determines in writing that there is an immediate need to award the contract and that waiting until SBA makes its determination will be disadvantageous to the Government. Notwithstanding such a determination, the provisions of paragraph (d) of this section apply to the procurement in question.

* * * * *

(d) * * *

(2) A contracting officer may award a contract to a protested concern after the D/HUB has determined either that the protested concern is an eligible HUBZone or has dismissed all protests against it. If the AA/GCBD subsequently overturns the initial determination or dismissal, the contracting officer may apply the appeal decision to the procurement in question.

(3) A contracting officer shall not award a contract to a protested concern that the D/HUB has determined is not an eligible HUBZone for the procurement in question.

(i) If a contracting officer receives such a determination after contract award, and no appeal has been filed, the contracting officer shall terminate the award.

(ii) If a timely appeal is filed after contract award, the contracting officer must consider whether performance can be suspended until an appellate decision is rendered.

(iii) If the AA/GCBD affirms the initial determination finding the protested concern ineligible, the contracting officer shall either terminate the contract or not exercise the next option.

(4) The contracting officer must update the Federal Procurement Data System and other procurement reporting databases to reflect the final agency HUBZone decision (the D/HUB's decision if no appeal is filed or the decision of the AA/GCBD).

(5) A concern found to be ineligible is precluded from applying for HUBZone certification for 12 months from the date of the final agency decision (the D/HUB's decision if no appeal is filed or the decision of the AA/GCBD).

§ 126.805 [Amended]

■ 15. Amend § 126.805 by removing paragraph (g) and redesignating paragraph (h) as paragraph (g).

PART 134—RULES OF PROCEDURE GOVERNING CASES BEFORE THE OFFICE OF HEARINGS AND APPEALS

■ 16. The authority citation for part 134 continues to read as follows:

Authority: 5 U.S.C. 504; 15 U.S.C. 632, 634(b)(6), 637(a), 637(m), 648(1), 656(i), and 687(c); E.O. 12549, 51 FR 6370, 3 CFR, 1986 Comp., p. 189.

Subpart C—Rules of Practice for Appeals From Size Determinations and NAICS Code Designations

■ 17. Revise § 134.304 to read as follows:

§ 134.304 Commencement of appeals from size determinations and NAICS code designations.

(a) Size appeals must be filed within 15 calendar days after receipt of the formal size determination.

(b) NAICS code appeals must be filed within 10 calendar days after issuance of the solicitation, or amendment to the solicitation affecting the NAICS code or size standard. However, SBA may file a NAICS code appeal at any time before offers or bids are due.

(c) An untimely appeal will be dismissed.

■ 18. Amend § 134.316 by redesignating paragraphs (a), (b), (c), and (d) as paragraphs (c), (d), (e) and (f), respectively, and adding new paragraphs (a) and (b) to read as follows:

§ 134.316 The decision.

(a) The Judge shall issue a size appeal decision, insofar as practicable, within 60 calendar days after close of the record.

(b) The Judge shall issue a NAICS code appeal decision as soon as practicable after close of the record.

* * * * *

Subpart E—Rules of Practice for Appeals From Service-Disabled Veteran Owned Small Business Concern Protests

§ 134.504 [Removed and Reserved]

■ 19. Remove and reserve § 134.504.

§ 134.514 [Amended]

■ 20. Amend § 134.514 by removing the second sentence.

§ 134.515 [Amended]

■ 21. Amend § 134.515(b) by removing the word "service" in the second sentence and adding in its place the word "issuance."

Dated: January 25, 2011.

Karen Mills,

Administrator.

[FR Doc. 2011–2177 Filed 2–1–11; 8:45 am]

BILLING CODE 8025–01–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 117

[Docket No. USCG–2011–0036]

Drawbridge Operation Regulation; Bayou Tigre, Vermillion Parish, LA

AGENCY: Coast Guard, DHS.

ACTION: Notice of temporary deviation from regulations.

SUMMARY: The Commander, Eighth Coast Guard District, has issued a temporary deviation from the regulation governing the operation of the Bayou Tigre (LA 330) bridge across Bayou Tigre, mile 2.3, near Delcambre, Vermillion Parish, Louisiana. This deviation is necessary to allow timely bridge rehabilitation to improve overall traffic, boat and pedestrian safety. This deviation allows the bridge to remain closed to vessel traffic.

DATES: This deviation is effective from 12:01 a.m. on March 1, 2011 through 11:59 p.m. on April 1, 2011.

ADDRESSES: Documents mentioned in this preamble as being available in the docket are part of docket USCG–2011–0036 and are available online by going to *http://www.regulations.gov,* inserting USCG–2011–0036 in the "Keyword" box and then clicking "Search". They are also available for inspection or copying at the Docket Management Facility (M–30), U.S. Department of Transportation, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue, SE., Washington, DC 20590, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

FOR FURTHER INFORMATION CONTACT: If you have questions on this rule, call or e-mail Mr. Jim Wetherington, Bridge Management Specialist, District 8 Bridge Branch, U.S. Coast Guard; telephone 504–671–2128 e-mail *james.r.wetherington@uscg.mil.* If you have questions on viewing the docket, call Renee V. Wright, Program Manager, Docket Operations, telephone 202–366–9826.

SUPPLEMENTARY INFORMATION: The Louisiana Department of Transportation and Development requests a temporary deviation from the published regulation for the Bayou Tigre (LA 330) bridge (5 feet vertical clearance when closed at mean high water) across Bayou Tigre as required by 33 CFR 117.5: Except as otherwise authorized or required by this part, drawbridges must open promptly and fully for the passage of vessels when a request or signal to open is given in accordance with this subpart. Currently, according to 33 CFR 117.507, the draw of the Bayou Tigre (LA 330) bridge shall open on signal if at least four hours notice is given.

The Louisiana Department of Transportation and Development requests a deviation to allow the bridge to remain closed to marine traffic from 12:01 a.m. on March 1, 2011 through 11:59 p.m. on April 1, 2011. This time period has been coordinated through the waterway users and the responsible Coast Guard Units. There is no alternative route around the project.

This deviation will allow the rehabilitation of the bridge to be completed in a timely fashion. This rehabilitation is necessary to extend the bridge life and optimize traffic and boat operations. It will also improve overall traffic, boat and pedestrian safety.

The deviation dates and schedule were chosen to minimize significant effect on vessel traffic. Any vessel that does not require an opening of the drawspan may pass at any time; the vertical clearance is five feet mean high water when closed.

In accordance with 33 CFR 117.35(e), the drawbridge must return to its regular operating schedule immediately at the end of the designated time period.

This deviation from the operating regulations is authorized under 33 CFR 117.35. This deviation may be terminated/cancelled at any time via Broadcast Notice to Mariners.

Dated: January 21, 2011.

David M. Frank,

Bridge Administrator.

[FR Doc. 2011–2223 Filed 2–1–11; 8:45 am]

BILLING CODE 9110–04–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 117

[Docket No. USCG–2011–0033]

Drawbridge Operation Regulation; Pocomoke River, Pocomoke City, MD

AGENCY: Coast Guard, DHS.

ACTION: Notice of temporary deviation from regulations.

SUMMARY: The Commander, Fifth Coast Guard District, has issued a temporary deviation from the regulations governing the operation of the Route 675 Bridge across Pocomoke River, mile 15.6, at Pocomoke City, MD. The deviation restricts the operation of the draw span to facilitate mechanical repairs.

DATES: This deviation is effective from 7 a.m. on February 14, 2011 to 11:59 p.m. on February 26, 2011.

ADDRESSES: Documents mentioned in this preamble as being available in the docket are part of docket USCG–2011–0033 and are available online by going to *http://www.regulations.gov*, inserting USCG–2011–0033 in the "Keyword" box and then clicking "Search". They are also available for inspection or copying at the Docket Management Facility (M–30), U.S. Department of Transportation, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue, SE., Washington, DC 20590, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

FOR FURTHER INFORMATION CONTACT: If you have questions on this rule, call or e-mail Mr. Waverly W. Gregory, Jr., Bridge Administrator, Fifth District; Coast Guard; telephone 757–398–6222, e-mail *Waverly.W.Gregory@uscg.mil.* If you have questions on viewing the docket, call Renee V. Wright, Program Manager, Docket Operations, telephone 202–366–9826.

SUPPLEMENTARY INFORMATION: The Maryland State Highway Administration (SHA), who owns and operates this double leaf bascule drawbridge, has requested a temporary deviation from the current operating schedule to facilitate the repairs by replacing the existing solenoid brakes on the main motors with thruster brakes. Under the regular operating schedule required by 33 CFR 117.569(b), the bridge opens on signal, except between November 1 and March 31 the draw must open only if at least five hours advance notice is given.

The Route 675 Bridge across Pocomoke River, mile 15.6 at Pocomoke City MD, has a vertical clearance in the closed position of three feet above mean high water and five feet above mean low water. Vessels that can transit under the bridge without an opening may do so at any time. Under this temporary deviation, the SHA will maintain the bridge in the closed position to vessels beginning at 7 a.m. on February 14, 2011 until and including 11:59 p.m. on February 26, 2011.

Historically, the bridge has had one opening or less during the month of February in the last three years.

The Coast Guard will inform users of the waterway through our Local and Broadcast Notices to Mariners of the closure periods for the bridge so that vessels can arrange their transits to minimize any impact caused by the temporary deviation. There are no alternate routes for vessels transiting this section of the Pocomoke River; however, the drawbridge will be able to open in the event of an emergency.

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

Dated: January 21, 2011.

Waverly W. Gregory, Jr.,

Chief, Bridge Administration Branch, Fifth Coast Guard District.

[FR Doc. 2011–2224 Filed 2–1–11; 8:45 am]

BILLING CODE 9110–04–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA–HQ–OPP–2009–0676; FRL–8860–4]

Isobutane; Exemption From the Requirement of a Tolerance

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes an exemption from the requirement of a tolerance for residues of isobutane (CAS Reg. No. 75–28–5) when used as an inert ingredient (propellant) in pesticide formulations applied to growing crops and raw agricultural commodities after harvest, and when used as an inert ingredient (propellant) in pesticide formulations applied to animals (used for food). Landis International, on behalf of Whitmire Micro-Gen, submitted a petition to EPA under the Federal Food, Drug, and Cosmetic Act (FFDCA), requesting establishment of an exemption from the requirement of a tolerance. This regulation eliminates the need to establish a maximum permissible level for residues of isobutane.

DATES: This regulation is effective February 2, 2011. Objections and requests for hearings must be received on or before April 4, 2011 and must be filed in accordance with the instructions provided in 40 CFR part 178 (*see also* Unit I.C. of the **SUPPLEMENTARY INFORMATION**).

ADDRESSES: EPA has established a docket for this action under docket identification (ID) number EPA–HQ–OPP–2009–0676. 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.,* Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the Internet and will be publicly available only in hard copy form. Publicly available docket materials are available 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 Docket Facility is open 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: Elizabeth Fertich, Registration Division (7505P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001; telephone number: (703) 347–8560; e-mail address: *fertich.elizabeth@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. How can I get electronic access to other related information?

You may access a frequently updated electronic version of 40 CFR part 180 through the Government Printing Office's e-CFR site at *http://www.gpoaccess.gov/ecfr.* To access the harmonized test guidelines referenced in this document electronically, please go to *http://www.epa.gov/ocspp* and select "Test Methods and Guidelines."

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

Under FFDCA section 408(g), 21 U.S.C. 346a, any person may file an objection to any aspect of this regulation and may also request a hearing on those objections. You must file your objection or request a hearing on this regulation in accordance with the instructions provided in 40 CFR part 178. To ensure proper receipt by EPA, you must identify docket ID number EPA–HQ–OPP–2009–0676 in the subject line on the first page of your submission. All objections and requests for a hearing must be in writing, and must be received by the Hearing Clerk on or before April 4, 2011. Addresses for mail and hand delivery of objections and hearing requests are provided in 40 CFR 178.25(b).

In addition to filing an objection or hearing request with the Hearing Clerk as described in 40 CFR part 178, please submit a copy of the filing that does not contain any CBI for inclusion in the public docket. Information not marked confidential pursuant to 40 CFR part 2 may be disclosed publicly by EPA without prior notice. Submit a copy of your non-CBI objection or hearing request, identified by docket ID number EPA–HQ–OPP–2009–0676, 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.

II. Petition for Exemption

In the **Federal Register** of October 7, 2009 (74 FR 51597) (FRL–8792–7), EPA issued a notice pursuant to section 408 of FFDCA, 21 U.S.C. 346a, announcing the filing of a pesticide petition (PP 9E7586) by Whitmire Micro-Gen, c/o Landis International, P.O. Box 5126, Valdosta, GA 31603–5126. The petition requested that 40 CFR 180.910 and 40 CFR 180.930 be amended by establishing an exemption from the requirement of a tolerance for residues of isobutane (CAS Reg. No. 75–28–5) when used as an inert ingredient (propellant) in pesticide formulations applied pre- and post-harvest and pesticide formulations applied to animals. That notice referenced a summary of the petition prepared by

Landis International, on behalf of Whitmire Micro-Gen, the petitioner, which is available in the docket, *http://www.regulations.gov.* There were no comments received in response to the notice of filing.

III. Inert Ingredient Definition

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

IV. Aggregate Risk Assessment and Determination of Safety

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

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

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

A. Toxicological Profile

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

Isobutane is an asphyxiant and acute exposure may cause tachypnea and tachycardia. While direct contact with the liquid may cause burns, the vapor has no effects on the skin and eyes. Sudden death has also been reported from abusive "sniffing" of products containing isobutane, especially lighter refills. In a safety assessment of isobutane as a cosmetic ingredient (1982), dermal irritation in humans was very slight and transient erythema occurred randomly. Repeated inhalation exposure did not result in any changes in electroencephalograms, adrenocortical function, pulmonary function, neurological response, subjective response, cardiac function or cognitive response.

Acute toxicity data on isobutane were limited to inhalation exposure and eye and skin irritation. Isobutane was not acutely toxic via the inhalation route and was basically non-irritating to the skin and eyes of rabbits.

Several studies were found in which monkeys, rabbits, and rats were exposed to formulations or to mixtures containing isobutane. No toxicity was reported for two species of monkeys and one species of rabbit exposed for 90 days to various formulations containing isobutane.

No effects on survival, body weight, hematology, clinical pathology, or liver and kidney weights were observed in rats exposed to 0, 1,000, or 4,500 ppm (equivalent to 0, 622 or 2,803 milligrams/kilogram/day (mg/kg/day) of a 50:50 mixture of isobutane: isopentane for 13 weeks, however clinical signs included hunched posture, lethargy and crusted eyes in both exposure groups. There were no clinical signs of toxicity observed and no gross or microscopic lesions seen in Sprague-Dawley rats exposed to 0, 44, 432, or 4,437 ppm (equivalent to 0, 27, 269, or 2,763 mg/kg/day) of a mixture containing 25% each of n-butane, isobutane, n-pentane, and isopentane for 3 weeks.

In a 4-week sub-chronic toxicity study combined with reproduction/developmental toxicity screening and neurotoxicity screening study, Sprague Dawley CD rats were treated with isobutane (purity 99.0%) to assess the repeated dose, reproductive and developmental toxicity potential of this material when administered by whole body inhalation exposure. A no-observed-adverse effect level (NOAEL) of 9,000 ppm (equivalent to 5,600 mg/kg/day) was concluded for general systemic/neurotoxic (parental) endpoints in this study. Based on decreased male and female fertility and increased post-implantation loss in the 9,000 ppm group, the fertility and reproductive endpoints NOAEL was determined to be 3,000 ppm (equivalent to 1,867 mg/kg/day). There were no effects on offspring survival, body weight and development up to post-natal day 4. A NOAEL of 9,000 ppm (equivalent to 5,600 mg/kg/day) was concluded for developmental effects. No effects on functional observational battery parameters and motor activity were observed in this study.

In terms of neurotoxicity, acute toxicity studies show effects on the central nervous system (CNS) with rodents more sensitive than dogs. Exposure to a concentration of 55% was lethal in dogs, while 41–52% was lethal to mice within 2–3 minutes. The 10-minute EC_{50} for CNS effects was listed as 200,000 ppm (equivalent to 124,560 mg/kg/day) for the rat.

Several tests were found measuring the cardiopulmonary toxicity of isobutane. No effects were seen in anesthetized Rhesus monkeys exposed for 5 minutes to 5% isobutane through a tracheal cannula. Effects on the heart were shown in the dog with concentration-related decreased

contractility, pressure, and output measured between 2–10% isobutane. Mongrel dogs were also anesthetized and exposed to isobutane through a tracheal cannula. Blood pressure and heart rate were not affected by exposure. All concentrations significantly increased pulmonary resistance and decreased pulmonary compliance. Similarly, anesthetized male Osburn-Mendel rats exposed to 27% isobutane showed apnea after 8.7 minutes of exposure followed by cardiac arrest; decreased respiratory rate, tidal volume, and pulmonary compliance and increased airway resistance were also found. In another test with anesthetized male Swiss mice, 20–40% isobutane did not induce cardiac arrhythmia, but did sensitize the heart to epinephrine-induced arrhythmia.

No evidence of an increase in mutation frequency was found in five strains of Salmonella typhimurium exposed to up to 50% isobutane in air. Strains TA98, TA100, TA1535, TA1537, and TA1538 were exposed for 6 hours with and without metabolic activation. No chronic toxicity or carcinogenicity studies with isobutane were identified. However, the concern for carcinogenicity is low based on rapid metabolism, lack of mutagenicity and lack of systemic toxicity at doses up to 1,867 mg/kg/day. In addition, the Agency used a qualitative structure activity relationship (SAR) database, DEREK11, to determine if there were structural alerts suggestive of carcinogenicity. No structural alerts were identified.

Specific information on the studies received and the nature of the adverse effects caused by, as well as the no-observed-adverse-effect-level (NOAEL) and the lowest-observed-adverse-effect-level (LOAEL) from the toxicity studies can be found at *http://www.regulations.gov* in the document "PC Code 800015: Isobutane (CAS Reg. No. 75–28–5); Human Health Risk Assessment and Ecological Effects Assessment to the Support Proposed Exemption from the Requirement of a Tolerance When Used as an Inert Ingredient in Pesticide Formulations" at [6] in docket ID number EPA–HQ–OPP–2009–0676.

B. Toxicological Points of Departure/Levels of Concern

Due to the low potential hazard of isobutane, quantitative dietary, occupational and residential exposure assessments are not necessary. In a 4-week sub-chronic toxicity study combined with reproduction/developmental toxicity screening and neurotoxicity screening study, exposure of male and female rats to target concentrations of 900, 3,000 or 9,000 ppm (equivalent to 560, 1,867, and 5,600 mg/kg/day) of isobutane by whole-body inhalation for four weeks resulted in no general systemic/neurotoxic effects. Based on decreased male and female fertility and increased post-implantation loss in the 5,600 mg/kg/day group, the fertility and reproductive endpoints NOAEL was determined to be 1,867 mg/kg/day. There were no effects on offspring survival, body weight and development up to post-natal day 4. A NOAEL of 5,600 mg/kg/day was concluded for developmental effects. Since no toxicity was observed at high doses, quantitative risk assessment is deemed unnecessary.

C. Exposure Assessment

No hazard was identified for the acute and chronic dietary assessment (food and drinking water), or for the short-, intermediate-, and long-term residential assessments, and therefore no aggregate risk assessments were performed. Available toxicological studies indicate lack of systemic toxicity at doses up to 1,867 mg/kg/day. Therefore, no quantitative dietary or occupational and residential risk assessment was conducted.

1. *Dietary exposure from food and feed uses* and drinking water. In evaluating dietary exposure to isobutane, EPA considered exposure under the proposed exemption from the requirement of a tolerance. Since toxicity effects were seen only at high doses for isobutane, a quantitative exposure assessment for isobutane was not conducted. Any possible dietary exposure to isobutane from its use as an inert ingredient in pesticide products would be through consumption of food to which pesticide products containing it have been applied and possibly through drinking water (from runoff). Isobutane is expected to exist in the atmosphere as a gas and volatilize rapidly from surface water and soil. This will reduce the amount of isobutane that is available for uptake by plants. Run-off into surface water is not anticipated due to rapid volatization, and therefore, contributions of concern to drinking water are not expected.

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

Isobutane is widely used as a propellant in a variety of household products, such as cleaners and air fresheners. It is also used in nonfood use insecticide products and personal care products. Considering the low toxicity of isobutane, residues of concern are not anticipated from residential exposures (inhalation and dermal) and therefore a quantitative aggregate risk assessment was not performed.

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

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

D. Safety Factor for Infants and Children

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

The toxicity database is sufficient for isobutane and potential exposure is adequately characterized given the low toxicity of the chemical. In terms of hazard, there are low concerns and no residual uncertainties regarding prenatal and/or postnatal toxicity. In the OECD 422 study via the inhalation route, the NOAEL for general systemic toxicity and neurotoxicity was 5,600 mg/kg/day (the highest dose tested). Based on decreased male and female fertility and increased post-implantation loss in the

5,600 mg/kg/day group, the fertility and reproductive endpoints NOAEL was determined to be 1,867 mg/kg/day. There were no effects on offspring survival, body weight and development up to post-natal day 4. A NOAEL of 5,600 mg/kg/day was concluded for developmental effects. Based on this information, there is no concern at this time for increased sensitivity to infants and children to isobutane when used as an inert ingredient in pesticide formulations and a safety factor analysis has not been used to assess risk. For the same reason, EPA has determined that an additional safety factor is not needed to protect the safety of infants and children.

E. Aggregate Risks and Determination of Safety

Given the lack of concern for hazard posed by isobutane, EPA concludes that there are no dietary or aggregate dietary/non-dietary risks of concern as a result of exposure to isobutane in food and water or from residential exposure. Residues of concern are not anticipated for dietary exposure (food and drinking water) or for residential exposure (dermal and inhalation) from the use of isobutane as an inert ingredient in pesticide products. As discussed above, EPA expects aggregate exposure to isobutane to pose no appreciable dietary risk given that the data show a lack of any systemic toxicity at doses up to 1,867 mg/kg/day and a lack of any apparent developmental effects.

Taking into consideration all available information on isobutane, EPA has determined that there is a reasonable certainty that no harm to any population subgroup, including infants and children, will result from aggregate exposure to isobutane under reasonable foreseeable circumstances. Therefore, the establishment of an exemption from tolerance under 40 CFR 180.910 for residues of isobutane when used as an inert ingredient in pesticide formulations applied pre- and post-harvest and under 40 CFR 180.930 for residues of isobutane when used as an inert ingredient in pesticide formulations applied to animals, is safe under FFDCA section 408.

V. Other Considerations

A. Analytical Enforcement Methodology

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

B. International Residue Limits

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

The Codex has not established a MRL for isobutane.

VI. Conclusions

Therefore, an exemption from the requirement of a tolerance is established under 40 CFR 180.910 and 40 CFR 180.930 for isobutane (CAS Reg. No. 75–28–5) when used as an inert ingredient (propellant) in pesticide formulations applied pre- and post-harvest and when applied to animals.

VII. Statutory and Executive Order Reviews

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

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

This final rule directly regulates growers, food processors, food handlers, and food retailers, not States or Tribes, nor does this action alter the relationships or distribution of power and responsibilities established by Congress in the preemption provisions of section 408(n)(4) of FFDCA. As such, the Agency has determined that this action will not have a substantial direct effect on States or Tribal governments, on the relationship between the national government and the States or Tribal governments, or on the distribution of power and responsibilities among the various levels of government or between the Federal Government and Indian Tribes. Thus, the Agency has determined that Executive Order 13132, entitled *Federalism* (64 FR 43255, August 10, 1999) and Executive Order 13175, entitled *Consultation and Coordination with Indian Tribal Governments* (65 FR 67249, November 9, 2000) do not apply to this final rule. In addition, this final rule does not impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act of 1995 (UMRA) (Pub. L. 104–4).

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).

VIII. Congressional Review Act

The Congressional Review Act, 5 U.S.C. 801 *et seq.,* generally provides that before a rule may take effect, the agency promulgating the rule must submit a rule report to each House of the Congress and to the Comptroller General of the United States. EPA will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of this final rule in the **Federal Register**. This final rule is not a "major rule" as defined by 5 U.S.C. 804(2).

List of Subjects in 40 CFR Part 180

Environmental protection, Administrative practice and procedure,

Agricultural commodities, Pesticides and pests, Reporting and recordkeeping requirements.

Dated: January 24, 2011.

Lois Rossi,

Director, Registration Division, Office of Pesticide Programs.

Therefore, 40 CFR chapter I is amended as follows:

PART 180—[AMENDED]

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

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

■ 2. In the table to § 180.910 add alphabetically a new inert ingredient to read as follows:

§ 180.910 Inert ingredients used pre- and post-harvest; exemptions from the requirement of a tolerance.

* * * * *

Inert ingredients	Limits	Uses
* * * *	*	* *
Isobutane (CAS Reg. No. 75–28–5)	None	Propellant.
* * * *	*	* *

■ 3. In the table to § 180.930, add alphabetically a new inert ingredient to read as follows:

§ 180.930 Inert ingredients applied to animals; exemptions from the requirement of a tolerance.

* * * * *

Inert ingredients	Limits	Uses
* * * *	*	* *
Isobutane (CAS Reg. No. 75–28–5)	None	Propellant.
* * * *	*	* *

[FR Doc. 2011–2265 Filed 2–1–11; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA–HQ–OPP–2010–0385; FRL–8860–3]

Cyprodinil; Pesticide Tolerances

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation amends tolerances for residues of cyprodinil in or on fruit, pome, group 11 and apple wet pomace. This regulation also establishes tolerances for meat byproducts of cattle, goats, horses and sheep. Syngenta Crop Protection requested these tolerances under the Federal Food, Drug, and Cosmetic Act (FFDCA).

DATES: This regulation is effective February 2, 2011. Objections and requests for hearings must be received on or before April 4, 2011, and must be filed in accordance with the instructions provided in 40 CFR part 178 (*see also* Unit I.C. of the **SUPPLEMENTARY INFORMATION**).

ADDRESSES: EPA has established a docket for this action under docket identification (ID) number EPA–HQ–OPP–2010–0385. 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.,* Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the Internet and will be publicly available only in hard copy form. Publicly available docket materials are available 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 Docket Facility is open 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: Lisa Jones, Registration Division (7505P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001; telephone number: (703) 308–9424; e-mail address: *jones.lisa@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 those engaged in the following activities:

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

You may access a frequently updated electronic version of EPA's tolerance regulations at 40 CFR part 180 through the Government Printing Office's e-CFR site at *http://www.gpoaccess.gov/ecfr.*

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

Under FFDCA section 408(g), 21 U.S.C. 346a, any person may file an objection to any aspect of this regulation and may also request a hearing on those objections. You must file your objection or request a hearing on this regulation in accordance with the instructions provided in 40 CFR part 178. To ensure proper receipt by EPA, you must identify docket ID number EPA–HQ–OPP–2010–0385 in the subject line on the first page of your submission. All objections and requests for a hearing must be in writing, and must be received by the Hearing Clerk on or before April 4, 2011. Addresses for mail and hand delivery of objections and hearing requests are provided in 40 CFR 178.25(b).

In addition to filing an objection or hearing request with the Hearing Clerk as described in 40 CFR part 178, please submit a copy of the filing that does not contain any CBI for inclusion in the public docket. Information not marked confidential pursuant to 40 CFR part 2 may be disclosed publicly by EPA without prior notice. Submit a copy of your non-CBI objection or hearing request, identified by docket ID number EPA–HQ–OPP–2010–0385, 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.

II. Summary of Petitioned-For Tolerance

In the **Federal Register** of June 8, 2010 (75 FR 32466) (FRL–8827–5), EPA issued a notice pursuant to section 408(d)(3) of FFDCA, 21 U.S.C. 346a(d)(3), announcing the filing of a pesticide petition (PP 0F7696) by Syngenta Crop Protection, P.O. Box 18300, Greensboro, NC 27409. The petition requested that 40 CFR 180.532 be amended by raising tolerances for residues of the fungicide cyprodinil, in or on fruit, pome, group 11 from 0.1 parts per million (ppm) to 1.7 ppm. That notice referenced a summary of the petition prepared by Syngenta Crop Protection, the registrant, which is available in the docket, *http://www.regulations.gov.* There were no comments received in response to the notice of filing.

Based upon review of the data supporting the petition, EPA has increased the tolerance for apple, wet pomace from 0.15 ppm to 4.6 ppm. EPA has also established tolerances for meat byproducts of cattle, goats, horses, and sheep at 0.02 ppm. The reason for this change is explained in Unit IV.C.

III. Aggregate Risk Assessment and Determination of Safety

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

Consistent with section 408(b)(2)(D) of FFDCA, and the factors specified in section 408(b)(2)(D) of FFDCA, EPA has reviewed the available scientific data and other relevant information in support of this action. EPA has sufficient data to assess the hazards of and to make a determination on aggregate exposure for cyprodinil including exposure resulting from the tolerances established by this action. EPA's assessment of exposures and risks associated with cyprodinil follows.

A. Toxicological Profile

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

Cyprodinil has low acute toxicity via the oral, dermal, and inhalation routes. Cyprodinil is mildly irritating to the eyes and negligibly irritating to the skin. It is a dermal sensitizer. The major target organs of cyprodinil are the liver in both rats and mice and the kidney in rats. Liver effects observed consistently in subchronic and chronic studies in rats and mice include increased liver weights, increases in serum clinical chemistry parameters associated with adverse effects on liver function, hepatocyte hypertrophy, and hepatocellular necrosis. Adverse kidney effects include tubular lesions and inflammation following subchronic exposure of male rats. The hematopoietic system also appeared to be a target of cyprodinil, causing mild anemia in rats exposed subchronically. Chronic effects in dogs were limited to decreased body-weight gain, decreased food consumption and decreased food efficiency. There was no evidence of increased susceptibility in the developmental rat or rabbit study following *in utero* exposure or in the 2-generation reproduction study following prenatal or postnatal exposure. There was no evidence of neuropathological or other neurological effects in the available subchronic neurotoxicity study. The results of a preliminary immunotoxicity study provided no evidence for immunotoxicity. There was no evidence of carcinogenic potential in either the rat chronic toxicity/carcinogenicity or mouse carcinogenicity studies.

B. Toxicological Points of Departure/Levels of Concern

Once a pesticide's toxicological profile is determined, EPA identifies toxicological points of departure (POD) and levels of concern (LOC) to use in evaluating the risk posed by human exposure to the pesticide. For hazards that have a threshold below which there is no appreciable risk, the toxicological POD is used as the basis for derivation of reference values for risk assessment. PODs are developed based on a careful analysis of the doses in each toxicological study to determine the dose at which no adverse effects are

observed (the NOAEL) and the lowest dose at which adverse effects of concern are identified (the LOAEL). Uncertainty/safety factors are used in conjunction with the POD to calculate a safe exposure level—generally referred to as a population-adjusted dose (PAD) or a reference dose (RfD)—and a safe margin of exposure (MOE). For non-threshold risks, the Agency assumes that any amount of exposure will lead to some degree of risk. Thus, the Agency estimates risk in terms of the probability of an occurrence of the adverse effect expected in a lifetime. For more information on the general principles EPA uses in risk characterization and a complete description of the risk assessment process, *see http://www.epa.gov/pesticides/factsheets/riskassess.htm.*

A summary of the toxicological endpoints for cyprodinil used for human risk assessment is discussed in Unit III.A of the final rule published in the **Federal Register** of April 28, 2010 (75 FR 22242) (FRL–8818–8).

C. Exposure Assessment

1. *Dietary exposure from food and feed uses.* In evaluating dietary exposure to cyprodinil, EPA considered exposure under the petitioned-for tolerances as well as all existing cyprodinil tolerances in 40 CFR 180.532. EPA assessed dietary exposures from cyprodinil in food as follows:

i. *Acute exposure.* Quantitative acute dietary exposure and risk assessments are performed for a food-use pesticide, if a toxicological study has indicated the possibility of an effect of concern occurring as a result of a 1-day or single exposure. Such effects were identified for cyprodinil. In estimating acute dietary exposure, EPA used the Dietary Exposure Evaluation Model–Food Consumption Intake Database (DEEM–FCID™, Version 2.03), which uses food consumption data from the U. S. Department of Agriculture (USDA) Continuing Surveys of Food Intakes by Individuals (CSFII) from 1994–1996 and 1998. As to residue levels in food, EPA performed a screening level acute dietary exposure analysis for the population subgroup females 13 to 49 only. No acute endpoint was identified for the remaining population subgroups. Tolerance level residues and 100 percent crop treated (PCT) assumptions were used. DEEM default and empirical processing factors were used to modify the tolerance values.

ii. *Chronic exposure.* In conducting the chronic dietary exposure assessment, EPA used the DEEM–FCID™, Version 2.03, which uses food consumption data from the USDA 1994–1996 and 1998 CSFII. A moderately refined chronic dietary exposure analysis was performed for the general U.S. population and various population subgroups. Average field trial residues for pome fruit, tolerance level residues for the remaining commodities, and 100 PCT assumptions were used. DEEM default and empirical processing factors were used.

iii. *Cancer.* EPA determines whether quantitative cancer exposure and risk assessments are appropriate for a food-use pesticide based on the weight of the evidence from cancer studies and other relevant data. If quantitative cancer risk assessment is appropriate, cancer risk may be quantified using a linear or non-linear approach. If sufficient information on the carcinogenic mode of action is available, a threshold or non-linear approach is used and a cancer RfD is calculated based on an earlier non-cancer key event. If carcinogenic mode of action data are not available, or if the mode of action data determine a mutagenic mode of action, a default linear cancer slope factor approach is utilized. Data summarized in Table 2 of the document "Human Health Risk—Cyprodinil Increased Pome Fruit Tolerance", pp. 24 through 29, in docket ID number EPA–HQ–OPP–2010–0385 at *http://www.regulations.gov,* showed no evidence of carcinogenic potential in either the rat chronic toxicity/carcinogenicity or mouse carcinogenicity studies. EPA therefore concluded that cyprodinil does not pose a cancer risk to humans. Therefore a dietary exposure assessment for the purpose of assessing cancer risk is unnecessary.

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

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

Based on the Pesticide Root Zone Model/Exposure Analysis Modeling System (PRZM/EXAMS) and Screening Concentration in Ground Water (SCI–GROW) models the estimated drinking water concentrations (EDWCs) of cyprodinil for acute exposures are 34.79 parts per billion (ppb) for surface water and 0.0861 ppb for ground water and for chronic exposures for non-cancer assessments are estimated to be 24.65 ppb for surface water and 0.0861 ppb for ground water.

Modeled estimates of drinking water concentrations were directly entered into the dietary exposure model. For acute dietary risk assessment, the water concentration value of 34.79 ppb was used to assess the contribution to drinking water. For chronic dietary risk assessment, the water concentration value of 24.65 ppb was used to assess the contribution to drinking water.

3. *From non-dietary exposure.* The term "residential exposure" is used in this document to refer to non-occupational, non-dietary exposure (*e.g.,* for lawn and garden pest control, indoor pest control, termiticides, and flea and tick control on pets). Cyprodinil is not registered for any specific use patterns that would result in residential exposure.

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

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

http://www.epa.gov/pesticides/cumulative.

D. Safety Factor for Infants and Children

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

2. *Prenatal and postnatal sensitivity.* The database is considered adequate for selection of study endpoints and determination of a dose/response to characterize the potential prenatal or postnatal toxicity of cyprodinil to infants and children. No increase in susceptibility was seen in developmental toxicity studies in rat and rabbit or reproductive toxicity studies in the rat. Toxicity to offspring was observed at dose levels the same or greater than those causing maternal or parental toxicity. Based on the results of developmental and reproductive toxicity studies, there is not a concern for increased qualitative and/or quantitative susceptibility following *in utero* exposure to cyprodinil.

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

i. The toxicology database for cyprodinil is largely complete, missing only the recently-required acute neurotoxicity study and the functional immunotoxicity study. EPA has determined that an additional uncertainty factor is not needed to account for the lack of these studies for the following reasons:

The functional immunotoxicity study for cyprodinil is not expected to alter the RfD. A preliminary immunotoxicity study was submitted. The study did not meet all requirements, but is considered Upgradeable/Guideline. The registrant must either submit a required Natural Killer cell activity assay or provide justification that it is not needed. Otherwise, the results of the preliminary study provided no evidence of immunotoxicity. Specifically, there were no treatment-related effects on absolute, adjusted, or relative spleen or thymus weights; no effects on specific activity or total activity of splenic IgM antibody-forming cells to the T cell-dependent antigen sRBC. There is no evidence in the other existing studies that cyprodinil targets the immune system. No other immunotoxicity studies have been submitted.

The acute neurotoxicity study is not expected to alter the RfD for cyprodinil because the available data show no evidence of neurotoxic potential for cyprodinil. The NOAEL from an acute study is unlikely to be appreciably lower than the NOAEL of 600 mg/kg/day from the subchronic neurotoxicity study. Neurotoxicity was not observed in subchronic neurotoxicity study or the prenatal developmental toxicity studies in rats and rabbits.

ii. A developmental neurotoxicity study is not required. As noted, the available data show no evidence of neurotoxic potential for cyprodinil.

iii. There is no evidence that cyprodinil results in increased susceptibility in *in utero* rats or rabbits in the prenatal developmental studies or in young rats in the 2–generation reproduction study.

iv. There are no residual uncertainties identified in the exposure databases. The acute dietary food exposure assessments were performed based on 100 PCT and tolerance-level residues. The chronic dietary food exposure assessments were performed based on average field trial residues for pome fruit, tolerance level residues for the remaining commodities, and 100 PCT assumptions. EPA made conservative (protective) assumptions in the ground and surface water modeling used to assess exposure to cyprodinil in drinking water. These assessments will not underestimate the exposure and risks posed by cyprodinil.

E. Aggregate Risks and Determination of Safety

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

1. *Acute risk.* Using the exposure assumptions discussed in this unit for acute exposure, the acute dietary exposure from food and water to cyprodinil will occupy 4% of the aPAD for females 13 to 49 years old, the population group receiving the greatest exposure.

2. *Chronic risk.* Using the exposure assumptions described in this unit for chronic exposure, EPA has concluded that chronic exposure to cyprodinil from food and water will utilize 86% of the cPAD for children 1 to 2 years old the population group receiving the greatest exposure.

3. *Aggregate cancer risk for U.S. population.* Based on the lack of evidence of carcinogenicity in two adequate rodent carcinogenicity studies, cyprodinil is not expected to pose a cancer risk to humans.

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

IV. Other Considerations

A. Analytical Enforcement Methodology

Adequate High Performance Liquid Chromatography, using ultra-violet detection (HPLC/UV) methods with column switching (Syngenta Methods AG–631 and AG–631B) are available for enforcing tolerances of cyprodinil on plant commodities. The level of quantitation (LOQs) for these methods range from 0.01 to 0.05 ppm depending on the plant commodities. Method AG–631B also contains procedures for confirmatory analysis by gas chromatography with nitrogen phosphorus detection (GC/NPD).

An adequate HPLC/mass spectrometry method (GRM010.01A) is also available for enforcing tolerances in livestock commodities. This method determines residues of both parent and the metabolite CGA–304075 (free and conjugated), expressed as parent. The LOQ is 0.01 ppm for each analyte for a combined LOQ of 0.02 ppm.

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

B. International Residue Limits

In making its tolerance decisions, EPA seeks to harmonize U.S. tolerances with international standards whenever possible, consistent with U.S. food safety standards and agricultural practices. EPA considers the international maximum residue limits

(MRLs) established by the Codex Alimentarius Commission (Codex), as required by FFDCA section 408(b)(4). The Codex Alimentarius is a joint U.N. Food and Agriculture Organization/ World Health Organization food standards program, and it is recognized as an international food safety standards-setting organization in trade agreements to which the United States is a party. EPA may establish a tolerance that is different from a Codex MRL; however, FFDCA section 408(b)(4) requires that EPA explain the reasons for departing from the Codex level.

The Codex has established MRLs for residues of cyprodinil in/on apple (0.05 mg/kg, the LOQ) and pear (1 mg/kg). There is also a currently established Canadian MRL for residues of cyprodinil in/on pome fruit (0.1 ppm); but none is established in Mexico. It is not possible to harmonize with Codex and Canadian MRLs for residues of cyprodinil in/on pome fruit commodities because the proposed use in the United States results in residue levels greater than the Codex and Canadian MRLs due to the shorter preharvest interval in the United States.

C. Revisions to Petitioned-For Tolerances

Based on the submitted apple field trial and available apple processing data, the currently established tolerance for residues of cyprodinil in apple wet pomace will need to be increased from 0.15 ppm to 4.6 ppm to cover the proposed amended uses of cyprodinil on pome fruit. Additionally, the Agency has determined the currently established 0.02 ppm tolerance level for meat byproducts of cattle, goats, horses, and sheep are adequate but the currently established tolerance expression for livestock commodities should be changed to reflect measurements of both parent and metabolite CGA–304075.

V. Conclusion

Therefore, tolerances are established for residues of cyprodinil, in or on pome fruit at 1.7 ppm and in apple wet pomace at 4.6 ppm. Tolerances are also established for cyprodinil and (free and conjugated) CGA–304075, expressed in parent equivalents on meat byproducts of cattle, goats, horses, and sheep at 0.02 ppm.

VI. Statutory and Executive Order Reviews

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

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

This final rule directly regulates growers, food processors, food handlers, and food retailers, not States or Tribes, nor does this action alter the relationships or distribution of power and responsibilities established by Congress in the preemption provisions of section 408(n)(4) of FFDCA. As such, the Agency has determined that this action will not have a substantial direct effect on States or Tribal governments, on the relationship between the national government and the States or Tribal governments, or on the distribution of power and responsibilities among the various levels of government or between the Federal Government and Indian Tribes. Thus, the Agency has determined that Executive Order 13132, entitled *Federalism* (64 FR 43255, August 10, 1999) and Executive Order 13175, entitled *Consultation and Coordination with Indian Tribal Governments* (65 FR 67249, November 9, 2000) do not apply to this final rule. In addition, this final rule does not impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act of 1995 (UMRA) (Pub. L. 104–4).

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).

VII. Congressional Review Act

The Congressional Review Act, 5 U.S.C. 801 *et seq.,* generally provides that before a rule may take effect, the agency promulgating the rule must submit a rule report to each House of the Congress and to the Comptroller General of the United States. EPA will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of this final rule in the **Federal Register**. This final rule is not a "major rule" as defined by 5 U.S.C. 804(2).

List of Subjects in 40 CFR Part 180

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

Dated: January 24, 2011.

Lois Rossi,

Director, Registration Division, Office of Pesticide Programs.

Therefore, 40 CFR chapter I is amended as follows:

PART 180—[AMENDED]

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

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

■ 2. Section 180.532 is amended by revising paragraph (a) to read:

§ 180.532 Cyprodinil; tolerances for residues.

(a) *General.* (1) Tolerances are established for residues of the fungicide cyprodinil, including its metabolites and degradates, in or on the commodities in the table below. Compliance with the tolerance levels specified below is to be determined by measuring only cyprodinil 4-cyclopropyl-6-methyl-*N*-phenyl-2-pyrimidinamine.

Commodity	Parts per million
Almond	0.02
Almond, hulls	8.0
Apple, wet pomace	4.6
Avocado	1.2
Bean, dry	0.6
Bean, succulent	0.6
Brassica, head and stem, subgroup 5A	1.0
Brassica, leafy greens, subgroup 5B	10.0

Commodity	Parts per million
Bushberry subgroup 13B	3.0
Caneberry subgroup 13A	10
Canistel	1.2
Canola, seed [1]	0.03
Citrus, dried pulp	8.0
Citrus, oil	340
Fruit, pome	1.7
Fruit, stone	2.0
Grape	2.0
Grape, raisin	3.0
Herb subgroup 19A, dried, except parsley	15.0
Herb subgroup 19A, fresh, except parsley	3.0
Juneberry	3.0
Kiwifruit	1.8
Leafy greens subgroup 4A, except spinach 35	30
Lemon	0.60
Lime	0.60
Lingonberry	3.0
Longan	2.0
Lychee	2.0
Mango	1.2
Onion, bulb	0.60
Onion, green	4.0
Papaya	1.2
Parsley, dried leaves	170
Parsley, leaves	35
Pistachio	0.10
Pulasan	2.0
Rambutan	2.0
Salal	3.0
Sapodilla	1.2
Sapote, black	1.2
Sapote, mamey	1.2
Spanish lime	2.0
Star apple	1.2
Strawberry	5.0
Tomatillo	0.45
Tomato	0.45
Tomato, paste	1.0
Turnip, greens	10.0
Vegetable, cucurbit, group 9	0.70
Vegetable, leaves of root and tuber, group 2	10
Vegetable, root, except sugar-beet, subgroup 1B 41	0.75
Watercress	20

[1] Import only.

(2) Tolerances are established for residues of the fungicide cyprodinil, including its metabolites and degradates, in the commodities in the table below. Compliance with the tolerance levels specified below is to be determined by measuring only the sum of cyprodinil 4-cyclopropyl-6-methyl-*N*-phenyl-2-pyrimidinamine and free and conjugated CGA–304075 4-(4-cyclopropyl-6-methyl-pyrimidin-2-ylamino)-phenol, calculated as the stoichiometric equivalent of cyprodinil.

Commodity	Parts per million
Cattle, meat byproducts	0.02
Goat, meat byproducts	0.02
Horse, meat byproducts	0.02
Sheep, meat byproducts	0.02

* * * * *

[FR Doc. 2011–2157 Filed 2–1–11; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA–HQ–OPP–2009–0980; FRL–8861–1]

Fluazifop-P-butyl; Pesticide Tolerances

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes tolerances for residues of fluazifop-P-butyl in or on multiple commodities which are identified and discussed later in this document. Syngenta Crop Protection, Inc., requested these tolerances under the Federal Food, Drug, and Cosmetic Act (FFDCA).

DATES: This regulation is effective February 2, 2011. Objections and requests for hearings must be received on or before April 4, 2011, and must be filed in accordance with the instructions provided in 40 CFR part 178 (*see also* Unit I.C. of the **SUPPLEMENTARY INFORMATION**).

ADDRESSES: EPA has established a docket for this action under docket identification (ID) number EPA–HQ–OPP–2009–0980. 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.,* Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the Internet and will be publicly available only in hard copy form. Publicly available docket materials are available 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 Docket Facility is open 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: Susan Stanton, Registration Division (7505P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001; telephone number: (703) 305–5218; e-mail address: *stanton.susan@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 those engaged in the following activities:

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

You may access a frequently updated electronic version of EPA's tolerance regulations at 40 CFR part 180 through the Government Printing Office's e-CFR site at *http://www.gpoaccess.gov/ecfr.* To access the harmonized test guidelines referenced in this document electronically, please go to *http://www.epa.gov/ocspp* and select "Test Methods and Guidelines."

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

Under FFDCA section 408(g), 21 U.S.C. 346a, any person may file an objection to any aspect of this regulation and may also request a hearing on those objections. You must file your objection or request a hearing on this regulation in accordance with the instructions provided in 40 CFR part 178. To ensure proper receipt by EPA, you must identify docket ID number EPA–HQ–OPP–2009–0980 in the subject line on the first page of your submission. All objections and requests for a hearing must be in writing, and must be

received by the Hearing Clerk on or before April 4, 2011. Addresses for mail and hand delivery of objections and hearing requests are provided in 40 CFR 178.25(b).

In addition to filing an objection or hearing request with the Hearing Clerk as described in 40 CFR part 178, please submit a copy of the filing that does not contain any CBI for inclusion in the public docket. Information not marked confidential pursuant to 40 CFR part 2 may be disclosed publicly by EPA without prior notice. Submit a copy of your non-CBI objection or hearing request, identified by docket ID number EPA–HQ–OPP–2009–0980, 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.

II. Summary of Petitioned-For Tolerances

In the **Federal Register** of January 6, 2010 (75 FR 864) (FRL–8801–5), EPA issued a notice pursuant to section 408(d)(3) of FFDCA, 21 U.S.C. 346a(d)(3), announcing the filing of a pesticide petition (PP 9F7624) by Syngenta Crop Protection, Inc., P.O. Box 18300, Greensboro, NC 27419–8300. The petition requested that 40 CFR 180.411 be amended by establishing tolerances for residues of the herbicide, fluazifop-P-butyl, in or on banana and plantains at 0.01 parts per million (ppm); citrus (whole fruit), citrus (oil), and citrus (juice) at 0.05 ppm; citrus (dried pulp) at 0.40 ppm; grapes at 0.01 ppm; sugarbeet (root) at 0.25 ppm; sugarbeet (top) at 1.5 ppm; sugarbeet (dried pulp) at 1.0 ppm; and sugarbeet (molasses) at 3.5 ppm.

In the **Federal Register** of February 4, 2010 (75 FR 5790) (FRL–8807–5), EPA issued a notice pursuant to section 408(d)(3) of FFDCA, 21 U.S.C. 346a(d)(3), announcing the filing of a pesticide petition (PP 9E7651) by Syngenta Crop Protection, Inc., P.O. Box 18300, Greensboro, NC 27419–8300. The petition requested that 40 CFR 180.411 be amended by establishing import tolerances for residues of fluazifop-P-butyl in or on potato, tuber at 1.1 ppm; potato, peel (wet) at 1.1 ppm; potato, chips at 3.0 ppm; and potato, granules/flakes at 5.0 ppm. That notice incorrectly identified fluazifop-P-butyl as an insecticide. A corrected notice, identifying fluazifop-P-butyl as an herbicide, was issued in the **Federal Register** of March 10, 2010 (75 FR 11171) (FRL–8810–8).

Those notices referenced summaries of the petitions prepared by Syngenta Crop Protection, Inc., the registrant, which are available in the dockets (PP9F7641, docket ID number EPA–HQ–OPP–2009–0833; and PP9E7651, docket ID number EPA–HQ–OPP–2009–0980), *http://www.regulations.gov.* There were no comments received in response to the notices of filing.

Based upon review of the data supporting the petition, EPA has determined that the proposed tolerances for plantains, sugarbeet (top), and potato peel (wet) are unnecessary. EPA has also revised several of the proposed commodity terms and tolerances levels, as well as the proposed tolerance expression. The reasons for these changes are explained in Unit IV.C.

III. Aggregate Risk Assessment and Determination of Safety

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

Consistent with section 408(b)(2)(D) of FFDCA, and the factors specified in section 408(b)(2)(D) of FFDCA, EPA has reviewed the available scientific data and other relevant information in support of this action. EPA has sufficient data to assess the hazards of and to make a determination on aggregate exposure for fluazifop-P-butyl including exposure resulting from the tolerances established by this action. EPA's assessment of exposures and risks associated with fluazifop-P-butyl follows.

A. Toxicological Profile

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

In characterizing the toxicity of fluazifop-P-butyl, EPA considered data on both fluazifop-P-butyl and fluazifop butyl. Fluazifop-P-butyl is the resolved, herbicidally-active isomer (R enantiomer) of fluazifop-butyl. The toxicity database for fluazifop-butyl is largely complete with sufficient toxicity data on fluazifop-P-butyl to demonstrate similar toxicity between the resolved and unresolved compounds.

Fluazifop-P-butyl has low acute toxicity by the oral, dermal, and inhalation routes of exposure. It is mildly irritating to the eye and skin and is not a skin sensitizer. In repeated-dose studies, the liver and kidney were the main target organs with toxicity expressed as liver toxicity in the presence of peroxisome proliferation and exacerbation of age-related kidney toxicity. The most sensitive endpoints were seen in the rat (decreased testes and epididymal weights in male rats and decreased pituitary and uterine weights in female rats), most likely due to the longer retention time of the major metabolite (fluazifop acid) in the rat. Fluazifop-P-butyl is classified as "Not likely to be carcinogenic to humans," based on the lack of evidence of carcinogenicity in acceptable studies in rats and hamsters. The hamster was selected for cancer study, rather than the mouse, because liver peroxisome proliferation in hamsters more closely resembles what is found for human liver cells. There is no evidence that fluazifop butyl or fluazifop-P-butyl is mutagenic.

There was no evidence of neurotoxicity or neuropathology in the available studies. Marginal increases in brain weights at termination were observed in a sub-chronic toxicity study in rats and in a carcinogenicity study performed on hamsters; however, they were only seen at higher doses not considered relevant to human exposure.

The toxicity database for fluazifop-butyl and fluazifop-P-butyl includes 7

developmental toxicity studies (5 in rats and 2 in rabbits) and a 2-generation reproduction toxicity study in rats. Fetal effects (including delayed ossification, delayed development of the urinary tract, and diaphragmatic hernias) were consistent findings across the five rat developmental toxicity studies. Maternal toxicity in these studies was observed primarily as decreased weight/weight gain, with maternal effects occurring at higher doses (100/300 milligram/kilogram/day (mg/kg/day)) than doses resulting in fetal effects (2.0/5.0 mg/kg/day). In the rabbit developmental studies, developmental effects (nominal increases in delayed ossification, total litter loss, abortions, small fetuses, and cloudy eyes in one study; and an increased incidence of 13th rib and delayed ossification in sternebrae 2 in the second study) occurred at doses also causing maternal toxicity (abortions, death, and weight loss). Similarly, in the reproduction toxicity study in rats, offspring effects (decreased viability in the F_1 and F_2 pups during lactational day 1, 4, 11, 18, and 25; and decreased F_2 pup weight on lactational day 25) occurred at doses also resulting in parental toxicity (decreased spleen weight in males and increased absolute and relative liver and kidney weights and geriatric nephropathy in females). Reproductive toxicity was observed in this study as decreased absolute and relative testes and epididymal weight in males and, in females, decreased pituitary and uterine weights.

For fluazifop, there were some indications of potential immunotoxicity in the form of thymic involution, altered spleen weights, lymphadenopathy and bone marrow myelogram changes in the chronic toxicity study in dogs. The significance of these effects is discussed in detail in Unit III.D.

Specific information on the studies received and the nature of the adverse effects caused by fluazifop-P-butyl as well as the no-observed-adverse-effect-level (NOAEL) and the lowest-observed-adverse-effect-level (LOAEL) from the toxicity studies can be found at *http://www.regulations.gov* in the document "Revised Fluazifop-P-Butyl. Amended Human Health Risk Assessment to Support Use on Bananas, Citrus, Grapes, Sugar Beets, and the Establishment of a Tolerance on Imported Potatoes," pg. 60 in docket ID number EPA–HQ–OPP–2009–0980.

B. Toxicological Points of Departure/Levels of Concern

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

A summary of the toxicological endpoints for fluazifop-P-butyl used for human risk assessment is shown in Table 1 of this Unit.

TABLE 1—SUMMARY OF TOXICOLOGICAL DOSES AND ENDPOINTS FOR FLUAZIFOP-P-BUTYL FOR USE IN HUMAN HEALTH RISK ASSESSMENT

Exposure/scenario	Point of departure and uncertainty/safety factors	RfD, PAD, LOC for risk assessment	Study and toxicological effects
Acute dietary (Females 13 to 50 years of age).	NOAEL = 50 milligrams/kilograms/day (mg/kg/day) UF_A = 10x. UF_H = 10x FQPA SF = 1x	Acute RfD = 0.50 mg/kg/day aPAD = 0.50mg/kg/day	Developmental Toxicity in Rats. Developmental LOAEL = 200 mg/kg/day based on diaphragmatic hernia.
Acute dietary (General population including infants and children).	An appropriate endpoint attributable to a single dose was not identified in the available studies, including the developmental toxicity studies.		
Chronic dietary (All populations).	NOAEL= 0.74 mg/kg/day UF_A = 10x UF_H = 10x FQPA SF = 1x	Chronic RfD = 0.0074 mg/kg/day cPAD = 0.0074 mg/kg/day	2-generation Reproduction in Rats. LOAEL = 5.8 mg/kg/day in males and 7.1 mg/kg/day in females based on decreased testes & epididymal weights in males, and uterine & pituitary weights in females.
Incidental oral short-term (1 to 30 days).	NOAEL= 100 mg/kg/day UF_A = 10x UF_H = 10x FQPA SF = 1x	LOC for MOE = 100	Developmental Toxicity in Rats. Maternal LOAEL = 300 mg/kg/day based on maternal body weight gain decrement during GD 7–16.
Incidental oral intermediate-term (1 to 6 months).	NOAEL= 0.74 mg/kg/day UF_A= 10x UF_H= 10x FQPA SF = 1x	LOC for MOE = 100	2-generation Reproduction in Rats. Parental/systemic LOAEL = 5.8 mg/kg/day in males and 7.1 mg/kg/day in females based on decreased testes & epididymal weights in males, and uterine & pituitary weights in females.

TABLE 1—SUMMARY OF TOXICOLOGICAL DOSES AND ENDPOINTS FOR FLUAZIFOP-P-BUTYL FOR USE IN HUMAN HEALTH RISK ASSESSMENT—Continued

Exposure/scenario	Point of departure and uncertainty/safety factors	RfD, PAD, LOC for risk assessment	Study and toxicological effects
Dermal short-term (1 to 30 days).	Oral study NOAEL = 2.0 mg/kg/day (dermal absorption rate = 9% at 2 mg dose and 2% at 200 mg dose.) UF_A = 10x UF_H = 10x FQPA SF = 1x	LOC for MOE = 100	Developmental Toxicity in Rats. Developmental LOAEL = 5.0 mg/kg/day based on fetal weight decrement, hydroureter, and delayed ossification.
Dermal intermediate-term (1 to 6 months) and long-term (<6 months).	Oral study NOAEL= 0.74 mg/kg/day (dermal absorption rate = 9% at 2 mg dose and 2% at 200 mg dose.) UF_A = 10x UF_H = 10x FQPA SF = 1x	LOC for MOE = 100	2-generation Reproduction in Rats. Parental/systemic LOAEL = 5.8 mg/kg/day in males and 7.1 mg/kg/day in females based on decreased testes & epididymal weights in males, and uterine & pituitary weights in females.
Inhalation short-term (1 to 30 days).	Oral study NOAEL = 2.0 mg/kg/day (inhalation absorption rate = 100%). UF_A = 10x UF_H = 10x FQPA SF = 1x	LOC for MOE = 100	Developmental Toxicity in Rats Developmental LOAEL = 5.0 mg/kg/day based on fetal weight decrement, hydroureter, and delayed ossification.
Intermediate-term (1 to 6 months) and long-term (<6 months).	Oral study NOAEL = 0.74 mg/kg/day (inhalation absorption rate = 100%). UF_A = 10x UF_H = 10x FQPA SF = 1x	LOC for MOE = 100	2-generation Reproduction in Rats. Parental/systemic LOAEL = 5.8 mg/kg/day in males and 7.1 mg/kg/day in females based on decreased testes & epididymal weights in males, and uterine & pituitary weights in females.
Cancer (Oral, dermal, inhalation).	Not likely to be carcinogenic to humans.		

UF_A = extrapolation from animal to human (interspecies). UF_H = potential variation in sensitivity among members of the human population (intraspecies). UF_L = use of a LOAEL to extrapolate a NOAEL. UF_S = use of a short-term study for long-term risk assessment. UF_{DB} = to account for the absence of data or other data deficiency. FQPA SF = Food Quality Protection Act Safety Factor. PAD = population adjusted dose (a = acute, c = chronic). RfD = reference dose. MOE = margin of exposure. LOC = level of concern.

C. Exposure Assessment

1. *Dietary exposure from food and feed uses.* In evaluating dietary exposure to fluazifop-P-butyl, EPA considered exposure under the petitioned-for tolerances as well as all existing fluazifop-P-butyl tolerances in 40 CFR 180.411. EPA assessed dietary exposures from fluazifop-P-butyl in food as follows:

i. *Acute exposure.* Quantitative acute dietary exposure and risk assessments are performed for a food-use pesticide, if a toxicological study has indicated the possibility of an effect of concern occurring as a result of a 1-day or single exposure. Such effects were identified for fluazifop-P-butyl for women of childbearing age (13 to 49 years old). In estimating acute dietary exposure, EPA used food consumption information from the U. S. Department of Agriculture (USDA) 1994–1996 Nationwide Continuing Surveys of Food Intakes by Individuals (CSFII). As to residue levels in food, EPA assumed that all foods contain tolerance-level residues (adjusted to account for all metabolites of concern, based on the ratio of parent and metabolites found in plant metabolism studies) and that 100% of all crops are treated with fluazifop-P-butyl. Default processing factors were used to estimate residues in processed commodities.

ii. *Chronic exposure.* In conducting the chronic dietary exposure assessment EPA used the food consumption data from the USDA 1994–1996 and 1998 CSFII. As to residue levels in food, EPA assumed that residues were present either at tolerance or average field trial levels. As in the acute dietary exposure assessment, residue levels were adjusted to account for all metabolites of concern. Percent crop treated (PCT) data were used to refine exposure estimates for several currently registered crop uses; 100 PCT was assumed for all new crop commodities. Default processing factors were used to estimate residues in processed commodities.

iii. *Cancer.* Based on the data summarized in Unit III.A., EPA has concluded that fluazifop-P-butyl does not pose a cancer risk to humans. Therefore, a dietary exposure assessment for the purpose of assessing cancer risk is unnecessary.

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

Section 408(b)(2)(F) of FFDCA states that the Agency may use data on the actual percent of food treated for assessing chronic dietary risk only if:

- *Condition a:* The data used are reliable and provide a valid basis to show what percentage of the food derived from such crop is likely to contain the pesticide residue.

• *Condition b:* The exposure estimate does not underestimate exposure for any significant subpopulation group.

• *Condition c:* Data are available on pesticide use and food consumption in a particular area, the exposure estimate does not understate exposure for the population in such area. In addition, the Agency must provide for periodic evaluation of any estimates used. To provide for the periodic evaluation of the estimate of PCT as required by FFDCA section 408(b)(2)(F), EPA may require registrants to submit data on PCT.

The Agency estimated the PCT for existing uses as follows: Asparagus 2.5%; carrot 10%; cherry 1%; cottonseed 2.5%; dry beans 1%; garlic 5%; onion (dry bulb) 15%; peach 2.5%; peanut 1%; pepper (non-bell) 1%; and sweet potato 10%.

In most cases, EPA uses available data from the U. S. Department of Agriculture/National Agricultural Statistics Service (USDA/NASS), proprietary market surveys, and the National Pesticide Use Database for the chemical/crop combination for the most recent 6 to7 years. EPA uses an average PCT for chronic dietary risk analysis. The average PCT figure for each existing use is derived by combining available public and private market survey data for that use, averaging across all observations, and rounding to the nearest 5%, except for those situations in which the average PCT is less than one. In those cases, 1% is used as the average PCT and 2.5% is used as the maximum PCT. EPA uses a maximum PCT for acute dietary risk analysis. The maximum PCT figure is the highest observed maximum value reported within the recent 6 years of available public and private market survey data for the existing use and rounded up to the nearest multiple of 5%.

The Agency believes that the three conditions discussed in Unit III.C.1.iv. have been met. With respect to Condition a, PCT estimates are derived from Federal and private market survey data, which are reliable and have a valid basis. The Agency is reasonably certain that the percentage of the food treated is not likely to be an underestimation. As to Conditions b and c, regional consumption information and consumption information for significant subpopulations is taken into account through EPA's computer-based model for evaluating the exposure of significant subpopulations including several regional groups. Use of this consumption information in EPA's risk assessment process ensures that EPA's exposure estimate does not understate exposure for any significant subpopulation group and allows the Agency to be reasonably certain that no regional population is exposed to residue levels higher than those estimated by the Agency. Other than the data available through national food consumption surveys, EPA does not have available reliable information on the regional consumption of food to which fluazifop-P-butyl may be applied in a particular area.

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

Based on the Pesticide Root Zone Model/Exposure Analysis Modeling System (PRZM/EXAMS) and Screening Concentration in Ground Water (SCI–GROW) models, the estimated drinking water concentrations (EDWCs) of fluazifop-P-butyl for acute exposures are estimated to be 33.4 parts per billion (ppb) for surface water and 1.56 ppb for ground water. The EDWCs for chronic exposures for non-cancer assessments are estimated to be 6.6 ppb for surface water and 1.56 ppb for ground water.

Modeled estimates of drinking water concentrations were directly entered into the dietary exposure model. For acute dietary risk assessment, the water concentration value of 33.4 ppb was used to assess the contribution to drinking water. For chronic dietary risk assessment, the water concentration of value 6.6 ppb was used to assess the contribution to drinking water.

3. *From non-dietary exposure.* The term "residential exposure" is used in this document to refer to non-occupational, non-dietary exposure (*e.g.,* for lawn and garden pest control, indoor pest control, termiticides, and flea and tick control on pets).

Fluazifop-P-butyl is currently registered for the following uses that could result in residential exposures: Turfgrass and broadleaf ornamentals. EPA assessed residential exposure using the following assumptions: Homeowners that apply fluazifop-P-butyl products may be exposed to fluazifop-P-butyl for short-term durations via the dermal and inhalation routes. There is also the potential for post-application exposure of adults and children from activities on treated turf areas, such as home lawns. Short-term dermal exposure of adults and children, as well as incidental oral (hand-to-mouth, object-to-mouth, and soil ingestion) exposure of children may occur. Further information regarding EPA standard assumptions and generic inputs for residential exposures may be found at *http://www.epa.gov/pesticides/trac/science/trac6a05.pdf.*

4. *Cumulative effects from substances with a common mechanism of toxicity.* Section 408(b)(2)(D)(v) of FFDCA requires that, when considering whether to establish, modify, or revoke a tolerance, the Agency consider "available information" concerning the cumulative effects of a particular pesticide's residues and "other substances that have a common mechanism of toxicity." EPA has not found fluazifop-P-butyl to share a common mechanism of toxicity with any other substances, and fluazifop-P-butyl does not appear to produce a toxic metabolite produced by other substances. For the purposes of this tolerance action, therefore, EPA has assumed that fluazifop-P-butyl does not have a common mechanism of toxicity with other substances. For information regarding EPA's efforts to determine which chemicals have a common mechanism of toxicity and to evaluate the cumulative effects of such chemicals, *see* EPA's Web site at *http://www.epa.gov/pesticides/cumulative*.

D. Safety Factor for Infants and Children

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

2. *Prenatal and postnatal sensitivity.* The pre- and postnatal toxicity database for fluazifop/fluazifop-P-butyl includes five rat and two rabbit developmental toxicity studies as well as a 2-generation reproduction toxicity study in rats. As discussed in Unit III.A, there was evidence of quantitative susceptibility of fetuses to fluazifop-P-butyl exposure in the rat developmental toxicity studies. The degree of concern for the increased susceptibility is low and there

is no residual uncertainty based on the following considerations: The endpoint of concern (delayed ossifications) is considered to be a developmental delay as opposed to a malformation or variation which would be considered to be more serious in nature; there were considerable variations in the incidences among the five rat studies; the NOAELs/LOAELs for this effect were well defined and consistent across these studies; and a developmental endpoint of concern (diaphragmatic hernia) is used for assessing acute dietary risk. Also, there was no evidence (quantitative or qualitative) of increased susceptibility of fetuses or offspring in the rabbit developmental studies or in the 2-generation rat reproduction toxicity study.

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

i. The toxicity database for fluazifop-P-butyl is adequate to assess pre- and postnatal toxicity, lacking only acute and sub-chronic neurotoxicity studies and immunotoxicity testing. Ninety-day dermal and inhalation toxicity studies are also required to confirm the PODs selected for assessing dermal and inhalation exposures based on route-to-route extrapolations from oral studies. EPA does not believe an additional uncertainty factor is needed to account for the lack of these studies for the following reasons:

a. *Ninety-day dermal and inhalation studies.* Fluazifop-P-butyl is expected to show similar toxicity by the inhalation and oral routes because of its metabolism by blood into the acid form and excretion in this manner. Further, EPA selected a conservative (protective) POD from a developmental toxicity study (NOAEL of 2.0 mg/kg/day) to assess both short-term dermal and inhalation exposures. The NOAEL from the available 28-day dermal study is considerably higher (100 mg/kg/day).

Although a POD from an oral study was used to assess residential handler inhalation risks for fluazifop-P-butyl, EPA does not believe this aggregate risk assessment is under-protective of adult handlers. Handler MOEs based on the extrapolated endpoint are quite high (14,000 to 1.1 million), and the contribution of residential exposure to aggregate risk is small. Therefore, even if an inhalation study were to provide a lower POD than the oral study, it's not expected to have a significant impact on aggregate risk.

b. *Neurotoxicity.* There was no evidence of neurotoxicity or neuropathology in the available studies. Marginal increases in brain weights at termination were observed in a sub-chronic toxicity study in rats, and in a carcinogenicity study performed on hamsters; however, they were only seen at higher doses not considered relevant to human exposure.

c. *Immunotoxicity.* There were some indications of potential immunotoxicity in the form of thymic involution, altered spleen weights, lymphadenopathy and bone marrow myelogram changes in the chronic toxicity study in dogs. EPA's concern for these effects is low, based on the following considerations: Thymic involution was of slight severity in only 1 female treated with the mid-dose; the response was equivocal in the males, as there was no dose-response relationship (incidence and severity) and controls also exhibited thymic involution. One control dog had severe thymic involution; the statistical and biological significance of the alterations in spleen weights could not be assessed because of the large variation in the weights of control dogs. Also, the alterations were inconsistent between dogs that died (these dogs displayed increased adrenal weights) and dogs that survived (these dogs displayed decreased adrenal weights); lymphadenopathy was observed only at the high dose (125 mg/kg/day) and the response is questionable, since the colony of dogs used in the study had excessive health problems that included lymphadenopathy; the bone marrow myelogram changes were small and variable and not considered dose-related; and none of the potential immunological signs in the dog were seen in the rat, the most sensitive species. For these reasons, EPA considered the results of the chronic dog study to be unreliable. The colony of dogs used in the study had excessive health problems that may have impacted normal immune status, so that apparent immunotoxic effects were observed even in some untreated control animals. Moreover, no immunotoxic effects were observed in the sub-chronic dog study, a study where healthy animals were used. EPA therefore concludes that the available data do not warrant an additional uncertainty factor (UF) to account for the lack of an immunotoxicity study.

ii. As noted previously in this unit, there is no indication that fluazifop-P-butyl is a neurotoxic chemical and there is no need for a developmental neurotoxicity study or additional UFs to account for neurotoxicity.

iii. Although there is evidence of increased quantitative susceptibility in *in utero* rats in the prenatal developmental studies, the degree of concern for developmental effects is low, and EPA did not identify any residual uncertainties after establishing toxicity endpoints and traditional UFs to be used in the risk assessment of fluazifop-P-butyl.

iv. There are no significant residual uncertainties identified in the exposure databases. A citrus processing study and data on the stability of fluazifop-P-butyl in processed potato commodities are required; however, EPA does not expect these data to have a measurable impact on exposure estimates for fluazifop-P-butyl. Data are available which demonstrate fluazifop-P-butyl is stable in a wide variety of frozen crop commodities, including potatoes. As such, EPA expects fluazifop to be stable in frozen potato processed commodities but is requiring data to confirm its stability in these fractions. The submitted citrus processing study was determined to be inadequate and EPA is, therefore, requiring that another study be conducted. In the interim, EPA is establishing tolerances for processed citrus commodities using worst-case concentration factors that will not underestimate residues of fluazifop-P-butyl in these commodities.

The acute dietary food exposure assessment was performed based on tolerance-level residues and 100 PCT. The chronic assessment was refined for some commodities using reliable PCT information and anticipated residues values calculated from guideline field trial studies. EPA made conservative (protective) assumptions in the ground and surface water modeling used to assess exposure to fluazifop-P-butyl in drinking water. EPA used similarly conservative assumptions to assess postapplication exposure of children as well as incidental oral exposure of toddlers. These assessments will not underestimate the exposure and risks posed by fluazifop-P-butyl.

E. Aggregate Risks and Determination of Safety

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

1. *Acute risk.* An acute aggregate risk assessment takes into account acute exposure estimates from dietary consumption of food and drinking water. Using the exposure assumptions discussed in this unit for acute exposure, the acute dietary exposure from food and water to fluazifop-P-butyl will occupy 13% of the aPAD for females 13 to 49 years old, the only population group for which an acute dietary endpoint of concern was identified.

2. *Chronic risk.* Using the exposure assumptions described in this unit for chronic exposure, EPA has concluded that chronic exposure to fluazifop-P-butyl from food and water will utilize 40% of the cPAD for children, 1 to 2 years old, the population group receiving the greatest exposure. Based on the explanation in Unit III.C.3., regarding residential use patterns, chronic residential exposure to residues of fluazifop-P-butyl is not expected.

3. *Short-term risk.* Short-term aggregate exposure takes into account short-term residential exposure plus chronic exposure to food and water (considered to be a background exposure level). Fluazifop-P-butyl is currently registered for uses that could result in short-term residential exposure, and the Agency has determined that it is appropriate to aggregate chronic exposure through food and water with short-term residential exposures to fluazifop-P-butyl.

Using the exposure assumptions described in this unit for short-term exposures, EPA has concluded the combined short-term food, water, and residential exposures result in aggregate MOEs of 150 for adults and 250 for children. The MOE for adults includes chronic exposure from food and water plus short-term residential handler and post-application exposure of adult females (the adult population with the highest estimated exposure). The MOE for children includes chronic exposure from food and water plus combined dermal and incidental oral short-term, post-application exposures. Because EPA's level of concern for fluazifop-P-butyl is a MOE of 100 or below, these MOEs are not of concern.

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

5. *Aggregate cancer risk for U.S. population.* Based on the lack of evidence of carcinogenicity in two adequate rodent carcinogenicity studies, fluazifop-P-butyl is not expected to pose a cancer risk to humans.

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

IV. Other Considerations

A. Analytical Enforcement Methodology

Adequate enforcement methodology (High Performance Liquid Chromatography/Ultra-Violet Spectrometry (HPLC/UV)) is available to enforce the tolerance expression. The method is available in *Pesticide Analytical Methods (PAM),* Volume II or may be requested from: Chief, Analytical Chemistry Branch, Environmental Science Center, 701 Mapes Rd., Ft. Meade, MD 20755–5350; telephone number: (410) 305–2905; e-mail address: *residuemethods@epa.gov.*

B. International Residue Limits

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

The Codex has not established a MRL for fluazifop-P-butyl.

C. Revisions to Petitioned-For Tolerances

EPA has determined that the proposed tolerances for plantains, sugarbeet (top), and potato peel (wet) are unnecessary. Residues of fluazifop-P-butyl on plantains will be covered by the tolerance for banana (40 CFR 180.1); and tolerances are no longer required for sugarbeet tops, which were removed from the Table I (Significant Feedstuffs Derived from Agricultural Crops Fed to Beef, Dairy, Poultry, and Swine) of the residue chemistry guidelines (860.1000 OPPTS Harmonized Test Guidelines) in June, 2008. A tolerance is not needed for potato peel, since processing data demonstrate that residues do not concentrate in the peel. Residues in the peel will, therefore, be covered by the tolerance for potato.

EPA has also revised several of the proposed commodity terms and tolerances levels. Commodity terms were revised as follows to comply with the Agency's Food and Feed Vocabulary: "Citrus (whole fruit)," "grapes," "potato tuber," "sugarbeet (roots)," "sugarbeet (dried pulp)," and "sugarbeet (molasses)" were revised to read "fruit, citrus, group 10;" "grape;" "potato;" "beet, sugar, roots;" "beet, sugar, dried pulp;" and "beet, sugar, molasses;" respectively.

The proposed tolerance for citrus was reduced from 0.05 ppm to 0.03 ppm, the limit of quantitation (LOQ) of the residue analytical method, since all field trial residues were below the LOQ. The citrus processing study was inadequate for determining appropriate tolerances in processed citrus commodities. Therefore, maximum theoretical concentration factors were used in conjunction with the citrus field trial results (all <0.03 ppm) to derive tolerances for citrus oil and juice (proposed at 0.05 ppm) of 30.0 ppm and 0.06 ppm, respectively. A maximum theoretical concentration factor is not available for citrus pulp; however, a recent analysis of data for 27 different pesticides showed concentration of residues in citrus pulp of between 2x and 13x. EPA, therefore, used a concentration factor of 13x in conjunction with field trial results to derive an appropriate tolerance of 0.40 ppm for citrus pulp, the same level proposed by the petitioner.

Finally, EPA is revising the requested tolerance expression for fluazifop-P-butyl in accordance with current Agency guidance. EPA is also making this change for the existing fluazifop-P-butyl tolerances. The revised tolerance expression makes clear that the tolerances cover residues of the

herbicide fluazifop-P-butyl, including its metabolites and degradates, but that compliance with the tolerance levels is to be determined by measuring only the sum of fluazifop-P-butyl, butyl(R)-2-[4-[[5-(trifluoromethyl)-2-pyridinyl]oxy]phenoxy]propanoate, and the free and conjugated forms of the resolved isomer of fluazifop, (R)-2-[4-[[5-(trifluoromethyl)-2-pyridinyl]oxy]phenoxy]propanoic acid, calculated as the stoichiometric equivalent of fluazifop, in or on the commodity. EPA has determined that it is reasonable to make this change final without prior proposal and opportunity for comment, because public comment is not necessary, in that the change has no substantive effect on the tolerance, but rather is merely intended to clarify the existing tolerance expression.

V. Conclusion

Therefore, tolerances are established for residues of fluazifop-P-butyl, including its metabolites and degradates, in or on banana at 0.01 ppm; beet, sugar, dried pulp at 1.0 ppm; beet, sugar, molasses at 3.5 ppm; beet, sugar, roots at 0.25 ppm; citrus, dried pulp at 0.40 ppm; citrus, juice at 0.06 ppm; citrus, oil at 30.0 ppm; fruit, citrus, group 10 at 0.03 ppm; grape at 0.01 ppm; potato at 1.0 ppm; potato, chips at 2.0 ppm; and potato, granules/flakes at 4.0 ppm. Compliance with the tolerance levels is to be determined by measuring only the sum of fluazifop-P-butyl, butyl(R)-2-[4-[[5-(trifluoromethyl)-2-pyridinyl]oxy]phenoxy]propanoate, and the free and conjugated forms of the resolved isomer of fluazifop, (R)-2-[4-[[5-(trifluoromethyl)-2-pyridinyl]oxy]phenoxy]propanoic acid, calculated as the stoichiometric equivalent of fluazifop, in or on the commodity.

VI. Statutory and Executive Order Reviews

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

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

This final rule directly regulates growers, food processors, food handlers, and food retailers, not States or Tribes, nor does this action alter the relationships or distribution of power and responsibilities established by Congress in the preemption provisions of section 408(n)(4) of FFDCA. As such, the Agency has determined that this action will not have a substantial direct effect on States or Tribal governments, on the relationship between the national government and the States or Tribal governments, or on the distribution of power and responsibilities among the various levels of government or between the Federal Government and Indian Tribes. Thus, the Agency has determined that Executive Order 13132, entitled *Federalism* (64 FR 43255, August 10, 1999) and Executive Order 13175, entitled *Consultation and Coordination with Indian Tribal Governments* (65 FR 67249, November 9, 2000) do not apply to this final rule. In addition, this final rule does not impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act of 1995 (UMRA) (Pub. L. 104–4).

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).

VII. Congressional Review Act

The Congressional Review Act, 5 U.S.C. 801 *et seq.,* generally provides that before a rule may take effect, the agency promulgating the rule must submit a rule report to each House of the Congress and to the Comptroller General of the United States. EPA will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of this final rule in the **Federal Register**. This final rule is not a "major rule" as defined by 5 U.S.C. 804(2).

List of Subjects in 40 CFR Part 180

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

Dated: January 18, 2011.

Lois Rossi,

Director, Registration Division, Office of Pesticide Programs.

Therefore, 40 CFR chapter I is amended as follows:

PART 180—[AMENDED]

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

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

■ 2. Section 180.411 is amended by revising paragraph (a) introductory text and alphabetically adding the following commodities to the table in paragraph (a) and revising paragraph (c) the introductory text to read as follows:

§ 180.411 Fluazifop-P-butyl; tolerances for residues.

(a) *General.* Tolerances are established for residues of the herbicide fluazifop-P-butyl, including its metabolites and degradates, in or on the following commodities in the table. Compliance with the tolerance levels specified in the table below is to be determined by measuring only the sum of fluazifop-P-butyl, butyl(R)-2-[4-[[5-(trifluoromethyl)-2-pyridinyl]oxy]phenoxy]propanoate, and the free and conjugated forms of the resolved isomer of fluazifop, (R)-2-[4-[[5-(trifluoromethyl)-2-pyridinyl]oxy]phenoxy]propanoic acid, calculated as the stoichiometric equivalent of fluazifop, in or on the commodity.

Commodity	Parts per million
Banana	0.01
* * * * *	
Beet, sugar, dried pulp	1.0
Beet, sugar, molasses	3.5
Beet, sugar, roots	0.25
* * * * *	
Citrus, dried pulp	0.40
Citrus, juice	0.06
Citrus, oil	30.0

Commodity	Parts per million
* * * * *	
Fruit, citrus, group 10	0.03
* * * * *	
Grape	0.01
* * * * *	
Potato[1]	1.0
Potato, chips[1]	2.0
Potato, granules/flakes[1]	4.0
* * * * *	

[1] No U.S. registrations.

* * * * *

(c) *Tolerances with regional registrations.* Tolerances with regional registrations are established for residues of the herbicide fluazifop-P-butyl, including its metabolites and degradates, in or on the following commodities in the table. Compliance with the tolerance levels specified in the table below is to be determined by measuring only the sum of fluazifop-P-butyl, butyl(R)-2-[4-[[5-(trifluoromethyl)-2-pyridinyl]oxy]phenoxy]propanoate, and the free and conjugated forms of the resolved isomer of fluazifop, (R)-2-[4-[[5-(trifluoromethyl)-2-pyridinyl]oxy]phenoxy]propanoic acid, calculated as the stoichiometric equivalent of fluazifop, in or on the commodity.

* * * * *

[FR Doc. 2011–1779 Filed 2–1–11; 8:45 am]

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA–HQ–OPP–2008–0125; FRL–8860–1]

Sulfentrazone; Pesticide Tolerances

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes tolerances for residues of sulfentrazone in or on multiple commodities. Additionally, this regulation deletes existing tolerances on commodities superseded by the establishment of crop subgroups. This regulation also deletes a time-limited tolerance on bean, succulent seed without pod (lima bean and cowpea), as the tolerance expired on December 31, 2007. Interregional Research Project Number 4 (IR–4) requested these tolerances under the Federal Food, Drug, and Cosmetic Act (FFDCA).

DATES: This regulation is effective February 2, 2011. Objections and requests for hearings must be received on or before April 4, 2011, and must be filed in accordance with the instructions provided in 40 CFR part 178 (*see* also Unit I.C. of the **SUPPLEMENTARY INFORMATION**).

ADDRESSES: EPA has established a docket for this action under docket identification (ID) number EPA–HQ–OPP–2008–0125. 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.,* Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the Internet and will be publicly available only in hard copy form. Publicly available docket materials are available 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 Docket Facility is open 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: Laura Nollen, Registration Division (7505P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001; *telephone number:* (703) 305–7390; *e-mail address: nollen.laura@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 those engaged in the following activities:

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

You may access a frequently updated electronic version of EPA's tolerance regulations at 40 CFR part 180 through the Government Printing Office's e-CFR site at *http://www.gpoaccess.gov/ecfr.*

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

Under FFDCA section 408(g), 21 U.S.C. 346a, any person may file an objection to any aspect of this regulation and may also request a hearing on those objections. You must file your objection or request a hearing on this regulation in accordance with the instructions provided in 40 CFR part 178. To ensure proper receipt by EPA, you must identify docket ID number EPA–HQ–OPP–2008–0125 in the subject line on the first page of your submission. All objections and requests for a hearing must be in writing, and must be received by the Hearing Clerk on or before April 4, 2011. Addresses for mail and hand delivery of objections and hearing requests are provided in 40 CFR 178.25(b).

In addition to filing an objection or hearing request with the Hearing Clerk as described in 40 CFR part 178, please submit a copy of the filing that does not contain any CBI for inclusion in the public docket. Information not marked confidential pursuant to 40 CFR part 2 may be disclosed publicly by EPA without prior notice. Submit a copy of your non-CBI objection or hearing request, identified by docket ID number EPA–HQ–OPP–2008–0125, 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.

II. Summary of Petitioned-For Tolerances

In the **Federal Register** of March 12, 2008 (73 FR 13225) (FRL–3854–6), EPA issued a notice pursuant to section 408(d)(3) of FFDCA, 21 U.S.C. 346a(d)(3), announcing the filing of a pesticide petition (PP 7E7308) by IR–4, 500 College Road East, Suite 201 W., Princeton, NJ 08540. The petition requested that 40 CFR 180.498 be amended by establishing tolerances for residues of the combined free and conjugated residues of the herbicide sulfentrazone, [*N*-[2,4-dichloro-5-[4-(difluoromethyl)-4,5-dihydro-3-methyl-5-oxo-1*H*-1,2,4-triazol-1-yl]phenyl]methanesulfonamide] and its metabolites HMS [*N*-(2,4-dichloro-5-(4-(difluoromethyl)-4,5-dihydro-3-hydroxymethyl-5-oxo-1*H*-1,2,4-triazol-1-yl)phenyl)methanesulfonamide] and DMS [(*N*-2,4-dichloro-5-[4-(difluoromethyl)-4,5-dihydro-5-oxo-1*H*-1,2,4-triazol-1-yl)phenyl)methanesulfonamide] in or on food commodities *Brassica,* head and stem, subgroup 5A at 0.20 parts per million (ppm); *Brassica,* leafy greens, subgroup 5B at 0.35 ppm; melon, subgroup 9A at 0.10 ppm; vegetable, fruiting, group 8 at 0.05 ppm; okra at 0.05 ppm; pea, succulent at 0.05 ppm; flax at 0.05 ppm; strawberry at 0.05 ppm; and vegetable, tuberous and corn, subgroup 1C at 0.15 ppm. That notice referenced a summary of the petition prepared on behalf of IR–4 by FMC Corporation, the registrant, which is available in the docket, *http://www.regulations.gov.* Comments were received on the notice of filing. EPA's response to these comments is discussed in Unit IV.C.

Based upon review of the data supporting the petition, EPA has revised the proposed tolerance levels for several commodities. Additionally, the EPA has assessed several additional fruiting vegetable commodities in order to establish the revised and expanded fruiting vegetable group 8–10. EPA has also revised the tolerance expression for all established commodities to be consistent with current Agency policy. The reasons for these changes are explained in Unit IV.D.

III. Aggregate Risk Assessment and Determination of Safety

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

Consistent with section 408(b)(2)(D) of FFDCA, and the factors specified in section 408(b)(2)(D) of FFDCA, EPA has reviewed the available scientific data and other relevant information in support of this action. EPA has sufficient data to assess the hazards of and to make a determination on aggregate exposure for sulfentrazone including exposure resulting from the tolerances established by this action. EPA's assessment of exposures and risks associated with sulfentrazone follows.

A. Toxicological Profile

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

Sulfentrazone has low acute toxicity via the oral, dermal, and inhalation routes of exposure. It is a mild eye irritant, but not a dermal irritant or sensitizer. Subchronic and chronic toxicity studies in rats, mice and dogs identified the hematopoietic system as the target of sulfentrazone. Protoporphyrinogen oxidase inhibition in the mammalian species may result in disruption of heme synthesis. In these studies, disruption of heme synthesis was observed at about the same dose levels across species except in the case of mice, where the effects were seen at a slightly higher dose. The hematotoxicity occurred around the same dose level for short- through long-term exposure without increasing in severity.

In the oral and dermal rat developmental toxicity studies, decreased fetal body weights and reduced/delayed skeletal ossifications were noted at doses that were not maternally toxic. In rabbits, developmental effects such as decreased pup viability were observed at a maternally toxic dose (clinical signs, abortions and decreased body weight gains). In the 2-generation reproduction study in rats, offspring effects such as decreased body weights and decreased litter survival were observed at a maternally toxic dose (slightly decreased body weight gain).

In the acute neurotoxicity study, an increased incidence of clinical signs (staggered gait, splayed hind limbs, and abdominal gripping), changes in functional observation battery (FOB) parameters, and decreased motor activity were observed; however, complete recovery was observed within 14 days and there was no evidence of neuropathology. In the subchronic neurotoxicity study, clinical signs of toxicity, increased motor activity, and/or decreased body weights, body weight gain, and food consumption were observed. There was no evidence of neuropathology in either study. In a published, non-guideline developmental toxicity study in the rat (de Castro, *et al.,* 2007), several dose-dependent effects (delayed ear opening, decreased grip response and rearing frequency, and increased surface righting reflex reaction time) were reported in pups whose mothers were treated with sulfentrazone. However, this study had several shortcomings that limit its use for regulatory purposes.

Carcinogenicity studies in rats and mice showed no evidence of increased incidence of tumor formation due to treatment with sulfentrazone. Therefore, the EPA classified sulfentrazone as "not likely to be carcinogenic to humans." The available mutagenicity studies indicate that sulfentrazone is weakly clastogenic in the *in vitro* mouse lymphoma assay in the absence of S9 activation; however, the response was not evident in the presence of S9 activation. Sulfentrazone is neither mutagenic in bacterial cells, nor clastogenic in male or female mice *in vivo.*

Specific information on the studies received and the nature of the adverse effects caused by sulfentrazone as well as the no-observed-adverse-effect-level (NOAEL) and the lowest-observed-adverse-effect-level (LOAEL) from the toxicity studies can be found at *http://www.regulations.gov* in document: "Sulfentrazone; REVISED Section 3 Registration Request to Add New Uses on: *Brassica,* Head and Stem, Subgroup 5A; *Brassica,* Leafy Greens, Subgroup 5B; Melon, Subgroup 9A; Fruiting

Vegetable, Group 8 and Okra; Pea, Succulent; Flax; Strawberry; and Tuberous and Corm Vegetable, Subgroup 1C. Human-Health Risk Assessment." pp. 51–56 in docket ID number EPA–HQ–OPP–2008–0125.

B. Toxicological Points of Departure/ Levels of Concern

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

The doses and toxicological endpoints selected for several exposure scenarios including the acute dietary endpoints for females 13–49 years old, the chronic dietary endpoint, and the short- and intermediate-term inhalation endpoint have been revised since the last risk assessment based on a re-evaluation of the toxicology database. The updated endpoints are protective of sulfentrazone's developmental toxicity, which was the critical effect in the database and observed via both the oral and dermal routes of exposure.

The acute dietary endpoint is based on increased gestation duration, reduced prenatal viability (fetal and litter), reduced litter size, increased number of stillborn pups, reduced postnatal survival (pups and litter), and pup body weight deficits throughout lactation in both generations of offspring observed in a 2-generation reproductive toxicity study in rats. The developmental effects were reported in the presence of mild maternal toxicity (slightly decreased body-weight gain, particularly in F_1 females). It has been EPA's practice to consider various forms of developmental toxicity such as reduced prenatal viability, reduced litter size, and increased number of stillborn pups as single-dose effects and, therefore, relevant for the acute dietary (females aged 13–49) exposure scenario, in order to protect against potential exposure of pregnant females. It should be noted that the fetal body weight deficits and retardation in skeletal development (including decreased numbers of caudal vertebral and metacarpal ossification sites) reported in the oral rat prenatal developmental toxicity study were also evaluated for this acute dietary endpoint. However, it was concluded that such effects are unlikely due to a single dose event and are more appropriate for a repeated-exposure scenario. Furthermore, EPA has not traditionally considered delays in ossification (and related fetal body weight deficits) to be single dose effects.

The chronic dietary endpoint is based on developmental toxicity (decreased fetal weights and delay in skeletal ossification) that was observed in the oral developmental toxicity study in the rat. This study provides the lowest NOAEL in the database, and the effects are similar to those observed in offspring (decreased body weight) at a slightly higher dose in the 2-generation reproduction study in rats. In addition, choice of the developmental toxicity study in the rat protects against exposure of women throughout their entire lifespan, which includes their childbearing years.

The short- and intermediate-term inhalation endpoints are based on developmental toxicity (decreased fetal weights, delay in skeletal ossification) that was observed in the oral developmental toxicity study in the rat. An oral study was chosen for this exposure scenario in the absence of an inhalation toxicity study. Assuming 100% absorption via the inhalation route, the oral developmental toxicity study protects pregnant women who might be exposed via inhalation against the critical effect observed in the sulfentrazone database, developmental toxicity.

The endpoints for the other exposure scenarios remain the same. A summary of the toxicological endpoints for sulfentrazone used for human risk assessment is shown in Table 1 of this unit.

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

Exposure/scenario	Point of departure and uncertainty/ safety factors	RfD, PAD, LOC for risk assessment	Study and toxicological effects
Acute dietary (Females 13–49 years of age).	NOAEL = 14 milligrams/kilogram/ day (mg/kg/day). UF_A = 10x UF_H = 10x FQPA SF = 1x	Acute RfD = 0.14 mg/kg/day. aPAD = 0.14 mg/ kg/day.	2-Generation Reproductive Toxicity Study—Rat, Offspring Toxicity LOAEL= 33 (M) and 40 (F) mg/kg/day based on reduced prenatal viability (fetal & litter), reduced litter size, increased number of stillborn pups, reduced pup and litter postnatal survival and decreased pup body weights throughout lactation.
Acute dietary (General population including infants and children).	NOAEL = 250 mg/ kg/day. UF_A = 10x UF_H = 10x FQPA SF = 1x	Acute RfD = 2.5 mg/kg/day. aPAD = 2.5 mg/kg/ day.	Acute-Neurotoxicity Study—Rat, LOAEL = 750 mg/kg/day based on increased incidence of clinical signs and FOB parameters and decreased motor activity.
Chronic dietary (All populations).	NOAEL= 10 mg/kg/ day. UF_A = 10x UF_H = 10x FQPA SF = 1x	Chronic RfD = 0.1 mg/kg/day. cPAD = 0.1 mg/kg/ day.	Prenatal Developmental Toxicity—Rat, Developmental LOAEL = 25 mg/kg/ day, based upon decreased mean fetal weights, and retardation in skeletal development evidenced by an increased number of litters with any variation and by decreased number of caudal vertebral and metacarpal ossification sites.

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

Exposure/scenario	Point of departure and uncertainty/ safety factors	RfD, PAD, LOC for risk assessment	Study and toxicological effects
Incidental oral short-term (1 to 30 days) and intermediate-term (1 to 6 months).	NOAEL= 14 mg/kg/day. UF_A = 10x ..... UF_H = 10x ..... FQPA SF = 1x	LOC for MOE = 100.	2-Generation Reproduction Study—Rat, LOAEL = 33 mg/kg/day based on decreased pup body weights during lactation and reduced postnatal survival in both generations.
Dermal short-term (1 to 30 days) and intermediate-term. (1 to 6 months)	Dermal (or oral) study NOAEL = 100 mg/kg/day. UF_A = 10x ..... UF_H = 10x ..... FQPA SF = 1x	LOC for MOE = 100.	Dermal Developmental Study—Rat, LOAEL = 250 mg/kg/day based on decreased fetal body weight; increased incidences of fetal variations: hypoplastic or wavy ribs, incompletely ossified lumbar vertebral arches, and incompletely ossified ischia or pubes; and reduced number of thoracic vertebral and rib ossification sites.
Inhalation short-term (1 to 30 days).	Inhalation (or oral) study NOAEL= 10 mg/kg/day (inhalation absorption rate = 100%). UF_A = 10x ..... UF_H = 10x ..... FQPA SF = 1x	LOC for MOE = 100.	Prenatal Developmental Toxicity—Rat, Developmental LOAEL = 25 mg/kg/day, based upon decreased mean fetal weights, and retardation in skeletal development evidenced by an increased number of litters with any variation and by decreased number of caudal vertebral and metacarpal ossification sites.
Cancer (Oral, dermal, inhalation).	Sulfentrazone is classified as "not likely to be carcinogenic to humans."		

UF_A = extrapolation from animal to human (interspecies). UF_H = potential variation in sensitivity among members of the human population (intraspecies). UF_L = use of a LOAEL to extrapolate a NOAEL. UF_S = use of a short-term study for long-term risk assessment. UF_{DB} = to account for the absence of data or other data deficiency. FQPA SF = Food Quality Protection Act Safety Factor.

C. Exposure Assessment

1. *Dietary exposure from food and feed uses.* In evaluating dietary exposure to sulfentrazone, EPA considered exposure under the petitioned-for tolerances as well as all existing sulfentrazone tolerances in 40 CFR 180.498. EPA assessed dietary exposures from sulfentrazone in food as follows:

i. *Acute exposure.* Quantitative acute dietary exposure and risk assessments are performed for a food-use pesticide, if a toxicological study has indicated the possibility of an effect of concern occurring as a result of a 1-day or single exposure. Such effects were identified for sulfentrazone. EPA performed separate acute risk assessments for females 13–49 years old and for the general population, including infants and children, based on different endpoints and aPADs. In estimating acute dietary exposure, EPA used food consumption information from the United States Department of Agriculture (USDA) 1994–1996 and 1998 Nationwide Continuing Surveys of Food Intake by Individuals (CSFII). As to residue levels in food, EPA used tolerance-level residues, Dietary Exposure Evaluation Model (DEEM)™ (ver. 7.81) default processing factors, and assumed 100 percent crop treated (PCT) for all commodities.

ii. *Chronic exposure.* In conducting the chronic dietary exposure assessment EPA used the food consumption data from the USDA 1994–1996 and 1998 CSFII. As to residue levels in food, EPA used tolerance-level residues, DEEM™ (ver. 7.81) default processing factors, and assumed 100 PCT for all commodities.

iii. Cancer. Based on the data summarized in Unit III.A., EPA has concluded that sulfentrazone does not pose a cancer risk to humans. Therefore, a dietary exposure assessment for the purpose of assessing cancer risk is unnecessary.

iv. *Anticipated residue and PCT information.* EPA did not use anticipated residue and/or PCT information in the dietary assessment for sulfentrazone. Tolerance level residues and/or 100 PCT were assumed for all food commodities.

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

Sulfentrazone and 3-carboxylic acid sulfentrazone are the residues of concern in drinking water. Therefore, the First Index Reservoir Screening Tool (FIRST) model was used to estimate concentrations of sulfentrazone and 3-carboxylic acid sulfentrazone in surface water, and the Screening Concentration in Ground Water (SCI–GROW) model was utilized to estimate concentrations in ground water. The estimated drinking water concentrations (EDWCs) of sulfentrazone and 3-carbyoxylic acid sulfentrazone for acute exposures are estimated to be 35.8 parts per billion (ppb) for surface water and 26.0 ppb for ground water. For chronic exposures for non-cancer assessments, EDWCs are estimated to be 7.8 ppb for surface water and 26.0 ppb for ground water.

Modeled estimates of drinking water concentrations were directly entered into the dietary exposure model. For acute dietary risk assessment, the water concentration value of 35.8 ppb was used to assess the contribution to drinking water. For chronic dietary risk assessment, the water concentration of value 26.0 ppb was used to assess the contribution to drinking water.

3. *From non-dietary exposure.* The term "residential exposure" is used in this document to refer to non-occupational, non-dietary exposure (*e.g.,* for lawn and garden pest control, indoor pest control, termiticides, and

flea and tick control on pets). Sulfentrazone is currently registered for the following use that could result in residential exposures: residential home lawns/turf and recreational turf, such as golf courses (application by professional applicators only). EPA assessed residential exposure using the following assumptions: Adults were assessed for potential short-term dermal and inhalation handler exposure from applying sulfentrazone to residential turf/home lawns and for short-term postapplication dermal exposure from contact with treated residential and recreational turf (home lawns and golf courses). Youths, ages 10–12 years old, were selected as a representative population to assess postapplication dermal exposure from contact with treated residential and recreational turf (home lawns and golf courses). Children, ages 3–6 years old, were selected as a representative population to assess for postapplication dermal and incidental oral (hand-to-mouth, object-to-mouth, soil ingestion and episodic ingestion of granules) exposure to residential turf/home lawns. As short- and intermediate-term points of departure are the same, the short-term assessment is considered protective of intermediate-term exposures. For children, however, while all three incidental oral exposures were aggregated for short-term exposures, the intermediate-term postapplication exposure scenario included only the soil ingestion incidental oral pathway, as this is the only pathway assumed to potentially result in intermediate-term exposures. Chronic exposures are not expected and were not assessed.

Further information regarding EPA standard assumptions and generic inputs for residential exposures may be found at *http://www.epa.gov/pesticides/trac/science/trac6a05.pdf.*

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

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

D. Safety Factor for Infants and Children

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

2. *Prenatal and postnatal sensitivity.* There is evidence of increased quantitative susceptibility following *in utero* exposure in the oral and dermal rat developmental toxicity studies. Developmental effects, including decreased fetal body weights and reduced/delayed skeletal ossifications were observed at doses that were not maternally toxic. In the 2-generation reproduction study in rats, offspring effects such as decreased body weights and decreased litter survival were observed at a slightly maternally toxic dose (slightly decreased body weight gain), indicating possible slightly increased qualitative susceptibility. Additionally, several dose-dependent effects were observed in rat pups whose mothers were treated with sulfentrazone in a published non-guideline rat developmental toxicity study.

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

i. The toxicity database for sulfentrazone is complete except for immunotoxicity testing. Recent changes to 40 CFR part 158 require immunotoxicity testing (OPPTS Test Guideline 870.7800) for pesticide registration. However, the existing data are sufficient for endpoint selection for exposure/risk assessment scenarios, and for evaluation of the requirements under the FQPA. The toxicology database for sulfentrazone does not show any evidence of treatment-related effects on the immune system; the overall weight of evidence is consistent with this chemical being a PPO inhibitor resulting in disruption of heme biosynthesis and subsequent effects on red blood cell dysfunction (*e.g.,* anemia). Unlike white blood cells (leukocytes) which are cells of the immune system, red blood cells function to deliver oxygen to body tissues and are not involved in eliciting an immune response. Furthermore, there is no indication in the sulfentrazone database of any effect on leukocyte counts (an indicator of immune function). Thus, the overall weight of evidence indicates that this chemical does not directly target the immune system. Sulfentrazone also does not belong to a class of chemicals (*e.g.,* the organotins, heavy metals, or halogenated aromatic hydrocarbons) that would be expected to be immunotoxic. Based on the above considerations, EPA does not believe that conducting a functional immunotoxicity study will result in a lower point of departure than that currently used for overall risk assessment. Therefore, an additional database UF to account for potential immunotoxicity does not need to be applied.

ii. The toxicity database for sulfentrazone does not trigger the need for a developmental neurotoxicity (DNT) study. There are no indications in any of the studies available that the nervous system is a target for sulfentrazone. The FOB findings were very non-specific signs of toxicity (perianal staining, colored tears) and motor activity changes only occurred at higher doses following acute exposure with rapid reversibility, also indicating general toxicity rather than specific neurotoxicity. The lack of neuropathological findings further supports the non-specific nature of the signs observed. In addition, there is a literature DNT study available for sulfentrazone. The only reliable effects seen in this study involved effects on physical and reflex development, which are known to be affected by body weight. Therefore, these effects are likely secondary to the effects (including body weight deficits) reported in the 2-generation reproductive toxicity study. EPA employed an independent statistical method to evaluate the literature DNT in an effort to determine if these effects were consistent with effects observed in other guideline studies at these same dose levels. The results of that analysis indicate that the results of the literature DNT study are consistent with what was observed in the rat 2-generation

reproduction study and that the studies used for risk assessment (NOAEL of 10 mg/kg/day from the developmental toxicity study in rat and the NOAEL of 14 mg/kg/day from the 2–generation reproduction study), are protective of the observations made at ≥25 mg/kg/day in the literature study for which a NOAEL was not attained. Based on the weight of evidence, there is no uncertainty related to developmental neurotoxicity.

iii. There is evidence of increased quantitative susceptibility following *in utero* exposure in the oral and dermal developmental toxicity studies in rats and possible evidence of slightly increased qualitative susceptibility of offspring in the 2-generation rat reproduction study. However, concern is low because clear NOAELs have been identified for the effects noted in these studies and both of the developmental toxicity studies have been chosen for endpoint selection, thereby protecting the relevant human subpopulations from the noted effects.

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

E. Aggregate Risks and Determination of Safety

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

1. *Acute risk.* Using the exposure assumptions discussed in this unit for acute exposure, the acute dietary exposure from food and water to sulfentrazone will occupy <1% of the aPAD for the general population, including infants and children. For females 13–49 years old, the acute dietary exposure to sulfentrazone from food and water will occupy 2.3% of the applicable aPAD chosen for that population subgroup.

2. *Chronic risk.* Using the exposure assumptions described in this unit for chronic exposure, EPA has concluded that chronic exposure to sulfentrazone from food and water will utilize 3.6% of the cPAD for children 1–2 years old, the population group receiving the greatest exposure. Based on the explanation in Unit III.C.3., regarding residential use patterns, chronic residential exposure to residues of sulfentrazone is not expected.

3. *Short- and intermediate-term risk.* Short- and intermediate-term aggregate exposure takes into account short- and intermediate-term residential exposure plus chronic exposure to food and water (considered to be a background exposure level). Sulfentrazone is currently registered for uses that could result in short- and intermediate-term residential exposure, and the Agency has determined that it is appropriate to aggregate chronic exposure through food and water with short- and intermediate-term residential exposures to sulfentrazone.

Using the exposure assumptions described in this unit for short- and intermediate-term exposures, EPA has concluded the combined short- and intermediate-term food, water, and residential exposures result in aggregate MOEs of 310 for the general U.S. population; 450 for children 1–2 years old for short-term exposures; and 590 for children 1–2 years old for intermediate-term exposures. Because EPA's level of concern for sulfentrazone is a MOE of 100 or below, these MOEs are not of concern.

4. *Aggregate cancer risk for U.S. population.* Based on the lack of evidence of carcinogenicity in two adequate rodent carcinogenicity studies, sulfentrazone is not expected to pose a cancer risk to humans.

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

IV. Other Considerations

A. Analytical Enforcement Methodology

Adequate enforcement methodology (gas chromatography (GC)) is available to enforce the tolerance expression. The method has been forwarded for inclusion in the Pesticides Analytical Manual, Volume II. The method may be requested from: Chief, Analytical Chemistry Branch, Environmental Science Center, 701 Mapes Rd., Ft. Meade, MD 20755–5350; *telephone number:* (410) 305–2905; *e-mail address: residuemethods@epa.gov.*

B. International Residue Limits

In making its tolerance decisions, EPA seeks to harmonize U.S. tolerances with international standards whenever possible, consistent with U.S. food safety standards and agricultural practices. EPA considers the international maximum residue limits (MRLs) established by the Codex Alimentarius Commission (Codex), as required by FFDCA section 408(b)(4). The Codex Alimentarius is a joint U.N. Food and Agriculture Organization/ World Health Organization food standards program, and it is recognized as an international food safety standards-setting organization in trade agreements to which the United States is a party. EPA may establish a tolerance that is different from a Codex MRL; however, FFDCA section 408(b)(4) requires that EPA explain the reasons for departing from the Codex level. There are no Codex, Canadian, or Mexican MRLs established for residues of sulfentrazone in or on the subject commodities.

C. Response to Comments

EPA received one comment to the Notice of Filing that had an objection to "the manufacture or sale" of sulfentrazone, citing the cruelty of animal testing as the main source of opposition. The Agency has received these same or similar comments from this commenter on numerous previous occasions. Please refer to the **Federal Register** of 70 FR 1349 (January 7, 2005) and 70 FR 37683 (June 30, 2005) for the Agency's previous responses to these and other similar comments.

D. Revisions to Petitioned-For Tolerances

Based upon review of the data supporting the petition, EPA revised the proposed tolerances for the following commodities: *Brassica,* leafy greens, subgroup 5B from 0.35 ppm to 0.40 ppm; melon, subgroup 9A from 0.10 ppm to 0.15 ppm; vegetable, fruiting, group 8 from 0.05 ppm to 0.15 ppm; okra from 0.05 ppm to 0.15 ppm; pea, succulent from 0.05 ppm to 0.15 ppm; flax from 0.05 ppm to 0.15 ppm; and strawberry from 0.05 ppm to 0.15 ppm. EPA revised the tolerance levels based on analysis of the residue field trial data using the Agency's Tolerance Spreadsheet in accordance with the Agency's *Guidance for Setting Pesticide Tolerances Based on Field Trial Data.*

Additionally, EPA was petitioned for tolerances on fruiting vegetable group 8

and a separate tolerance on okra. In the **Federal Register** of December 8, 2010 (75 FR 76284) (FRL–8853–8), EPA issued a final rule that revised the crop grouping regulations. As part of this action, EPA expanded and revised the existing fruiting vegetable crop group 8. Changes to crop group 8 included adding okra, cocona, African eggplant, pea eggplant, scarlet eggplant, goji berry, garden huckleberry, martynia, naranjilla, roselle, sunberry, bush tomato, currant tomato, and tree tomato; creating subgroups; revising the representative commodities; and naming the new crop group fruiting vegetable group 8–10. EPA indicated in the December 8, 2010 final rule as well as the earlier January 6, 2010 proposed rule (75 FR 807) (FRL–8801–2) that, for existing petitions for which a Notice of Filing had been published, the Agency would attempt to conform these petitions to the rule. Therefore, consistent with this rule, EPA has assessed and is establishing a tolerance on fruiting vegetable group 8–10.

Finally, the EPA has revised the tolerance expression to clarify (1) that, as provided in FFDCA section 408(a)(3), the tolerance covers metabolites and degradates of sulfentrazone not specifically mentioned; and (2) that compliance with the specified tolerance levels is to be determined by measuring only the specific compounds mentioned in the tolerance expression.

V. Conclusion

Therefore, tolerances are established for residues of the combined residues of free and conjugated forms of sulfentrazone (*N*-[2,4-dichloro-5-[4-(difluoromethyl)-4,5-dihydro-3-methyl-5-oxo-1*H*-1,2,4-triazol-1-yl]phenyl]methanesulfonamide) and its metabolites HMS (*N*-(2,4-dichloro-5-(4-(difluoromethyl)-4,5-dihydro-3-hydroxymethyl-5-oxo-1*H*-1,2,4-triazol-1-yl)phenyl)methanesulfonamide) and DMS (*N*-(2,4-dichloro-5-(4-(difluoromethyl)-4,5-dihydro-5-oxo-1*H*-1,2,4-triazol-1-yl)phenyl)methanesulfonamide, in or on *Brassica,* head and stem, subgroup 5A at 0.20 ppm; *Brassica,* leafy greens, subgroup 5B at 0.40 ppm; melon, subgroup 9A at 0.15 ppm; vegetable, fruiting, group 8–10 at 0.15 ppm; pea, succulent at 0.15 ppm; flax at 0.15 ppm; strawberry at 0.15 ppm; and vegetable, tuberous and corm, subgroup 1C at 0.15 ppm. Additionally, this regulation deletes existing individual tolerances in or on cabbage at 0.20 ppm and potato at 0.15 ppm, and further deletes the time-limited tolerance for bean, succulent seed without pod (lima bean and cowpea) at 0.1 ppm.

VI. Statutory and Executive Order Reviews

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

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

This final rule directly regulates growers, food processors, food handlers, and food retailers, not States or tribes, nor does this action alter the relationships or distribution of power and responsibilities established by Congress in the preemption provisions of section 408(n)(4) of FFDCA. As such, the Agency has determined that this action will not have a substantial direct effect on States or tribal governments, on the relationship between the national government and the States or tribal governments, or on the distribution of power and responsibilities among the various levels of government or between the Federal Government and Indian tribes. Thus, the Agency has determined that Executive Order 13132, entitled *Federalism* (64 FR 43255, August 10, 1999) and Executive Order 13175, entitled *Consultation and Coordination with Indian Tribal Governments* (65 FR 67249, November 9, 2000) do not apply to this final rule. In addition, this final rule does not impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act of 1995 (UMRA) (Public Law 104–4).

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).

VII. Congressional Review Act

The Congressional Review Act, 5 U.S.C. 801 *et seq.,* generally provides that before a rule may take effect, the agency promulgating the rule must submit a rule report to each House of the Congress and to the Comptroller General of the United States. EPA will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of this final rule in the **Federal Register**. This final rule is not a "major rule" as defined by 5 U.S.C. 804(2).

List of Subjects in 40 CFR Part 180

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

Dated: January 14, 2011.

Daniel J. Rosenblatt,

Acting Director, Registration Division, Office of Pesticide Programs.

Therefore, 40 CFR chapter I is amended as follows:

PART 180—[AMENDED]

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

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

■ 2. Section 180.498 is amended as follows:

■ i. Revise the introductory text of paragraph (a)(1);

■ ii. Revise the introductory text of paragraph (a)(2), remove the entries for "Cabbage" and "Potato" and add commodities to the table;

■ iii. Revise paragraph (b); and

■ iv. Revise the introductory text of paragraph (d), to read as follows:

§ 180.498 Sulfentrazone; tolerances for residues.

(a)(1) *General.* Tolerances are established for the combined residues of the free and conjugated forms of sulfentrazone, including its metabolites and degradates, in or on the commodities in the table below. Compliance with the tolerance levels

specified below is to be determined by measuring only the sum of sulfentrazone (*N*-[2,4-dichloro-5-[4-(difluoromethyl)-4,5-dihydro-3-methyl-5-oxo-1*H*-1,2,4-triazol-1-yl]phenyl]methanesulfonamide) and its metabolite HMS (*N*-(2,4-dichloro-5-(4-(difluoromethyl)-4,5-dihydro-3-hydroxymethyl-5-oxo-1*H*-1,2,4-triazol-1-yl)phenyl)methanesulfonamide, calculated as the stoichiometric equivalent of sulfentrazone in or on the following commodities.

* * * * *

(2) Tolerances are established for the combined residues of the free and conjugated forms of sulfentrazone, including its metabolites and degradates, in or on the commodities in the table below. Compliance with the tolerance levels specified below is to be determined by measuring only the sum of sulfentrazone (*N*-[2,4-dichloro-5-[4-(difluoromethyl)-4,5-dihydro-3-methyl-5-oxo-1*H*-1,2,4-triazol-1-yl]phenyl]methanesulfonamide) and its metabolites HMS (*N*-(2,4-dichloro-5-(4-(difluoromethyl)-4,5-dihydro-3-hydroxymethyl-5-oxo-1*H*-1,2,4-triazol-1-yl)phenyl)methanesulfonamide) and DMS (*N*-(2,4-dichloro-5-(4-(difluoromethyl)-4,5-dihydro-5-oxo-1*H*-1,2,4-triazol-1-yl)phenyl)methanesulfonamide, calculated as the stoichiometric equivalent of sulfentrazone in or on the following commodities.

Commodity	Parts per million
* * * * *	
Brassica, head and stem, subgroup 5A	0.20
Brassica, leafy greens, subgroup 5B	0.40
* * * * *	
Flax	0.15
* * * * *	
Melon, subgroup 9A	0.15
Pea, succulent	0.15
* * * * *	
Strawberry	0.15
* * * * *	
Vegetable, fruiting, group 8–10	0.15
Vegetable, tuberous and corm, subgroup 1C	0.15

(b) *Section 18 emergency exemptions.* Time-limited tolerances are established for the combined residues of the free and conjugated forms of sulfentrazone, including its metabolites and degradates, in connection with use of the pesticide under section 18 emergency exemptions granted by EPA. Compliance with the tolerance levels specified below is to be determined by measuring only the sum of sulfentrazone (*N*-[2,4-dichloro-5-[4-(difluoromethyl)-4,5-dihydro-3-methyl-5-oxo-1*H*-1,2,4-triazol-1-yl]phenyl]methanesulfonamide) and its metabolites HMS (*N*-(2,4-dichloro-5-(4-(difluoromethyl)-4,5-dihydro-3-hydroxymethyl-5-oxo-1*H*-1,2,4-triazol-1-yl)phenyl)methanesulfonamide) and DMS (*N*-(2,4-dichloro-5-(4-(difluoromethyl)-4,5-dihydro-5-oxo-1*H*-1,2,4-triazol-1-yl)phenyl)methanesulfonamide, calculated as the stoichiometric equivalent of sulfentrazone in or on the following commodities. These tolerances expire and are revoked on the dates specified in the following table.

Commodity	Parts per million	Expiration/ revocation date
Flax, seed	0.20	12/31/13
Strawberry	0.60	12/31/13

* * * * *

(d) *Indirect or inadvertent residues.* Tolerances are established for inadvertent and indirect combined residues of the free and conjugated forms of sulfentrazone, including its metabolites and degradates, in or on the commodities in the table below. Compliance with the tolerance levels specified below is to be determined by measuring only the sum of sulfentrazone (*N*-[2,4-dichloro-5-[4-(difluoromethyl)-4,5-dihydro-3-methyl-5-oxo-1*H*-1,2,4-triazol-1-yl]phenyl]methanesulfonamide) and its metabolites HMS (*N*-(2,4-dichloro-5-(4-(difluoromethyl)-4,5-dihydro-3-hydroxymethyl-5-oxo-1*H*-1,2,4-triazol-1-yl)phenyl)methanesulfonamide) and DMS (*N*-(2,4-dichloro-5-(4-(difluoromethyl)-4,5-dihydro-5-oxo-1*H*-1,2,4-triazol-1-yl)phenyl)methanesulfonamide, calculated as the stoichiometric equivalent of sulfentrazone in or on the following commodities when present therein as a result of the application of sulfentrazone to growing crops.

* * * * *

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA–HQ–OPP–2009–0796; FRL–8860–2]

Bispyribac-sodium; Pesticide Tolerances

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes tolerances for residues of bispyribac-sodium in or on fish, freshwater. Valent U.S.A. Corporation requested these tolerances under the Federal Food, Drug, and Cosmetic Act (FFDCA).

DATES: This regulation is effective February 2, 2011. Objections and requests for hearings must be received on or before April 4, 2011, and must be filed in accordance with the instructions provided in 40 CFR part 178 (see also Unit I.C. of the **SUPPLEMENTARY INFORMATION**).

ADDRESSES: EPA has established a docket for this action under docket identification (ID) number EPA–HQ–OPP–2009–0796. 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.,* Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the Internet and will be publicly available only in hard copy form. Publicly available docket materials are available 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 Docket Facility is open 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: Hope Johnson, Registration Division, Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001; telephone number: (703) 305–5410; e-mail address: *johnson.hope@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 those engaged in the following activities:

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

You may access a frequently updated electronic version of EPA's tolerance regulations at 40 CFR part 180 through the Government Printing Office's e-CFR site at *http://www.gpoaccess.gov/ecfr.* To access the harmonized test guidelines referenced in this document electronically, please go *http://www.epa.gov/ocspp* and select "Test Methods and Guidelines."

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

Under FFDCA section 408(g), 21 U.S.C. 346a, any person may file an objection to any aspect of this regulation and may also request a hearing on those objections. You must file your objection or request a hearing on this regulation in accordance with the instructions provided in 40 CFR part 178. To ensure proper receipt by EPA, you must identify docket ID number EPA–HQ–OPP–2009–0796 in the subject line on the first page of your submission. All objections and requests for a hearing must be in writing, and must be received by the Hearing Clerk on or before April 4, 2011. Addresses for mail and hand delivery of objections and hearing requests are provided in 40 CFR 178.25(b).

In addition to filing an objection or hearing request with the Hearing Clerk as described in 40 CFR part 178, please submit a copy of the filing that does not contain any CBI for inclusion in the public docket. Information not marked confidential pursuant to 40 CFR part 2 may be disclosed publicly by EPA without prior notice. Submit a copy of your non-CBI objection or hearing request, identified by docket ID number EPA–HQ–OPP–2009–0796, 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.

II. Summary of Petitioned-For Tolerance

In the **Federal Register** of January 6, 2010 (75 FR 864) (FRL–8801–5), EPA issued a notice pursuant to section 408(d)(3) of FFDCA, 21 U.S.C. 346a(d)(3), announcing the filing of a pesticide petition (PP 8F7509) by Valent U.S.A Corporation, 1600 Riviera Avenue, Suite 200, Walnut Creek, CA 94596. The petition requested that 40 CFR 180.577 be amended by establishing tolerances for residues of the herbicide bispyribac-sodium, sodium, 2,6-bis[(4,6-dimethoxy-pyrimidin-2-yl)oxy]benzoate, in or on fish, freshwater at 0.01 parts per million (ppm). That notice referenced a summary of the petition prepared by Valent U.S.A Corporation, the registrant, which is available in the docket, *http://www.regulations.gov.* There were no comments received in response to the notice of filing.

Based upon review of the data supporting the petition, EPA has revised the proposed tolerance expression. The reason for this change is explained in Unit IV.C.

III. Aggregate Risk Assessment and Determination of Safety

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

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

A. Toxicological Profile

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

The toxicological database for bispyribac-sodium is complete with the exception of immunotoxicity, acute neurotoxicity, and subchronic neurotoxicity studies, as well as a 28-day inhalation study. Bispyribac-sodium has a low acute toxicity profile and is not a dermal sensitizer. The liver and bile duct were identified as the target organs in the subchronic and chronic toxicity studies in rats, mice, and dogs, and the reproductive toxicity

study in rats. Repeated dermal applications at the limit dose did not elicit systemic toxicity or dermal irritation. Bispyribac-sodium was negative for carcinogenicity in feeding studies in rats and mice and is classified as a "not likely human carcinogen" and mutagenicity studies conducted with the parent and three major metabolites were negative. There was no evidence of fetal toxicity or offspring susceptibility in the developmental toxicity studies in rats and rabbits or in the reproductive toxicity study in rats. Bispyribac-sodium has shown no indications of central or peripheral nervous system toxicity in any study and does not appear to be structurally related to any other chemical that causes adverse nervous system effects.

Acute and subchronic neurotoxicity studies are not available for bispyribac-sodium. There were clinical signs of potential neurotoxicity (i.e., piloerection, subnormal temperature, and decreased spontaneous motor activity) in the combined rat chronic/carcinogenicity study. However, these clinical signs occurred at a low incidence in the high dose group and were not dose-dependent. The primary effects of the study were based on macro- and microscopic changes in the liver and choldedochus, decreased body weights, and decreased food efficiency. There are no other signs of neurotoxicity in the database.

Specific information on the studies received and the nature of the adverse effects caused by bispyribac-sodium as well as the no-observed-adverse-effect-level (NOAEL) and the lowest-observed-adverse-effect-level (LOAEL) from the toxicity studies can be found at *http://www.regulations.gov* in the document "Bispyribac-sodium; Human-Health Risk Assessment for New Product Registration for Aquatic Uses on Freshwater Fish" at page 28 in docket ID number EPA–HQ–OPP–2009–0796.

B. Toxicological Points of Departure/Levels of Concern

Once a pesticide's toxicological profile is determined, EPA identifies toxicological points of departure (POD) and levels of concern to use in evaluating the risk posed by human exposure to the pesticide. For hazards that have a threshold below which there is no appreciable risk, the toxicological POD is used as the basis for derivation of reference values for risk assessment. PODs are developed based on a careful analysis of the doses in each toxicological study to determine the dose at which no adverse effects are observed (the NOAEL) and the lowest dose at which adverse effects of concern are identified (the LOAEL). Uncertainty/safety factors are used in conjunction with the POD to calculate a safe exposure level—generally referred to as a population-adjusted dose (PAD) or a reference dose (RfD)—and a safe margin of exposure (MOE). For non-threshold risks, the Agency assumes that any amount of exposure will lead to some degree of risk. Thus, the Agency estimates risk in terms of the probability of an occurrence of the adverse effect expected in a lifetime. For more information on the general principles EPA uses in risk characterization and a complete description of the risk assessment process, see *http://www.epa.gov/pesticides/factsheets/riskassess.htm.* A summary of the toxicological endpoints for Bispyribac-sodium used for human risk assessment is shown in Table 1 of this unit.

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

Exposure scenario	Dose used in risk assessment, UF	FQPA SF and LOC for risk assessment	Study and toxicological effects
Acute Dietary *all populations*.	No appropriate endpoint attributable to a single exposure was identified.		
Chronic Dietary *all populations*.	NOAEL = 10 mg/kg/day ..... UF = 100	FQPA SF = 1X ..... cPAD = cRfD = 0.1 mg/kg/day	Chronic Toxicity Study—Dog LOAEL = 100 mg/kg/day based on dose-related increases in hyperplasia of the intrahepatic bile ducts in males and females and granulation of the liver in the females.
Short-Term Incidental Oral (1–30 days) (Residential).	NOAEL = 100 mg/kg/day	LOC for MOE = 100 (includes FQPA SF = 1X).	Developmental Toxicity Study—Rabbit Maternal LOAEL = 300 mg/kg/day based on lethargy, diarrhea and decreased body-weight gain in the range-finding study.
Intermediate-Term Incidental Oral (1–6 months) (Residential).	NOAEL = 100 mg/kg/day	LOC for MOE = 100 (includes FQPA SF = 1X).	90–Day Feeding Study—Dog LOAEL = 600 mg/kg/day based upon salivation and slight proliferation of intrahepatic bile duct.
Short-Term Inhalation (1–30 days) (Occupational/Residential).	Oral study NOAEL = 100 mg/kg/day (inhalation absorption rate = 100%).	LOC for MOE = 100 (Occupational) LOC for MOE = 100 (Residential, includes the FQPA SF = 1X).	Developmental Toxicity Study—Rabbit Maternal LOAEL = 300 mg/kg/day based on lethargy, diarrhea and decreased body-weight gain in the range-finding study.
Intermediate-Term Inhalation (1–6 months) (Occupational/Residential).	Oral study NOAEL = 100 mg/kg/day (inhalation absorption rate = 100%).	LOC for MOE = 100 (Occupational) LOC for MOE = 100 (Residential, includes the FQPA SF = 1X).	90-Day feeding study—Dog LOAEL = 600 mg/kg/day based upon salivation and slight proliferation of intrahepatic bile duct.
Long-Term Inhalation (≤6 months) (Occupational/Residential).	Oral study NOAEL = 10 mg/kg/day (inhalation absorption rate = 100%).	LOC for MOE = 100 (Occupational) LOC for MOE = 100 (Residential, includes the FQPA SF = 1X).	Chronic Toxicity Study—Dog LOAEL = 100 mg/kg/day based on dose-related increases in hyperplasia of the intrahepatic bile ducts in males and females and granulation of the liver in the females.
Cancer (oral, dermal, inhalation).	Not likely to be carcinogenic to humans.		

UF_A = extrapolation from animal to human (interspecies). UF_H = potential variation in sensitivity among members of the human population (intraspecies). UF_L = use of a LOAEL to extrapolate a NOAEL. UF_S = use of a short-term study for long-term risk assessment. UF_{DB} = to account for the absence of data or other data deficiency. FQPA SF = Food Quality Protection Act Safety Factor. PAD = population adjusted dose (a = acute, c = chronic). RfD = reference dose. MOE = margin of exposure. LOC = level of concern.

C. Exposure Assessment

1. *Dietary exposure from food and feed uses.* In evaluating dietary exposure to bispyribac-sodium, EPA considered exposure under the petitioned-for tolerances as well as all existing bispyribac-sodium tolerances in 40 CFR 180.577. EPA assessed dietary exposures from bispyribac-sodium in food as follows:

i. *Acute exposure.* Quantitative acute dietary exposure and risk assessments are performed for a food-use pesticide, if a toxicological study has indicated the possibility of an effect of concern occurring as a result of a 1-day or single exposure.

No such effects were identified in the toxicological studies for bispyribac-sodium; therefore, a quantitative acute dietary exposure assessment is unnecessary.

ii. *Chronic exposure.* In conducting the chronic dietary exposure assessment EPA used the food consumption data from the USDA 1994–1996 and 1998 CSFII. As to residue levels in food, EPA assumed tolerance-level residues (for all registered and proposed new uses), default processing factors, and 100% crop treated (CT).

iii. *Cancer.* Based on the data summarized in Unit III.A., EPA has concluded that bispyribac-sodium does not pose a cancer risk to humans. Therefore, a dietary exposure assessment for the purpose of assessing cancer risk is unnecessary.

iv. *Anticipated residue and percent crop treated (PCT) information.* EPA did not use anticipated residue and/or PCT information in the dietary assessment for bispyribac-sodium. Tolerance level residues and/or 100% CT were assumed for all food commodities.

2. *Dietary exposure from drinking water.* Because currently used Tier 1 aquatic exposure models are used to simulate agricultural uses and are not appropriate for determining estimated drinking water concentrations (EDWCs) for aquatic uses of pesticides applied directly to surface water bodies, the Agency used the maximum annual label target rate of 180 ppb for subsurface injection of bispyribac-sodium into water. This value represents the maximum cumulative concentration in water based on four applications, at unspecified intervals, needed to achieve a 45-ppb level of bispyribac-sodium in the water column. Because bispyribac-sodium is only moderately persistent and will undergo degradation in the environment between applications, this value can be considered conservative.

For chronic dietary risk assessment, the water concentration of value 180 ppb was used to assess the contribution to drinking water and was incorporated directly into the dietary assessment.

3. *From non-dietary exposure.* The term "residential exposure" is used in this document to refer to non-occupational, non-dietary exposure (e.g., for lawn and garden pest control, indoor pest control, termiticides, and flea and tick control on pets).

Bispyribac-sodium is currently registered for the following uses that could result in residential exposures: golf courses and sod farms. EPA assessed residential exposure using the following assumptions: No residential handler exposure is expected from the proposed and registered uses of bispyribac-sodium. Residential postapplication exposure following use of bispyribac-sodium on golf courses and sod farms is possible. A dermal postapplication assessment was not performed since there is no short-term dermal point of departure. For the proposed aquatic use, there is a potential for exposure to recreational users (*i.e.,* swimmers) in these water bodies. Postapplication exposure and risks were developed for the non-competitive adult and child swimmer. Exposure is expected to be short-term; however, since the short- and intermediate-term points of departure are the same, the short-term assessment is protective of intermediate-term exposures. Only oral postapplication exposure to recreational swimmers was assessed.

Further information regarding EPA standard assumptions and generic inputs for residential exposures may be found at *http://www.epa.gov/pesticides/trac/science/trac6a05.pdf.*

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

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

D. Safety Factor for Infants and Children

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

2. *Prenatal and postnatal sensitivity.* There is no indication of quantitative or qualitative increased susceptibility of rats or rabbits to *in utero* or postnatal exposure to bispyribac-sodium. In the rat prenatal developmental toxicity study in rats, no toxicity was observed in the dams or the fetuses up to the highest dose tested (1000 mg/kg/day). In the rabbit prenatal developmental toxicity study, the dams were more susceptible than the fetuses. Maternal toxicity at the LOAEL of 300 mg/kg/day included lethargy, diarrhea, and decreased body weight gain. There were no fetal effects. In the 2-generation reproduction study, the parents were more susceptible to than the offspring. At the parental LOAEL of 75.7 mg/, effects observed included mild choledocus (bile duct) hyperplasia. There were no reproductive effects. At the offspring LOAEL of 759 mg/kg/day, effects observed were decreased body weights and body-weight gains, liver weights, and increased incidence of consolidation and circumscribed areas in the liver.

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

i. The toxicity database for bispyribac-sodium is complete with the exception of immunotoxicity, acute neurotoxicity, subchronic neurotoxicity and a 28-day inhalation study.

The concern for neurotoxicity is low and there is no need for a developmental neurotoxicity study or additional UFs to account for neurotoxicity. There are no indications in any of the studies available that the nervous system is a target for

bispyribac-sodium. Although there were clinical signs potentially indicative of neurotoxicity (e.g., piloerection, subnormal temperature, and decreased spontaneous motor activity) in the combined rat chronic/carcinogenicity study, these effects were considered secondary to the critical effects (macro- and microscopic changes in the liver and choldedochus, decreased body weights, and decreased food efficiency). Additionally, treatment-related clinical signs only occurred at the highest dose tested (404 mg/kg/day) and were not dose-dependent. These effects are therefore attributed to general, systemic toxicity, not neurotoxicity. Although acute and subchronic neurotoxicity studies are now required as part of the revisions to 40 CFR part 158, the Agency does not believe that conducting these studies will result in a lower point of departure (POD) than that currently used for overall risk assessment, and therefore, a database uncertainty factor (UF_{DB}) is not needed to account for lack of these studies. The toxicology database for bispyribac-sodium does not show any evidence of treatment-related effects on the immune system. The overall weight of evidence suggests that this chemical does not directly target the immune system. An immunotoxicity study is required as a part of new data requirements in the 40 CFR part 158 for conventional pesticide registration; however, the Agency does not believe that conducting a functional immunotoxicity study will result in a lower point of departure than that currently used for overall risk assessment, and therefore, a database uncertainty factor (UF_{DB}) is not needed to account for lack of this study. A 28-day inhalation study is not available; however, the Agency has determined that the additional FQPA SF is not needed. Based on the very low vapor pressure of bispyribac-sodium (3.79×10^{-11} at 25°C) and because the residential use pattern is limited to golf courses and swimming areas, minimal potential for inhalation exposure is expected. Therefore, the risk estimate is conservative and is considered protective and the additional FQPA SF is not needed.

ii. There is no indication that bispyribac-sodium is a neurotoxic chemical and there is no need for a developmental neurotoxicity study or additional UFs to account for neurotoxicity.

iii. There is no evidence that bispyribac-sodium results in increased susceptibility in *in utero* rats or rabbits in the prenatal developmental studies or in young rats in the 2-generation reproduction study.

iv. There are no residual uncertainties identified in the exposure databases. The dietary food exposure assessments were performed based on 100% CT and tolerance-level residues. EPA made conservative (protective) assumptions in the ground and surface water modeling used to assess exposure to bispyribac-sodium in drinking water. EPA used similarly conservative assumptions to assess postapplication exposure of children as well as incidental oral exposure of toddlers. These assessments will not underestimate the exposure and risks posed by bispyribac-sodium.

E. Aggregate Risks and Determination of Safety

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

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

2. *Chronic risk.* Using the exposure assumptions described in this unit for chronic exposure, EPA has concluded that chronic exposure to bispyribac-sodium from food and water will utilize 12.5% of the cPAD for infants (<1 year old) the population group receiving the greatest exposure. Based on the explanation in Unit III.C.3., regarding residential use patterns, chronic residential exposure to residues of bispyribac-sodium is not expected.

3. *Short-term risk.* Short-term aggregate exposure takes into account short-term residential exposure plus chronic exposure to food and water (considered to be a background exposure level).

Bispyribac-sodium is currently registered for uses that could result in short-term residential exposure, and the Agency has determined that it is appropriate to aggregate chronic exposure through food and water with short-term residential exposures to bispyribac-sodium.

Using the exposure assumptions described in this unit for short-term exposures, EPA has concluded the combined short-term food, water, and residential exposures result in aggregate MOEs of 25,000 for the U.S. general population, 26,000 for adults 50+ years old, and 7,700 for all infants (<1 year old). Because EPA's level of concern for bispyribac-sodium is a MOE of 100 or below, these MOEs are not of concern.

4. *Intermediate-term risk.* Intermediate-term aggregate exposure takes into account intermediate-term residential exposure plus chronic exposure to food and water (considered to be a background exposure level). Because no intermediate-term adverse effect was identified, bispyribac-sodium is not expected to pose an intermediate-term risk. However, since the short- and intermediate-term points of departure are the same, the short-term aggregate assessment is protective of intermediate-term exposures.

5. *Aggregate cancer risk for U.S. population.* Based on the lack of evidence of carcinogenicity in two adequate rodent carcinogenicity studies, bispyribac-sodium is not expected to pose a cancer risk to humans.

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

IV. Other Considerations

A. Analytical Enforcement Methodology

Adequate enforcement methodology (high-performance liquid chromatography (HPLC) with tandem mass spectroscopy detection (MS/MS)) is available to enforce the tolerance expression. The method may be requested from: Chief, Analytical Chemistry Branch, Environmental Science Center, 701 Mapes Rd., Ft. Meade, MD 20755–5350; telephone number: (410) 305–2905; e-mail address: *residuemethods@epa.gov*.

B. International Residue Limits

In making its tolerance decisions, EPA seeks to harmonize U.S. tolerances with international standards whenever possible, consistent with U.S. food safety standards and agricultural practices. EPA considers the international maximum residue limits (MRLs) established by the Codex Alimentarius Commission (Codex), as required by FFDCA section 408(b)(4). The Codex Alimentarius is a joint U.N. Food and Agriculture Organization/World Health Organization food standards program, and it is recognized as an international food safety

standards-setting organization in trade agreements to which the United States is a party. EPA may establish a tolerance that is different from a Codex MRL; however, FFDCA section 408(b)(4) requires that EPA explain the reasons for departing from the Codex level.

The Codex has not established a MRL for bispyribac-sodium.

C. Revisions to Petitioned-For Tolerances

EPA is revising the requested tolerance expression for bispyribac-sodium. The revised tolerance expression makes clear that the tolerances cover residues of the herbicide bispyribac-sodium, including its metabolites and degradates, but that compliance with the tolerance levels is to be determined by measuring only bispyribac-sodium, (2,6-bis[(4,6-dimethoxy-2-pyrimidinyl)oxy]benzoic acid, sodium salt), in or on the commodity. EPA has determined that it is reasonable to make this change final without prior proposal and opportunity for comment, because public comment is not necessary, in that the change has no substantive effect on the tolerance, but rather is merely intended to clarify the existing tolerance expression.

V. Conclusion

Therefore, tolerances are established for residues of bispyribac-sodium, including its metabolites and degradates, in or on fish, freshwater at 0.01 ppm. Compliance with the tolerance level is to be determined by measuring only bispyribac-sodium, (2,6-bis[(4,6-dimethoxy-2-pyrimidinyl)oxy]benzoic acid, sodium salt), in or on the commodity.

VI. Statutory and Executive Order Reviews

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

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

This final rule directly regulates growers, food processors, food handlers, and food retailers, not States or tribes, nor does this action alter the relationships or distribution of power and responsibilities established by Congress in the preemption provisions of section 408(n)(4) of FFDCA. As such, the Agency has determined that this action will not have a substantial direct effect on States or tribal governments, on the relationship between the national government and the States or tribal governments, or on the distribution of power and responsibilities among the various levels of government or between the Federal Government and Indian tribes. Thus, the Agency has determined that Executive Order 13132, entitled *Federalism* (64 FR 43255, August 10, 1999) and Executive Order 13175, entitled *Consultation and Coordination with Indian Tribal Governments* (65 FR 67249, November 9, 2000) do not apply to this final rule. In addition, this final rule does not impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act of 1995 (UMRA) (Pub. L. 104–4).

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).

VII. Congressional Review Act

The Congressional Review Act, 5 U.S.C. 801 *et seq.,* generally provides that before a rule may take effect, the agency promulgating the rule must submit a rule report to each House of the Congress and to the Comptroller General of the United States. EPA will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of this final rule in the **Federal Register**. This final rule is not a "major rule" as defined by 5 U.S.C. 804(2).

List of Subjects in 40 CFR Part 180

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

Dated: January 18, 2011.

Lois Rossi,

Director, Registration Division, Office of Pesticide Programs.

Therefore, 40 CFR chapter I is amended as follows:

PART 180—[AMENDED]

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

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

■ 2. Section 180.577 is amended by revising paragraph (a) introductory text and alphabetically adding the following commodity to the table in paragraph (a) to read as follows:

§ 180.577 Bispyribac-sodium; tolerances for residues.

(a) *General.* Tolerances are established for residues of the herbicide bispyribac-sodium, including its metabolites and degradates, in or on the commodity listed below. Compliance with the tolerance level specified below is to be determined by measuring only bispyribac-sodium, (2,6-bis[(4,6-dimethoxy-2-pyrimidinyl)oxy]benzoic acid, sodium salt), in or on the following raw agricultural commodities:

Commodity	Parts per million
Fish, freshwater	0.01
* * * * *	

* * * * *

[FR Doc. 2011–2266 Filed 2–1–11; 8:45 am]

BILLING CODE 6560–50–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

50 CFR Part 622

[Docket No. 0907271173–0629–03]

RIN 0648–XA154

Fisheries of the Caribbean, Gulf of Mexico, and South Atlantic; Snapper-Grouper Fishery of the South Atlantic; Closure of the 2010–2011 Recreational Sector for Black Sea Bass in the South Atlantic

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

ACTION: Temporary rule; closure.

SUMMARY: NMFS closes the recreational sector for black sea bass in the portion of the exclusive economic zone (EEZ) of the South Atlantic through 35°15.19′ N. lat., the latitude of Cape Hatteras Light, North Carolina. NMFS has determined that the recreational annual catch limit (ACL) for black sea bass has been reached. This closure is necessary to protect the black sea bass resource.

DATES: The closure is effective 12:01 a.m., local time, February 12, 2011, until 12:01 a.m., local time, on June 1, 2011.

FOR FURTHER INFORMATION CONTACT: Catherine Bruger, telephone 727–824–5305, fax 727–824–5308, e-mail *Catherine.Bruger@noaa.gov.*

SUPPLEMENTARY INFORMATION: The snapper-grouper fishery of the South Atlantic is managed under the Fishery Management Plan for the Snapper-Grouper Fishery of the South Atlantic Region (FMP). The FMP was prepared by the South Atlantic Fishery Management Council (Council) and is implemented under the authority of the Magnuson-Stevens Fishery Conservation and Management Act (Magnuson-Stevens Act) by regulations at 50 CFR part 622. These regulations set the recreational ACL for black sea bass in the South Atlantic at 409,000 lb (185,519 kg), gutted weight, for the current fishing year, June 1, 2010, through May 31, 2011.

Background

Black sea bass are managed throughout their range. In the South Atlantic EEZ, black sea bass are managed by the Council from 35°15.19′ N. lat., the latitude of Cape Hatteras Light, North Carolina, south. From Cape Hatteras Light, North Carolina, through Maine, black sea bass are managed jointly by the Mid-Atlantic Fishery Management Council and the Atlantic States Marine Fisheries Commission. Therefore, the closure provisions contained in this notice are applicable to those vessels harvesting or possessing black sea bass from Key West, Florida, through Cape Hatteras Light, North Carolina.

Regulations effective January 31, 2011 (75 FR 82280, December 30, 2011), set the recreational ACL for black sea bass in the South Atlantic EEZ and established accountability measures, and require NMFS to close the recreational sector for black sea bass when the ACL is reached, or is projected to be reached, by filing a notification to that effect with the Office of the **Federal Register**. The accountability measures state if black sea bass are overfished and if recreational landings reach or are projected to reach the recreational ACL of 409,000 lb (185,519 kg), gutted weight, the Assistant Administrator for Fisheries, NOAA (AA), will close the recreational sector for black sea bass for the remainder of the fishing year (50 CFR 622.49(b)(5)(ii)). On, and after, the effective date of the closure, the bag and possession limit of black sea bass in or from the South Atlantic EEZ is zero. This zero bag and possession limit also applies in the South Atlantic on board a vessel for which a valid Federal charter vessel/headboat permit for South Atlantic snapper-grouper has been issued, without regard to where such species were harvested, *i.e.,* in State or Federal waters. Additionally, if black sea bass recreational landings exceed the ACL, without regard to overfished status, the AA will file a notification with the Office of the Federal Register, at or near the beginning of the following fishing year, to reduce the ACL for that fishing year by the amount of the overage.

Based on current statistics, NMFS has determined that the recreational ACL of 409,000 lb (185,519 kg), gutted weight, for black sea bass has been reached. Accordingly, NMFS is closing the recreational sector for black sea bass in the portion of the South Atlantic EEZ through Cape Hatteras Light, North Carolina, from 12:01 a.m., local time, February 12, 2011, until 12:01 a.m., local time, on June 1, 2011. Because this is the first time the recreational sector for black sea bass has closed, NMFS is delaying the closure until 12:01 a.m., local time, February 12, 2011, in order to contact state marine fishery agencies and fish houses, announce the closure on NOAA Weather Radio, and distribute a news bulletin to provide additional notice to the recreational fishermen. The closure is intended to prevent overfishing and increase the likelihood that the current recreational ACL will not be exceeded even further.

Classification

This action responds to the best scientific information available recently obtained from the fishery. The AA finds good cause to waive the requirement to provide prior notice and opportunity for public comment pursuant to the authority set forth at 5 U.S.C. 553(b)(B) as such prior notice and opportunity for public comment is unnecessary and contrary to the public interest. Such procedures would be unnecessary because the rule implementing the sector ACL and the associated requirement for closure of the sector when the ACL is met or projected to be met has already been subject to notice and comment, and all that remains is to notify the public of the closure. Allowing prior notice and opportunity for public comment is contrary to the public interest and impracticable because any additional delay in the closure of the recreational black sea bass sector could result in the recreational ACL being exceeded even further, which would incur larger overages to the ACL. Overages to the ACL trigger a second accountability measure which states that if recreational landings exceed the ACL, NMFS will file a notification with the Office of the Federal Register, at or near the beginning of the following fishing year, to reduce the ACL for that fishing year by the amount of the overage. Reducing the ACL even further for the following year would produce additional adverse economic impacts for black sea bass fishermen.

For the aforementioned reasons, the AA also finds good cause to waive the 30-day delay in the effectiveness of this action under 5 U.S.C. 553(d)(3).

This action is taken under 50 CFR 622.43(a) and is exempt from review under Executive Order 12866.

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

Dated: January 28, 2011.

Emily H. Menashes,

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

[FR Doc. 2011–2287 Filed 1–28–11; 4:15 pm]

BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

50 CFR Part 679

[Docket No. 0910131362–0087–02]

RIN 0648–XA187

Fisheries of the Exclusive Economic Zone Off Alaska; Pacific Cod by Vessels Harvesting Pacific Cod for Processing by the Inshore Component in the Central Regulatory Area of the Gulf of Alaska

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

ACTION: Temporary rule; closure.

SUMMARY: NMFS is prohibiting directed fishing for Pacific cod by vessels harvesting Pacific cod for processing by the inshore component in the Central Regulatory Area of the Gulf of Alaska (GOA). This action is necessary to prevent exceeding the A season allowance of the 2011 Pacific total allowable catch (TAC) apportioned to vessels harvesting Pacific cod for processing by the inshore component of the Central Regulatory Area of the GOA.

DATES: Effective 1200 hrs, Alaska local time (A.l.t.), January 29, 2011, through 1200 hrs, A.l.t., September 1, 2011.

FOR FURTHER INFORMATION CONTACT: Josh Keaton, 907–586–7228.

SUPPLEMENTARY INFORMATION: NMFS manages the groundfish fishery in the GOA exclusive economic zone according to the Fishery Management Plan for Groundfish of the Gulf of Alaska (FMP) prepared by the North Pacific Fishery Management Council under authority of the Magnuson-Stevens Fishery Conservation and Management Act. Regulations governing fishing by U.S. vessels in accordance with the FMP appear at subpart H of 50 CFR part 600 and 50 CFR part 679. Regulations governing sideboard protections for GOA groundfish fisheries appear at subpart B of 50 CFR part 680.

The A season allowance of the 2011 Pacific cod TAC apportioned to vessels harvesting Pacific cod for processing by the inshore component of the Central Regulatory Area of the GOA is 21,795 metric tons (mt), as established by the final 2010 and 2011 harvest specifications for groundfish of the GOA (75 FR 11749, March 12, 2010) and inseason adjustment (76 FR 469, January 5, 2010).

In accordance with § 679.20(d)(1)(i), the Administrator, Alaska Region, NMFS (Regional Administrator) has determined that the A season allowance of the 2011 Pacific cod TAC apportioned to vessels harvesting Pacific cod for processing by the inshore component of the Central Regulatory Area of the GOA will soon be reached. Therefore, the Regional Administrator is establishing a directed fishing allowance of 18,795 mt, and is setting aside the remaining 3,000 mt as bycatch to support other anticipated groundfish fisheries. In accordance with § 679.20(d)(1)(iii), the Regional Administrator finds that this directed fishing allowance has been reached. Consequently, NMFS is prohibiting directed fishing for Pacific cod by vessels harvesting Pacific cod for processing by the inshore component in the Central Regulatory Area of the GOA. This inseason action does not apply to vessels fishing under a cooperative quota permit in the cooperative fishery in the Rockfish Program for the Central GOA.

After the effective date of this closure the maximum retainable amounts at § 679.20(e) and (f) apply at any time during a trip.

Classification

This action responds to the best available information recently obtained from the fishery. The Assistant Administrator for Fisheries, NOAA (AA), finds good cause to waive the requirement to provide prior notice and opportunity for public comment pursuant to the authority set forth at 5 U.S.C. 553(b)(B) as such requirement is impracticable and contrary to the public interest. This requirement is impracticable and contrary to the public interest as it would prevent NMFS from responding to the most recent fisheries data in a timely fashion and would delay the directed fishing closure of Pacific cod by vessels harvesting Pacific cod for processing by the inshore component in the Central Regulatory Area of the GOA. NMFS was unable to publish a notice providing time for public comment because the most recent, relevant data only became available as of January 27, 2011.

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

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

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

Dated: January 28, 2011.

Emily H. Menashes,

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

[FR Doc. 2011–2278 Filed 1–28–11; 4:15 pm]

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Proposed Rules

Federal Register
Vol. 76, No. 22
Wednesday, February 2, 2011

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 LABOR

Mine Safety and Health Administration

30 CFR Part 104

RIN 1219–AB73

Pattern of Violations

AGENCY: Mine Safety and Health Administration, Labor.

ACTION: Proposed rule; notice of close of comment period.

SUMMARY: The Mine Safety and Health Administration (MSHA) is proposing to revise the Agency's existing regulation for pattern of violations (POV). MSHA has determined that the existing regulation does not adequately achieve the intent of the Federal Mine Safety and Health Act of 1977 (Mine Act) that the POV provision be used to address operators who have demonstrated a disregard for the safety and health of miners. Congress included the POV provision in the Mine Act so that operators would manage safety and health conditions at mines and find and fix the root causes of significant and substantial (S&S) violations to protect the safety and health of miners. The proposal would simplify the existing POV criteria, improve consistency in applying the POV criteria, and more adequately achieve the statutory intent. It would also encourage chronic violators to comply with the Mine Act and MSHA's safety and health standards.

DATES: MSHA must receive comments by midnight Eastern Standard Time on April 4, 2011.

ADDRESSES: Comments must be identified with "RIN 1219–AB73" and may be sent to MSHA by any of the following methods:

- *Federal E-Rulemaking Portal: http://www.regulations.gov.* Follow the on-line instructions for submitting comments.
- *Electronic mail: zzMSHAcomments@dol.gov.* Include "RIN 1219–AB73" in the subject line of the message.
- *Facsimile:* 202–693–9441. Include "RIN 1219–AB73" in the subject line of the message.
- *Regular Mail:* MSHA, Office of Standards, Regulations, and Variances, 1100 Wilson Boulevard, Room 2350, Arlington, Virginia 22209–3939.
- *Hand Delivery or Courier:* MSHA, Office of Standards, Regulations, and Variances, 1100 Wilson Boulevard, Room 2350, Arlington, Virginia. Sign in at the receptionist's desk on the 21st floor.

Information Collection Requirements: Comments concerning the information collection requirements of this proposed rule must be clearly identified with "RIN 1219–AB73" and sent to both the Office of Management and Budget (OMB) and MSHA. Comments to OMB may be sent by mail addressed to the Office of Information and Regulatory Affairs, Office of Management and Budget, New Executive Office Building, 725 17th Street, NW., Washington, DC 20503, Attn: Desk Officer for MSHA. Comments to MSHA may be transmitted by any of the methods listed above in this section.

FOR FURTHER INFORMATION CONTACT: April E. Nelson, Acting Director, Office of Standards, Regulations, and Variances, MSHA, at *nelson.april@dol.gov* (e-mail); 202–693–9440 (voice); or 202–693–9441 (facsimile).

SUPPLEMENTARY INFORMATION:

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I. Introduction

Availability of Information

Public Comments: MSHA will post all comments on the Internet without change, including any personal information provided. Access comments electronically at *http://www.msha.gov/regsinfo.htm.* Review comments in person at the Office of Standards, Regulations, and Variances, 1100 Wilson Boulevard, Room 2350, Arlington, Virginia. Sign in at the receptionist's desk on the 21st floor.

E-mail notification: MSHA maintains a list that enables subscribers to receive e-mail notification when the Agency publishes rulemaking documents in the **Federal Register**. To subscribe, go to *http://www.msha.gov/subscriptions/subscribe.aspx.*

Information Collection Supporting Statement: A copy of the information collection package can be obtained from the Department of Labor by electronic mail request to Michel Smyth at *smyth.michel@dol.gov* or by phone request to 202–693–4129.

II. Background and Regulatory History

A. Statutory Provision

In enacting the Mine Act, Congress included the pattern of violations (POV) provision in section 104(e) to provide MSHA with an additional enforcement tool to protect miners when the operator demonstrated a disregard for the safety and health of miners. The need for such a provision was forcefully demonstrated during the investigation of the Scotia Mine disaster, which occurred in 1976 in Eastern Kentucky. (S. Rep. No. 181, 95th Cong., 1st Sess. at 32.) As a result of explosions on March 9 and 11, 1976, caused by dangerous accumulations of methane, 23 miners and three mine inspectors lost their lives. The Scotia Mine had a chronic history of persistent, serious violations that were cited over and over by MSHA. After abating the violations, the operator would permit the same violations to recur, repeatedly exposing miners to the same hazards. The accident investigation showed that MSHA's then-existing enforcement program was unable to address the Scotia Mine's history of recurring violations.

The Mine Act places the ultimate responsibility for ensuring the safety and health of miners on mine operators. The legislative history of the Mine Act emphasizes that Congress reserved the POV provision for mine operators with a record of repeated S&S violations. Congress intended the POV sanction to attain remedial action from operators "who have not responded to the Agency's other enforcement efforts." (55 FR 31129) The legislative history states that Congress believed that the existence of a pattern would signal to both the

mine operator and the Secretary that "there is a need to restore the mine to effective safe and healthful conditions and that the mere abatement of violations as they are cited is insufficient." (S. Rep. No. 181, *supra* at 33.)

The Mine Act does not define "pattern of violations," but section 104(e)(4) authorizes the Secretary to establish criteria for determining when a pattern of violations of mandatory safety or health standards exists. Congress provided the Secretary with broad discretion in establishing pattern criteria, recognizing that MSHA may need to modify the criteria as experience dictates.

B. Regulatory History

MSHA first proposed a POV regulation in 1980 (45 FR 54656). That proposal included: Purpose and scope, initial screening, pattern criteria, issuance of notice, and termination of notice. Commenters were generally opposed to the 1980 proposal. They stated that the proposal was complex, too statistically oriented, overbroad, and vague. In addition, they stated that the rulemaking was untimely because of litigation then pending before the Federal Mine Safety and Health Review Commission (Commission) concerning MSHA's interpretation of the S&S provisions of the Mine Act. Commenters also stated that review of the Agency's then pending regulation for assessment of civil penalties could affect the POV proposal.

On February 8, 1985 (50 FR 5470), MSHA announced its withdrawal of the 1980 proposed rule and issued an advance notice of proposed rulemaking (ANPRM) that addressed many of the concerns expressed about the 1980 proposal. In the 1985 ANPRM, MSHA stated that it intended to focus on the safety and health record of each mine rather than on a strictly quantitative comparison of mines to industry-wide norms. In the ANPRM, MSHA stated that the Agency envisioned simplified criteria, focusing on two principal areas:

(1) Were S&S violations common to a particular hazard or did S&S violations throughout the mine represent an underlying health and safety problem, and

(2) Is the mine on a section 104(d) unwarrantable failure sequence, indicating that other enforcement measures had been ineffective.

MSHA requested suggestions for additional factors the Agency should use in determining whether a POV exists and requested ideas on administrative procedures for terminating a pattern notice.

MSHA published a second proposed rule on May 30, 1989 (54 FR 23156), which included criteria and procedures for identifying mines with a pattern of S&S violations. The 1989 proposal included procedures for initial identification of mines developing a pattern of violations; criteria for determining whether a pattern of violations exists at a mine; notification procedures that would provide both the mine operator and miners' representative an opportunity to respond to the Agency's evaluation that a pattern of violations may exist; and procedures for terminating a pattern notice. The 1989 proposal addressed the major issues raised by commenters. Commenters' primary concerns were MSHA's policies for enforcing the S&S provisions of the Mine Act, the civil penalty regulation, and MSHA's enforcement of the unwarrantable failure provision of the Mine Act. MSHA held two public hearings and issued a final rule on July 31, 1990 (55 FR 31128).

The existing rule established MSHA's criteria and procedures for identifying mines with a POV. The existing rule reflected MSHA's belief that Congress intended the POV sanction to be directed at restoring mines to a safe and healthful condition.

Until mid-2007, POV screening was decentralized and lacked a consistent, structured approach. MSHA District offices were responsible for conducting the required annual POV screening of mines. Following the accidents at the Sago, Darby, and Aracoma mines in early 2006, MSHA began developing a centralized, quantifiable POV screening process. MSHA initiated its newly developed *Pattern of Violations Screening Criteria and Scoring Model* in mid-2007 and updated and revised the screening criteria and procedures in 2010. MSHA uses a computer program based on this screening criteria and scoring model to generate lists of mines with a potential pattern of violations (PPOV).

III. Section-by-Section Analysis

MSHA is proposing the following changes to its existing pattern of violations regulation.

A. Section 104.1 Purpose and Scope

Proposed § 104.1 would provide the purpose and scope of the proposal and is unchanged from the existing provision.

B. Section 104.2 Pattern Criteria

Proposed § 104.2 would combine existing §§ 104.2 and 104.3. It would specify the general criteria that MSHA would use to identify mines with a pattern of violations. MSHA would review compliance, accident, injury, and illness records. MSHA believes that the proposed rule would simplify the process for determining whether a mine has a pattern of violations and would more accurately reflect the statutory intent. Consistent with the Mine Act, the proposed rule would eliminate all references to initial screening criteria.

Proposed § 104.2(a) would provide that the specific criteria (*e.g.,* number of S&S violations issued in the previous year) used in the review to identify mines with a pattern of S&S violations would be posted on MSHA's website at *http://www.msha.gov*. MSHA requests specific comments on how the agency should obtain comment during the development of, and periodic revision to, the POV screening criteria. MSHA also requests comments on the best methods for notifying mine operators of changes to these criteria. Under the proposal, MSHA would review:

(1) Citations for significant and substantial violations;

(2) Orders under section 104(b) of the Act for not abating significant and substantial violations;

(3) Citations and withdrawal orders under section 104(d) of the Act, resulting from the operator's unwarrantable failure to comply;

(4) Imminent danger orders under section 107(a) of the Act;

(5) Orders under section 104(g) of the Act requiring withdrawal of miners who have not received training and who the inspector declares to be a hazard to themselves and others;

(6) Enforcement measures, other than section 104(e) of the Act, which have been applied at the mine;

(7) Other information that demonstrates a serious safety or health management problem at the mine, such as accident, injury, and illness records; and

(8) Mitigating circumstances.

MSHA believes that posting the specific criteria and compliance data that the Agency would use on the website would allow mine operators to monitor their compliance record against the proposed POV criteria. Some mines have personnel who, currently, are requesting this information from MSHA. This website would reduce the effort for these mine operators. Access to this information through a searchable database would provide operators an opportunity to evaluate their record and determine whether they are approaching proposed POV criteria levels. This would enable operators to proactively implement measures to improve safety and health at their mines and to bring

their mines into compliance. Posting the specific pattern criteria on MSHA's website will promote openness and transparency and encourage operators to examine their compliance record more closely, ascertain whether they have any recurring problems, and enhance the safety and health of miners. MSHA believes that sharing this information facilitates a more proactive approach to safety and health on the part of all involved with miner safety and health. In addition, MSHA believes that the ready availability of compliance data will eliminate the need to inform operators of a potential pattern of violations (PPOV). MSHA believes that this is an improvement over the existing process because it allows operators to continually evaluate their compliance performance.

Under proposed § 104.2(a)(1), like the existing provision, MSHA would consider a mine's S&S violations.

Like the existing provision, proposed § 104.2(a)(2) would require MSHA to consider closure orders issued under section 104(b) of the Mine Act that resulted from S&S violations.

Proposed § 104.2(a)(3), like existing § 104.3(a)(3), would require MSHA to consider unwarrantable failure citations and withdrawal orders issued under sections 104(d)(1) and (d)(2) of the Mine Act. Unwarrantable failure citations and orders often constitute S&S violations that are the types of serious, repeated violations that Congress intended to address in a POV regulation.

Proposed § 104.2(a)(4), like existing § 104.2(a)(3), would require MSHA to consider imminent danger withdrawal orders issued under section 107(a) of the Mine Act.

Proposed § 104.2(a)(5), derived from existing § 104.2(b)(1), would require MSHA to consider orders issued under section 104(g) of the Act.

Proposed § 104.2(a)(6), like existing § 104.2(b)(1), would require that MSHA consider enforcement measures other than section 104(e) of the Act, which have been applied at the mine.

Proposed § 104.2(a)(7) would clarify MSHA's intent that the proposed POV criteria include consideration of operations with serious safety and health management problems. It is derived from the existing regulation and the legislative history of the Mine Act.[1] It would require MSHA to consider other information, such as accident, injury, and illness records, that may reveal a serious safety or health management problem at a mine. This other information may also include: Enforcement measures, other than POV, applied at the mine; evidence of the operator's lack of good faith in correcting the problem that results in repeated S&S violations; repeated S&S violations of a particular standard; repeated S&S violations of standards related to the same hazard; and any other relevant information. This is essentially the same information addressed in existing §§ 104.2(b)(2) to (b)(3) and 104.3(a)(1) and (a)(2). In addition, in making a determination under this aspect of the proposal, MSHA would consider: knowing and willful S&S violations; citations and orders issued in conjunction with an accident, including orders under sections 103(j) and (k) of the Mine Act; and S&S violations of safety and health standards that contribute to the cause of accidents and injuries. MSHA data and experience show that violations of approval, training, or recordkeeping regulations, for example, can significantly and substantially contribute to safety or health hazards. This is especially true where the mine operator allows similar violations to occur repeatedly.

Under proposed § 104.2(a)(8), like existing § 104.2(b)(4), MSHA would consider mitigating circumstances. Under this proposed provision, MSHA would consider the causes of repeated violations that may be beyond the operator's control, such as changes in mine ownership or mine management, and whether conditions at the mine show a trend of significant improvement.

Under this proposed provision and consistent with the legislative history, MSHA would allow operators to take proactive measures to bring their mines into compliance. For example, operators who compare their compliance record with the POV criteria and determine that they are approaching a pattern of violations level may work with MSHA to bring their mines into compliance to avoid a POV notice. Under the proposal, an operator may submit a written safety and health management program to the District Manager for approval. To obtain approval, operators should structure safety and health management programs so that MSHA can determine whether the program's parameters would result in meaningful, measurable, and significant reductions in S&S violations. The operator should develop a process and program with measurable benchmarks for abating specific violations that could lead to a POV and addressing these hazardous conditions at their mines. Using these benchmarks, operators would be able to use the MSHA database accessible through the Agency's Web site to monitor their safety and health record. Under the proposal, MSHA would consider an operator's effective implementation of an MSHA-approved safety and health management program as a mitigating circumstance.

The proposed rule would eliminate the existing requirement in § 104.3(b) that only citations and orders that have become final are to be used to identify mines with a potential pattern of violations. This proposal is consistent with the language of section 104(e), the legislative history of the Mine Act, and the purpose of section 104(e). In explaining the need for the POV enforcement tool, Congress pointed out that "the Scotia mine, as well as other mines, had an inspection history of recurrent violations, some of which were tragically related to the disasters, which the existing enforcement scheme was unable to address." (S. Rep. No. 181, 95th Cong., 1st Sess. at 32.) The use of the phrase "inspection history" indicates Congress' intent that POV determinations be based on inspection histories, *i.e.,* violations found by MSHA during inspections, rather than only on final citations and orders.

The Senate Report specifically noted similarities between sections 104(d) and 104(e) of the Mine Act and stated that the POV "sequence parallels the current unwarrantable failure sequence." (S. Rep. No. 181, *supra,* at 33.) This reflects Congress's intent that POV determinations, like section 104(d)(1) and (d)(2) determinations, need not be final orders. In addition, the Senate Report stated that it was "* * * the Committee's intention that the Secretary or his authorized representative [] have both [Section 104(d) and Section 104(e)] enforcement tools available, and that they [] be used simultaneously if the situation warrants." (*Id* at 34.) The proposal to consider non-final citations and orders to identify mines with a POV is consistent with the Mine Act.

The existing provision limiting MSHA's consideration of citations and orders to those that are final restricts MSHA's ability to achieve the purpose of the POV provision, consistent with Congressional intent. As stated in the Mine Act and its legislative history, the Secretary is given broad discretion to "make such rules as [she] deems necessary to establish criteria for determining when a pattern of violations" exists. (30 U.S.C. 814(e)(4)) Congress stated that the Secretary should "continually evaluate and modify the pattern of violations criteria as she deems necessary." (S. Rep. No.

[1] The Committee views the 105(d)(1) [now 104(e)] notice as indicating to both the mine operator and the Secretary that there exists at mine a serious safety and health management problem. (Legislative History, Committee Report, p. 620).

181, *supra* at 33.) MSHA's experience with enforcing section 104(e) has led the Agency to conclude that it is necessary to modify the final order criteria in its existing POV regulation.

In November 2010, there was a backlog of approximately 88,000 contested violations pending before the Commission. For cases disposed during November, 2010, it took, on average, 518 days for contested violations to become final. For a mine with contested citations and orders that have not become final, the final order provision does not allow MSHA to review the mine's complete recent compliance history when assessing whether a POV exists and hinders MSHA's ability to effectively enforce section 104(e) of the Mine Act. It can allow chronic violators to avoid or delay the POV sanction and to continue their repeated pattern of noncompliance with health and safety standards, without correcting the underlying problem. The final order provision in the existing regulation provides an incentive for operators to contest S&S violations to avoid being placed under a POV.

The fact that the Mine Act requires an operator to abate a hazard prior to contesting a violation provides further support for the proposed rule. Mine operators must correct the hazardous condition within the time set by the MSHA inspector, even if they challenge the violation. The proposal to eliminate the existing requirement that only final orders be used for POV determination would greatly enhance safety and health of miners. Fewer than one percent of citations are reversed. Over 700,000 violations were assessed civil penalties that became final orders during the five-year period 2006 through 2010, with 3,400 vacated after they were contested. During the same timeframe, 6,000 of the contested violations were modified from S&S to non-S&S.

Proposed § 104.2(b) would increase the frequency of MSHA's review of a mine for a POV from at least once per year under the existing regulation to at least twice per year. MSHA determined that an annual review would not adequately allow the Agency to identify mines with recurring S&S violations. The increased frequency of review would allow MSHA to more promptly identify mines with recurring S&S violations and take appropriate action. This proposal would also encourage operators to more closely examine their compliance records to determine whether greater efforts are necessary to comply with the Mine Act and MSHA's standards and regulations.

C. Section 104.3 Issuance of Notice

Proposed § 104.3, renumbered from existing § 104.4, would simplify the requirements for issuing a POV notice.

Proposed § 104.3(a) is similar to existing § 104.4(a). The proposal would provide that, when a mine has a POV, the District Manager will issue a POV notice to the mine operator that specifies the basis for the Agency's action. The District Manager will also provide a copy of the POV notice to the representative of miners. The proposed provision would delete all references to a PPOV; otherwise it is essentially unchanged from the existing requirement.

MSHA believes that this proposed action would allow the Agency to more effectively implement the POV provision in the Mine Act, consistent with legislative intent. MSHA's experience and data reveal that over the past 3 years, mine operators who received a PPOV letter reduced their S&S violations by at least 30 percent. In this same period, 6 of 62 operators received more than one PPOV letter. These mine operators temporarily reduced their S&S violations, but reverted back to allowing the same hazards to occur again and again without addressing the underlying causes.

Proposed § 104.3(b), essentially the same as existing § 104.4(d), would require that the mine operator post a copy of the POV notice on the mine bulletin board and that the notice remain posted until MSHA terminates the POV notice. Existing § 104.4(d) requires the operator to post all notifications issued under 30 CFR part 104 at the mine. The proposal would clarify that the operator post notifications issued under this part on the mine bulletin board.

Proposed § 104.3(c) is a new provision that would restate the intent of the Mine Act when a POV notice is issued. It essentially restates section 104(e)(1) of the Mine Act and would require MSHA to issue an order withdrawing all persons from the affected area of the mine if an authorized representative of the Secretary finds any S&S violation within 90 days after the issuance of the POV notice. No one would be allowed to enter the area affected by the violation until the condition has been abated, except those persons referred to in section 104(c) of the Mine Act who must enter the affected area to correct the violation.

Proposed § 104.3(d) is a new provision that would specifically restate the intent of the Mine Act when a POV notice is issued. It would provide that if a withdrawal order is issued under proposed § 104.3(c), any subsequent S&S violation will result in an order withdrawing all persons from the affected area of the mine until the authorized representative of the Secretary determines that the violation has been abated, except those persons identified in section 104(c) of the Mine Act.

D. Section 104.4 Termination of Notice

Proposed § 104.4, renumbered from existing § 104.5, addresses the termination of a POV notice and continues to provide that a POV notice will be terminated if MSHA finds no S&S violations during an inspection of the entire mine, or if no withdrawal order for S&S violations under section 104(e)(1) of the Mine Act has been issued within 90 days of the issuance of the POV notice. MSHA's Pattern of Violations (POV) Procedures Summary, posted on MSHA's website, also includes requirements for MSHA to conduct a complete inspection of the entire mine within 90 days of issuing the POV notice. The Procedures Summary states, in part, the following:

> Following notification to the operator of the issuance of a Notice of Pattern of Violations, the District Manager shall initiate appropriate inspection activities to ensure that the mine is inspected in its entirety during the following 90-day period and each succeeding inspection cycle until the POV notice is terminated.

Proposed § 104.4(b), renumbered from existing § 104.5(b), is unchanged.

IV. Preliminary Regulatory Economic Analysis

A. Executive Order 12866: Regulatory Planning and Review

Under Executive Order (E.O.) 12866, the Agency must determine whether a regulatory action is "significant" and subject to review by the Office of Management and Budget (OMB). Section 3(f) of E.O. 12866 defines a "significant regulatory action" as an action that is likely to result in a rule: (1) Having an annual effect on the economy of $100 million or more, or adversely and materially affecting a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or state, local, or tribal governments or communities (also referred to as "economically significant"); (2) creating serious inconsistency or otherwise interfering with an action taken or planned by another agency; (3) materially altering the budgetary impacts of entitlements, grants, user fees, or loan programs or the rights and obligations of recipients

thereof; or (4) raising novel legal or policy issues arising out of legal mandates, the President's priorities, or the principles set forth in this Executive Order.

MSHA has determined that this proposed rule would not have an annual effect of $100 million or more on the economy, and is not an economically "significant regulatory action" pursuant to section 3(f) of E.O. 12866. However, the proposed rule is a "significant" regulatory action because it would likely raise novel legal or policy issues. MSHA requests comments on the estimates of costs and benefits presented in this proposed rule.

MSHA has not prepared a separate preliminary regulatory economic analysis for this rulemaking. Rather, the analysis is presented below.

B. Industry Profile and Population at Risk

The proposed rule applies to all mines in the United States. MSHA divides the mining industry into two major sectors based on commodity: (1) coal mines and (2) metal and nonmetal mines. Each sector is further divided by type of operation, *e.g.,* underground mines or surface mines. The Agency maintains data on the number of mines and on mining employment by mine type and size. MSHA also collects data on the number of independent contractor firms and their employees. Each independent contractor is issued one MSHA contractor identification number, but may work at any mine.

For the 12 months ending January 2010, the average number of mines in operation was 14,100. These mines employed 297,000 miners, including contract workers and excluding office workers. There were 8,770 mine contractor firms with 88,000 employees, excluding office workers. Table IV–1 presents the total number of all mines and miners, by size of mine.

TABLE IV–1—AVERAGE 2009 NUMBER OF MINES AND EMPLOYMENT (EXCLUDING OFFICE EMPLOYEES), BY EMPLOYMENT SIZE

Size of mine	All mines	Employment at all mines, excluding office employees
1–19 Employees	11,816	56,489
20–500 Employees	2,234	123,181
501+ Employees	48	29,402
Contractors		87,740
Total	14,098	296,812

The estimated value of coal produced in U.S. coal mines in 2009 was $35.7 billion of which $18.5 billion was from underground coal and $17.2 billion from surface coal. The value of coal was estimated from the amount of coal produced and the price of coal. MSHA obtained the coal production estimates from the Agency's MSIS system and the price per ton for coal from the Department of Energy (DOE), Energy Information Administration (EIA), *Annual Coal Report 2009,* October 2010, Table 28.

The value of the U.S. mining industry's metal and nonmetal (M/NM) output in 2009 was estimated to be approximately $57.1 billion. Metal mining contributed an estimated $21.3 billion to the total while the nonmetal mining sector contributed an estimated $35.8 billion. The value of production estimates are from U.S. Department of the Interior (DOI), U.S. Geological Survey (USGS), *Mineral Commodity Summaries 2010,* January 2010, page 8.

The combined value of production from all U.S. mines in 2009 was $92.8 billion. Table IV–2 presents the estimated revenues for all mines, by size of mine.

TABLE IV–2—REVENUES AT ALL MINES, BY EMPLOYMENT SIZE, IN 2009

Size of mine	Revenues at all mines (million dollars)
1–19 Employees	$17,450
20–500 Employees	54,478
501+ Employees	20,856
Total	92,784

C. Benefits

Although MSHA does not have an historical basis from which to estimate the effects of placing a mine on a pattern of violations (POV), the Agency does have some experience with issuing potential pattern of violations (PPOV) notifications to operators. MSHA's data reveal that although most mine operators significantly improve health and safety conditions at their mines after receiving the PPOV notification, many later experienced both a decline in health and safety and an increase in S&S violations.

During June 2007 through September 2009, MSHA made PPOV evaluations on an average of every six to nine months. During that period, MSHA sent 68 PPOV notification letters to 62 mine operators (6 operators received more than one notification). After receiving the notification letter, of the mines that remained in operation to the next evaluation, 94 percent reduced the rate of S&S citations and orders by at least 30 percent and 77 percent reduced the rate of S&S citations and orders to levels at or below the national average for similar mines. However, as discussed previously in the preamble, improvements at some mines declined over time. Of the 62 mine operators that received PPOV notification letters during the review period, 6 received a second PPOV notification letter. In addition to the 6 mines that received two letters, 7 mines were identified in more than one evaluation as meeting the

PPOV criteria but were only sent one letter generally due to mitigating circumstances. Compliance at 13 of the 62 mines that received PPOV notification letters (21 percent) deteriorated such that each of these mines either was sent or could have been sent a second letter.

Under the existing rule, MSHA identifies mines that meet the screening criteria for PPOV. MSHA conducts a review to determine if there are mitigating circumstances and issues PPOV notification letters as appropriate. The proposed rule would delete the screening process as well as all references to a PPOV.

The proposed rule would establish general criteria that MSHA would use to identify mines with a pattern of S&S violations. MSHA would post specific criteria that MSHA would use in making POV determinations, including a searchable database of mine operator compliance information, on the Agency's website. Operators would be able to use the specific criteria and the information in the database to continually monitor their safety and health performance and determine whether they are approaching proposed POV criteria levels.

Under the proposed rule, MSHA would allow operators to take proactive measures to bring their mines into compliance. MSHA would consider an operator's effective implementation of an MSHA-approved safety and health management program as a mitigating circumstance when it comes to placing a mine on a POV.

Under the proposed rule, MSHA projects that operators would continually monitor their performance and, if they believe that they are approaching a POV, would take action to improve their safety and health performance. MSHA projects that, under the proposed rule, most mine operators who see that their mines are close to a POV would institute an MSHA-approved safety and health management program to lessen the probability of being placed on a POV and the possibility of being issued closures. MSHA projects that this would result in more mines taking action than those issued PPOV notifications under the existing procedure.

Closure orders can have a substantial impact on the ability of a mine to conduct its business. The threat of closure provides a strong incentive for operators to ensure that S&S violations do not recur. MSHA projects that few operators would risk such an occurrence.

MSHA projects that under the proposal, which would increase the frequency of MSHA's review of a mine for a POV from once to twice per year, on average, approximately 50 mine operators per year would submit a safety and health management program to MSHA for approval as a mitigating circumstance. Under the proposed rule, MSHA would allow operators to take proactive measures to bring their mines into compliance with MSHA standards and regulations, reducing the probability of these mines being on a POV. MSHA further projects that an average of approximately 10 mines per year (*i.e.,* those that would not take proactive action, such as instituting an MSHA-approved safety and health management program) would be issued POV notifications. MSHA requests comments on these estimates which are likely to vary from year to year.

MSHA used the Agency's experience with PPOV notification letters to estimate the impact that the proposed mitigating circumstance provision (including the opportunity for operators to submit safety and health management programs) would have on the number of nonfatal injuries at mines. MSHA determined that 62 mines which received PPOV notification letters (6 received two notifications) during the June 2007 through September 2009 period experienced, on average, 11 nonfatal injuries during the year prior to receiving the letter and eight nonfatal injuries during the year after receiving the letter. MSHA used the one year period before and after PPOV notification as a basis for comparison because, as was previously noted, improvements at some mines declined over time and because a longer period was not available for some mines (*i.e.,* mines that were issued PPOV notifications in September 2009).

Based on the projection that 50 mines per year would average three fewer nonfatal injuries in the first year after implementing an MSHA-approved safety and health management program, MSHA projects that the number of nonfatal injuries would be reduced by a minimum of 150 (50 mines × 3 nonfatal injuries per mine) per year. MSHA believes that this is a low estimate for the following reasons:

- It is likely that including measurable benchmarks for abating specific violations and addressing hazardous conditions in the MSHA-approved safety and health management programs would make these programs more effective than the measures that recipients of the PPOV notification letters have historically instituted.
- The estimate does not include any reductions in the number of fatalities. Because mine fatalities occur on a less frequent basis than do injuries, the Agency does not believe that it has a reliable basis upon which to project a reduction in fatalities. However, the Agency believes that the implementation of an MSHA-approved safety and health management program would reduce fatalities.
- The estimate does not include any projected improvement at the 10 mines that would not institute an MSHA-approved safety and health management program and would be placed on a POV. However, due to the high threshold for getting off a POV under the proposed rule, there would likely be injury reductions for this category.

MSHA also anticipates longer lasting improvements under the proposed rule. Of the 62 mines that received PPOV notification letters from June 2007 through September 2009, 13 did not have a full second year of data following receipt of the PPOV notification letter. Of the 49 mines that had two full years of data following receipt of the PPOV notification letter, 19 (39%) experienced an increase in the number of injuries in the second year following receipt of the PPOV notification letter compared to the first. MSHA believes that, under the proposed rule, fewer mines will experience such increases. Mines that have effectively implemented an MSHA-approved safety and health management program (to avoid being placed on a POV) would have procedures in place to continuously address hazardous conditions. Mines that successfully get off of a POV would have increased incentive (see the cost analysis) to remain off and would likely institute continuing measures to minimize violations and address hazardous conditions.

MSHA based its estimates of the monetary values for the benefits associated with the proposed rule on relevant literature. To estimate the monetary values of the reductions in nonfatal injuries, MSHA performed an analysis of the imputed value of injuries avoided based on a willingness-to-pay approach. This approach relies on the theory of compensating wage differentials (*i.e.,* the wage premium paid to workers to accept the risk associated with various jobs) in the labor market. A number of studies have shown a correlation between higher job risk and higher wages, suggesting that employees demand monetary compensation in return for incurring a greater risk.

Viscusi & Aldy (2003) conducted an analysis of studies that use a willingness-to-pay methodology to estimate the imputed value of life-saving programs (*i.e.,* meta-analysis) and

found that the value of each lost work-day injury prevented was approximately $50,000 in 2000 dollars. Using the GDP Deflator (U.S. Bureau of Economic Analysis, 2010), this yields an estimate of $62,000 for each lost work-day injury avoided in 2009 dollars.

MSHA recognizes that willingness-to-pay estimates involve uncertainty and imprecision. Although MSHA is using the Viscusi & Aldy (2003) study as the basis for monetizing the expected benefits of the proposed rule, the Agency does so with several reservations, given the methodological difficulties involved in estimating the compensating wage differentials (see Hintermann, Alberini, and Markandya, 2008). Furthermore, these estimates pooled across different industries may not capture the unique circumstances faced by miners. For example, some have suggested that the models be disaggregated to account for different levels of risk, as might occur in coal mining (see Sunstein, 2004). In addition, miners may have few options of alternative employers and, in some cases, only one employer (near-monopsony or monopsony) that may depress wages below those in a more competitive labor market. In the future, MSHA plans to work with other agencies to refine the approach taken in this proposed rule.

Based on the estimated prevention of 150 nonfatal injuries per year, the proposed rule would result in monetized benefits of approximately $9.3 million per year (150 nonfatal injuries × $62,000 per injury). MSHA believes that this is a low estimate for the total benefits of the proposed rule for the reasons stated above. MSHA solicits comments on the benefit estimates.

D. Compliance Costs

Proposed § 104.3(c) would require MSHA to issue an order withdrawing all persons from the affected area of the mine if any S&S violation is found within 90 days after the issuance of the POV notice. No one would be allowed to enter the area affected by the violation until the condition has been abated, except those persons who must enter the affected area to correct the violation.

Under proposed § 104.3(d), if a withdrawal order is issued under proposed § 104.3(c), any subsequent S&S violation would result in an order withdrawing all persons from the affected area of the mine until the authorized representative of the Secretary determines that the violation has been abated, except those persons who must enter the affected area to correct the violation.

Closure orders can have a substantial effect on the ability of a mine to conduct its business. The threat of closure provides a strong incentive for operators to ensure that S&S violations do not recur. As was noted under benefits, MSHA anticipates that few operators would risk such an occurrence. Rather than risking a POV and the possibility of a closure, MSHA projects that mine operators would monitor their compliance record against the proposed POV criteria using the Agency's website. MSHA estimates that it will take a supervisor an average of 5 minutes each month to monitor each mine's performance using the Agency's website. Based on the average supervisory wage rate for all mining in 2009 of $65.05 per hour, MSHA estimates that the yearly cost for all mine operators to monitor their performance would be about $0.9 million (14,098 mines × 5/60 hours per month × 12 months per year × $65.05 per hour).

However, MSHA believes that this may be an overestimate. As was noted above, some operators are currently requesting this information from MSHA. Making the information available on the Agency's Web site would reduce the costs for these mine operators. MSHA requests comments on the burden that monitoring compliance record against the proposed POV criteria using the Agency's Web site would place on mine operators.

MSHA projects that approximately 50 mine operators each year would submit a safety and health management program to MSHA for approval as a mitigating circumstance. MSHA believes that it would take management working with miners to develop and implement an effective safety and health management program. MSHA projects that developing such a program with meaningful and measurable benchmarks would take about 80 hours of a supervisor's time and 80 hours of miners' time. MSHA projects that it would take an additional 40 hours of a supervisor's time and 40 hours of miners' time during the approval process and that the cost for copying and mailing the program and revisions would be about $100. MSHA projects it will take 40 hours of a supervisor's time to implementing the program plus 120 hours of miners' time to run the program (based on an average size mine in terms of employment).

Although the proposed rule applies to all mining, based on the Agency's experience and due to the nature of the mining conditions, MSHA projects that the proposed rule would have a greater impact on underground coal mining than any other mining sector. During the period June 2007 through September 2009, underground coal mine operators received nearly 80 percent of the PPOV notifications. Rather than using the wage rates for all mining as was done to estimate the costs for monitoring mine performance, MSHA used the 2009 underground coal mine hourly wage rates of $84.70 for a supervisor and $35.30 for a miner to estimate these costs. Since the hourly wage rates in underground coal mining are higher than those in surface coal and metal/nonmetal mining, this approach could overstate the estimated costs.

The average cost of developing and implementing an approved safety and health program at a mine would be approximately $22,100 (160 hours of a supervisor's time × $84.70 per hour + 240 hours of miners' time × $35.30 per hour + $100). MSHA anticipates that, each year, the projected 50 mines that would choose to implement an MSHA-approved safety and health management program would incur costs of approximately $1.1 million.

Although MSHA does not have a historical basis from which to estimate the potential costs that would be incurred by a mine on a POV, MSHA determined that a good proxy for these costs would be the potential production lost during mine closures while the operators take the necessary actions to correct the safety and health violations. MSHA projects that a typical mine would lose about 0.5 percent of revenue as the result of closures (about 1 or 2 days for a large mine and a day or less for a small mine) and that lost revenue due to the closures would likely vary considerably among mines depending on the specific conditions in the mine. Some mines would likely incur greater than average losses while others would incur less than average losses.

As was noted above, based on the Agency's experience and due to the nature of the mining conditions, MSHA projects that the proposed rule would affect underground coal mining more than any other mining sector. MSHA, therefore, used the revenue in the underground coal sector to estimate potential production losses. The average number of underground coal mines in operation during a month in 2009 was 424. These mines generated an estimated $18.5 billion in revenue in 2009, an average of approximately $43.6 million per mine. One-half percent of an average mine's revenue is about $218,000.

MSHA estimates that the projected 10 mines that would be on a POV each year

would potentially incur about $2.2 million in production losses (10 mines × $218,000 per mine). Since the average revenue per underground coal mine is significantly higher than the average revenue produced by a mine in the entire mining industry (*i.e.,* $6.6 million per mine = $92.8 billion/14,098 mines), this approach could overstate the estimated costs.

MSHA estimates that the total yearly cost of the proposed rule would be $4.2 million; $0.9 million for monitoring the performance of each mine, $1.1 million for 50 mines developing and implementing MSHA-approved safety and health management programs, plus $2.2 million for 10 mines operating under a POV. MSHA's estimates do not include the cost of coming into compliance with the underlying regulatory requirements. Although these costs can be substantial, they were previously attributed to compliance with MSHA's existing regulations and are not new compliance costs resulting from the proposed rule. MSHA solicits comments on the cost estimates.

E. Net Benefits

This section presents a summary of the estimated net benefits of the proposed rule for informational purposes only. Under the Mine Act, MSHA is not required to use estimated net benefits as the basis for its decision to promulgate a rule.

Based on the estimated prevention of 150 nonfatal injuries per year, MSHA estimates that the proposed rule would result in monetized benefits of $9.3 million per year (150 nonfatal injuries per year × $62,000 per injury) compared to estimated costs of $4.2 million per year, for an estimated net benefit of approximately $5.1 million per year. MSHA solicits comments on the net benefit estimate.

V. Feasibility

MSHA has concluded that the requirements of the pattern of violations proposed rule are technologically and economically feasible.

A. Technological Feasibility

MSHA concludes that this proposed rule is technologically feasible. The proposed rule is not technology-forcing. In order to avoid a POV, mine operators would have to comply with existing MSHA regulations, which have previously been determined to be technologically feasible.

B. Economic Feasibility

MSHA also concludes that this proposed rule is economically feasible. Mine operators can avoid the expenses of being placed on a pattern of violations by complying with existing MSHA regulations, all of which have previously been found to be economically feasible. For those mine operators who are in danger of a POV, MSHA will consider the institution of an approved safety and health management program as a mitigating circumstance. MSHA expects few mines (about 10 per year) would incur the potential expenses associated with closures while on a POV.

MSHA has traditionally used a revenue screening test—whether the yearly compliance costs of a regulation are less than one percent of revenues—to establish presumptively that compliance with the regulation is economically feasible for the mining community. Based on this test, MSHA has concluded that the requirements of the proposed rule are economically feasible. The estimated annual compliance costs of the proposed rule to mine operators are $4.2 million, which are insignificant compared to total annual revenue of $92.8 billion for the mining industry (i.e., significantly less that one percent of the mining industry's $92.8 billion revenue, which is $928 million). Even if all of the costs were borne by the underground coal industry, the estimated $4.2 million cost of the proposed rule is about 0.02 percent of the underground coal industry's 2009 revenue of $18.5 billion. MSHA, therefore, concludes that compliance with the provisions of the proposed rule would be economically feasible for the mining industry.

VI. Regulatory Flexibility Act and Small Business Regulatory Enforcement Fairness Act (SBREFA)

Pursuant to the Regulatory Flexibility Act (RFA) of 1980, as amended by SBREFA, MSHA has analyzed the impact of the proposed rule on small businesses. Based on that analysis, MSHA has notified the Chief Counsel for Advocacy, Small Business Administration (SBA), and made the certification under the RFA at 5 U.S.C. 605(b) that the proposed rule would not have a significant economic impact on a substantial number of small entities. The factual basis for this certification is presented below.

A. Definition of a Small Mine

Under the RFA, in analyzing the impact of the proposed rule on small entities, MSHA must use the SBA definition for a small entity or, after consultation with the SBA Office of Advocacy, establish an alternative definition for the mining industry by publishing that definition in the **Federal Register** for notice and comment. MSHA has not taken such an action and is required to use the SBA definition. The SBA defines a small entity in the mining industry as an establishment with 500 or fewer employees.

In addition to examining small entities as defined by SBA, MSHA has also looked at the impact of this proposed rule on mines with fewer than 20 employees, which MSHA and the mining community have traditionally referred to as "small mines." These small mines differ from larger mines not only in the number of employees, but also in economies of scale in material produced, in the type and amount of production equipment, and in supply inventory. The costs of complying with the proposed rule and the impact of the proposed rule on small mines will also be different. It is for this reason that small mines are of special concern to MSHA.

MSHA concludes that it can certify that the proposed rule would not have a significant economic impact on a substantial number of small entities that would be covered by this proposed rule. The Agency has determined that this is the case both for mines with fewer than 20 employees and for mines with 500 or fewer employees.

B. Factual Basis for Certification

Mine operators can avoid the expenses of being placed on a POV by complying with MSHA regulations. Under the proposed rule, MSHA will consider the institution of an approved safety and health management program as a mitigating circumstance for those mine operators who are placed on a pattern. MSHA expects few mines (about 10 per year) would incur the potential expenses associated with closure orders under a POV.

MSHA initially evaluates the impacts on "small entities" by comparing the estimated compliance costs of a rule for small entities in the sector affected by the rule to the estimated revenues for the affected sector. When estimated compliance costs are less than one percent of the estimated revenues, the Agency believes it is generally appropriate to conclude that there is no significant economic impact on a substantial number of small entities. When estimated compliance costs exceed one percent of revenues, MSHA investigates whether a further analysis is required. Since it was not possible to accurately project the distribution of mines that would incur the estimated $4.2 million to comply with the proposed rule by commodity and size, MSHA examined the impact using several alternative assumptions.

The average number of mines in operation during a month in 2009 with 500 or fewer employees was 14,050. These mines generated an estimated $71.9 billion in revenue in 2009. Even if all of the costs were incurred by mines with 500 or fewer employees, the estimated $4.2 million in compliance costs would be less than 0.006 percent of the revenue generated by all small mines according to the SBA's definition.

The average number of underground coal mines in operation during a month in 2009 with 500 or fewer employees was 412. These mines generated an estimated $13.7 billion in revenue in 2009. Even if all of the costs were incurred by underground coal mines with 500 or fewer employees, the $4.2 million in compliance costs would be about 0.03 percent of the revenue generated by small underground coal mines according to the SBA's definition.

The average number of mines in operation during a month in 2009 with 1–19 employees was 11,816. These mines generated an estimated $17.4 billion in revenue in 2009. Even if all of the costs were incurred by mines with 1–19 employees, the estimated $4.2 million compliance costs would be about 0.02 percent of the revenue generated by all small mines with fewer than 20 employees.

The average number of underground coal mines in operation during a month in 2009 with 1–19 employees was 81. These mines generated an estimated $920 million in revenue in 2009. Even if all of the $4.2 million in compliance costs were incurred by underground coal mines with 1–19 employees, the costs would be about 0.45 percent of the revenue generated by small underground coal mines with fewer than 20 employees.

Moreover, mine operators can avoid any costs associated with being on a POV simply by complying with the law. If an operator has trouble complying and is in danger of being on POV, under the proposed rule, the implementation of an approved safety and health management program would serve as a mitigating circumstance.

Accordingly, MSHA has certified that the proposed rule would not have a significant economic impact on a substantial number of small entities.

VII. Paperwork Reduction Act of 1995

A. Summary

This proposed rule contains a collection-of-information requirement subject to review and approval by OMB under the Paperwork Reduction Act (PRA). MSHA estimates that under the proposed rule about 50 mines each year would develop and implement approved safety and health management programs. This would impose information collection requirements related to mitigating circumstances under proposed § 104.2(a)(8).

MSHA expects that developing an approved program with meaningful and measurable benchmarks would take about 160 hours of a supervisor's time at an hourly wage of $84.70 and 240 hours of miners' time at an hourly wage of $35.30. Costs for copying and mailing the program and revisions are estimated to be $100 per program.

The burden of developing and implementing an approved safety and health program is 400 hours per mine (160 + 240) and the average cost is approximately $22,100 (160 hours of a supervisor's time × $84.70 per hour + 240 hours of miners' time × $35.30 per hour + $100).

Burden Hours: 50 mines × 400 hours per mine = 20,000 hours.

Burden Costs: 50 mines × $100 per mine = $5,000.

B. Procedural Details

The information collection package for this proposed rule has been submitted to OMB for review under 44 U.S.C. 3504, paragraph (h) of the Paperwork Reduction Act of 1995, as amended (44 U.S.C. 3501 *et seq.*). MSHA requests comments to:

- Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;
- Evaluate the accuracy of the Agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;
- Enhance the quality, utility, and clarity of the information to be collected; and
- Minimize the burden of the 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.

Comments on the information collection requirements should be sent to both OMB and MSHA. Addresses for both offices can be found in the **ADDRESSES** section of this preamble. The regulated community is not required to respond to any collection of information unless it displays a current, valid, OMB control number. MSHA displays the OMB control numbers for the information collection requirements in its regulations in 30 CFR part 3.

VIII. Other Regulatory Considerations

A. The Unfunded Mandates Reform Act of 1995

MSHA has reviewed the proposed rule under the Unfunded Mandates Reform Act of 1995 (2 U.S.C. 1501 *et seq.*). MSHA has determined that this proposed rule would not include any federal mandate that may result in increased expenditures by State, local, or tribal governments; nor would it increase private sector expenditures by more than $100 million in any one year or significantly or uniquely affect small governments. Accordingly, the Unfunded Mandates Reform Act of 1995 requires no further Agency action or analysis.

B. Executive Order 13132: Federalism

This proposed rule would not have "federalism implications" because it would not "have substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government." Accordingly, under E.O. 13132, no further Agency action or analysis is required.

C. The Treasury and General Government Appropriations Act of 1999: Assessment of Federal Regulations and Policies on Families

Section 654 of the Treasury and General Government Appropriations Act of 1999 (5 U.S.C. 601 note) requires agencies to assess the impact of Agency action on family well-being. MSHA has determined that this proposed rule would have no effect on family stability or safety, marital commitment, parental rights and authority, or income or poverty of families and children. This proposed rule impacts only the mining industry. Accordingly, MSHA certifies that this proposed rule would not impact family well-being.

D. Executive Order 12630: Government Actions and Interference With Constitutionally Protected Property Rights

The proposed rule would not implement a policy with takings implications. Accordingly, under E.O. 12630, no further Agency action or analysis is required.

E. Executive Order 12988: Civil Justice Reform

This proposed rule was written to provide a clear legal standard for affected conduct and was carefully

reviewed to eliminate drafting errors and ambiguities, so as to minimize litigation and undue burden on the Federal court system. Accordingly, this proposed rule would meet the applicable standards provided in section 3 of E.O. 12988, Civil Justice Reform.

F. Executive Order 13045: Protection of Children From Environmental Health Risks and Safety Risks

This proposed rule would have no adverse impact on children. Accordingly, under E.O. 13045, no further Agency action or analysis is required.

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

This proposed rule would not have "tribal implications" because it would not "have substantial direct effects on one or more Indian tribes, on the relationship between the Federal government and Indian tribes, or on the distribution of power and responsibilities between the Federal government and Indian tribes." Accordingly, under E.O. 13175, no further Agency action or analysis is required.

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

Executive Order 13211 requires agencies to publish a statement of energy effects when a rule has a significant energy action (*i.e.,* it adversely affects energy supply, distribution or use). MSHA has reviewed this proposed rule for its energy effects because the proposed rule applies to the coal mining sector. Because this proposed rule would result in annual costs of approximately $4.2 million, most of which would be incurred by the coal mining industry, relative to annual coal mining industry revenues of $35.7 billion in 2009, MSHA has concluded that it is not a significant energy action because it is not likely to have a significant adverse effect on the supply, distribution, or use of energy. Accordingly, under this analysis, no further Agency action or analysis is required.

I. Executive Order 13272: Proper Consideration of Small Entities in Agency Rulemaking

MSHA has reviewed the proposed rule to assess and take appropriate account of its potential impact on small businesses, small governmental jurisdictions, and small organizations. MSHA has determined and certified that the proposed rule would not have a significant economic impact on a substantial number of small entities.

IX. References

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List of Subjects in 30 CFR Part 104

Administrative practice and procedure, Law enforcement, Mine safety and health, Reporting and recordkeeping requirements.

Dated: January 28, 2011.

Joseph A. Main,

Assistant Secretary of Labor for Mine Safety and Health.

For the reasons set out in the preamble, and under the authority of the Federal Mine Safety and Health Act of 1977 as amended by the Mine Improvement and New Emergency Response Act of 2006, MSHA is proposing to amend chapter I of title 30 of the Code of Federal Regulations by revising part 104 as follows:

PART 104—PATTERN OF VIOLATIONS

Sec.
104.1 Purpose and scope.
104.2 Pattern criteria.
104.3 Issuance of notice.
104.4 Termination of notice.

Authority: 30 U.S.C. 814(e), 957.

§ 104.1 Purpose and scope.

This part establishes the criteria and procedures for determining whether a mine operator has established a pattern of significant and substantial (S&S) violations at a mine. It implements section 104(e) of the Federal Mine Safety and Health Act of 1977 (Act) by addressing mines with an inspection history of recurrent S&S violations of mandatory safety or health standards that demonstrate a mine operator's disregard for the safety and health of miners. The purpose of the procedures in this part is the restoration of effective safe and healthful conditions at such mines.

§ 104.2 Pattern criteria.

(a) Specific pattern criteria will be posted on MSHA's Web site at *http://www.msha.gov* and used in the review to identify mines with a pattern of S&S violations. The review will include:

(1) Citations for significant and substantial violations;

(2) Orders under section 104(b) of the Act for not abating significant and substantial violations;

(3) Citations and withdrawal orders under section 104(d) of the Act, resulting from the operator's unwarrantable failure to comply;

(4) Imminent danger orders under section 107(a) of the Act;

(5) Orders under section 104(g) of the Act requiring withdrawal of miners who have not received training and who the inspector declares to be a hazard to themselves and others;

(6) Enforcement measures, other than section 104(e) of the Act, which have been applied at the mine;

(7) Other information that demonstrates a serious safety or health management problem at the mine such as accident, injury, and illness records; and

(8) Mitigating circumstances.

(b) At least two times each year, MSHA will review the compliance and accident, injury, and illness records of mines to determine if any mines meet the criteria posted on MSHA's Web site.

§ 104.3 Issuance of notice.

(a) When a mine has a pattern of violations, the District Manager will issue a pattern of violations notice to the mine operator that specifies the basis for the Agency's action. The District Manager will also provide a copy of this notice to the representative of miners.

(b) The mine operator shall post a copy of the notice on the mine bulletin board. The notice shall remain posted at the mine until it is terminated under § 104.4 of this part.

(c) If, on any inspection within 90 days after issuance of the pattern notice, an authorized representative of the Secretary finds any S&S violation, he shall issue an order for the withdrawal of all persons from the affected area, except those persons referred to in section 104(c) of the Act, until the condition has been abated.

(d) If a withdrawal order is issued under paragraph (c) of this section, any subsequent S&S violation will result in a withdrawal order that shall remain in effect until the authorized

representative of the Secretary determines that the violation has been abated.

§ 104.4 Termination of notice.

(a) Termination of a section 104(e)(1) pattern of violations notice shall occur when an MSHA inspection of the entire mine finds no S&S violations, or if no withdrawal order is issued by MSHA in accordance with section 104(e)(1) of the Act within 90 days of the issuance of the pattern notice.

(b) The mine operator may request an inspection of the entire mine or portion of the mine. No advance notice of the inspection shall be provided, and the scope of inspection shall be determined by MSHA. Partial mine inspections-covering the entire mine within 90 days shall constitute an inspection of the entire mine for the purposes of this part.

[FR Doc. 2011–2255 Filed 1–31–11; 8:45 am]

BILLING CODE 4510–43–P

DEPARTMENT OF DEFENSE

Office of the Secretary

32 CFR Part 156

[DOD–2008–OS–0160; RIN 0790–AI42]

Department of Defense Personnel Security Program (PSP)

AGENCY: Department of Defense.

ACTION: Proposed rule.

SUMMARY: This rule would update policies and responsibilities for the Department of Defense (DoD) Personnel Security Program (PSP) in accordance with the provisions of current U.S. Code, Public Laws, and Executive Orders (E.O.).

DATES: Comments must be received by April 4, 2011.

ADDRESSES: You may submit comments, identified by docket number and/or Regulatory Information Number (RIN) number and title, by any of the following methods:

- *Federal Rulemaking Portal: http://www.regulations.gov.* Follow the instructions for submitting comments.
- *Mail:* Federal Docket Management System Office, 1160 Defense Pentagon, OSD Mailroom 3C843, Washington, DC 20301–1160.

Instructions: All submissions received must include the agency name and docket number or Regulatory Information Number (RIN) for this **Federal Register** document. The general policy for comments and other submissions from members of the public is to make these submissions available for public viewing on the Internet at *http://www.regulations.gov* as they are received without change, including any personal identifiers or contact information.

FOR FURTHER INFORMATION CONTACT: Stacey Jefferson, (703) 604–1236.

SUPPLEMENTARY INFORMATION: The Department of Defense Directive (DoDD) 5200.2, Personnel Security Program (PSP), codified at 32 CFR 156, was issued April 9, 1999. The Department is reissuing the DoD Directive as a DoD Instruction to update existing policy regarding the DoD Personnel Security Program and also incorporate new policy related to Homeland Security Presidential Directive-12 (HSPD–12).

This rule provides PSP policy fundamental to preventing unauthorized disclosure of sensitive and classified information that could cause irreparable damage to national security. The policy portion relating to HSPD–12 implements investigative and adjudicative policy for the Department's personal identity verification credential.

Updates to the policy reflect Joint Security and Suitability Reform Team efforts to incorporate the foundational policy changes needed to implement reform. The Intelligence Reform and Terrorism Prevention Act of 2004, E.O. 13467, E.O. 12968, E.O. 10865, and HSPD–12 are some of the current Federal laws, directives and statutes that impact the DoD PSP. Since this rule was last published, additional executive orders have been issued directing alignment of security, suitability and reciprocal acceptance of prior investigations and favorable determinations.

The procedural guidance for the DoD PSP is currently being updated and will subsequently be proposed as rule codified at 32 CFR part 154. The investigative and adjudication procedural guidance for the DoD Federal personal identity verification credential pursuant HSPD–12 is undergoing coordination and will also be proposed a separate rule.

E.O. 12866, "Regulatory Planning and Review"

It has been certified that 32 CFR part 156 does not:

(1) Have an annual effect on the economy of $100 million or more or adversely affect in a material way the economy; a section of the economy; productivity; competition; jobs; the environment; public health or safety; or State, local, or tribunal 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 this E.O.

Section 202, Public Law 104–4, "Unfunded Mandates Reform Act"

It has been certified that 32 CFR part 156 does not contain a Federal mandate that may result in the expenditure by State, local and tribunal governments, in aggregate, or by the private sector, of $100 million or more in any one year.

Public Law 96–354, "Regulatory Flexibility Act" (5 U.S.C. 601)

It has been certified that 32 CFR part 156 is not subject to the Regulatory Flexibility Act (5 U.S.C. 601) because it would not, if promulgated, have a significant economic impact on a substantial number of small entities.

Public Law 96–511, "Paperwork Reduction Act" (44 U.S.C. Chapter 35)

It has been certified that 32 CFR part 156 does not impose reporting or recordkeeping requirements under the Paperwork Reduction Act of 1995.

E.O. 13132, "Federalism"

It has been certified that 32 CFR part 156 does not have federalism implications, as set forth in E.O. 13132. This rule does not have substantial direct effects on:

(1) The States;

(2) The relationship between the National Government and the States; or

(3) The distribution of power and responsibilities among the various levels of Government.

List of Subjects in 32 CFR Part 156

Government employees; Security measures.

Accordingly, 32 CFR part 156 is revised to read as follows.

PART 156—DEPARTMENT OF DEFENSE PERSONNEL SECURITY PROGRAM (PSP)

Sec.
156.1 Purpose.
156.2 Applicability.
156.3 Definitions.
156.4 Policy.
156.5 Responsibilities.
156.6 Procedures-sensitive positions, duties, and classified access.
156.7 Procedures—common access card investigation and adjudication.

Authority: E.O. 12968, as amended; E.O. 10450, as amended; E.O. 10865, as amended; E.O. 13526; E.O. 12829, as amended; E.O. 13467; E.O. 13488; E.O. 12333, as amended; sections 301 and 7532 of 5 U.S.C.; section 1072 of Public Law 110–181, as amended; section 278g–3 of 15 U.S.C.; section 11331 of 40 U.S.C.; title 10 U.S.C.; section 435c. and chapter 23 of 50 U.S.C.; and parts 731, 732 and 736 of 5 CFR.

§ 156.1 Purpose.

This part updates policies and responsibilities for the Department of Defense (DoD) Personnel Security Program (PSP) consistent with E.O. 12968, as amended; E.O. 10450, as amended; E.O. 10865, as amended; E.O. 13526; E.O. 12829, as amended; E.O. 13467; E.O. 13488; E.O. 12333, as amended; sections 301 and 7532 of 5 U.S.C.; section 1072 of Public Law 110–181, as amended; section 278g–3 of 15 U.S.C.; section 11331 of 40 U.S.C.; title 10 U.S.C.; parts 147, 154 through 156 of 32 CFR; section 435c. and chapter 23 of 50 U.S.C.; and parts 731, 732 and 736 of 5 CFR.

§ 156.2 Applicability.

This part applies to the Office of the Secretary of Defense, the Military Departments, the Office of the Chairman of the Joint Chiefs of Staff and the Joint Staff, the Combatant Commands, the Office of the Inspector General of the Department of Defense, the Defense Agencies, the DoD Field Activities, and all other organizational entities within the Department of Defense (hereafter referred to collectively as the "DoD Components").

§ 156.3 Definitions.

These terms and their definitions are for the purposes of this part:

Continuous evaluation. Defined in section 1.3(d) of E.O. 13467.

Fitness. Defined in E.O. 13488.

Sensitive position. Any position so designated under E.O. 10450, as amended.

§ 156.4 Policy.

It is DoD policy that:

(a) The Department shall establish and maintain a uniform DoD PSP using appropriate standards in accordance with E.O. 12968, as amended; E.O. 10450, as amended; E.O. 10865, as amended; E.O. 13526; E.O. 12829, as amended; E.O. 13467; E.O. 13488; E.O. 12333, as amended; parts 147, 154 through 156 of 32 CFR; parts 731, 732 and 736 of 5 CFR; sections 301 and 7532 of 5 U.S.C; section 1072 of Public Law 110–181, as amended; section 278g–3 of 15 U.S.C.; section 11331 of 40 U.S.C.; title 10 U.S.C.; section 435c. and chapter 23 of 50 U.S.C.; and the Intelligence Community Directive Number 704 (ICD 704).[1]

(b) Policies and procedures shall be aligned using consistent standards to the extent possible; provide for reciprocal recognition of existing investigations and favorable adjudications; be cost-effective, timely and provide efficient protection of the national interest; and provide fair treatment of those upon whom the Federal Government relies to conduct the Nation's business and protect national security.

(c) Discretionary judgments used to determine eligibility for access to classified information, to hold a sensitive position, or perform a sensitive duty are inherently governmental functions, and adjudications supporting these judgments shall be performed by appropriately trained and favorably adjudicated Government personnel or appropriate automated procedures.

(d) No negative inference may be raised solely on the basis of mental health counseling. Such counseling may be a positive factor in rendering eligibility determinations. However, mental health counseling, where relevant to adjudication for classified access or to hold a sensitive position, may justify further inquiry to assess risk factors that may be relevant to the DoD PSP.

(e) The Department of Defense shall not discriminate on the basis of race, color, religion, sex, national origin, disability, or sexual orientation, and no inference may be raised solely on the basis of an individual's sexual orientation.

(f) Discretionary judgments that determine eligibility for access to classified information, to hold a sensitive position, or perform a sensitive duty shall be clearly consistent with the interests of national security and any doubt shall be resolved in favor of national security.

(g) No person shall be deemed to be eligible for access to classified information, to hold a sensitive position, hold a DoD CAC, or perform a sensitive duty merely by reason of Federal service or contracting, licensee, certificate holder, or grantee status, or as a matter of right or privilege, or as a result of any particular title, rank, position, or affiliation.

(h) Eligibility for access to classified information, hold a sensitive position, or perform a sensitive duty shall be granted only to persons who are United States citizens for whom the investigative and adjudication process has been completed. However, based on mission needs, temporary eligibility may be granted prior to completion of the investigative and adjudicative process.

(i) As an exception, a non-U.S. citizen, who possesses an expertise that cannot be filled by a cleared or clearable U.S. citizen, may hold a sensitive position or granted a Limited Access Authorization for access to classified information in support of a specific DoD program, project, or contract.

(j) The Department shall establish investigative and adjudicative policy and procedures to determine whether to issue, deny or revoke CACs in accordance with the Homeland Security Presidential Directive (HSPD)–12;[2] Office of Management and Budget Memorandum (OMB) M–05–24;[3] Federal Information Processing Standards Publication 201–1(FIPS 201–1)[4]; Federal Acquisition Regulation[5]; section 278g–3 of title 15, U.S.C.; section 11331 of title 40, U.S.C., and the Office of Personnel Management (OPM) Memorandum, "Final Credentialing Standards for Issuing Personal Identity Verification Cards under HSPD–12."[6]

§ 156.5 Responsibilities.

(a) The Under Secretary of Defense for Intelligence (USD(I)) shall:

(1) Develop, coordinate, and oversee the implementation of policy, programs, and guidance for the DoD PSP. For the DoD intelligence agencies this responsibility shall be exercised in consultation with the Director of National Intelligence.

(2) In coordination with the Under Secretary of Defense for Personnel and Readiness (USD(P&R)) and the General Counsel of the Department of Defense (GC, DoD), establish policy for military and civilians for the CAC personnel security investigation (PSI) and adjudication in accordance with HSPD–12; E.O. 13467; E.O. 13488, section 11331 of title 40, U.S.C.; section 278g–3 of 15 U.S.C.; OMB Memo M–05–24; and OPM Memorandum, "Final Credentialing Standards for Issuing

[1] Copies available on the Internet at *http://www.dni.gov/electronic_reading_room/ICD_704.pdf.*

[2] Copies available on the Internet at *http://georgewbush-whitehouse.archives.gov/news/releases/2004/08/20040827-8.html.*

[3] Copies available on the Internet at *http://www.whitehouse.gov/sites/default/files/omb/memoranda/fy2005/m05-24.pdf.*

[4] Copies available on the Internet at *http://csrc.nist.gov/publications/fips/fips201-1/FIPS-201-1-chng1.pdf.*

[5] Copies available on the Internet at *https://www.acquisition.gov/Far/loadmainre.html.*

[6] Copies available on the Internet at *http://www.opm.gov/investigate/resources/final_credentialing_standards.pdf.*

Personal Identity Verification Cards under HSPD–12."

(3) In coordination with the Under Secretary of Defense for Acquisition, Technology and Logistics and the GC, DoD, establish policy for contractor fitness investigations and CAC adjudication, outside the purview of the National Industrial Security Program, under the terms of applicable contracts of HSPD–12; E.O. 13467; E.O. 13488, section 11331 of title 40, U.S.C.; section 278g–3 of 15 U.S.C.; OMB Memo M–05–24; and OPM Memorandum, "Final Credentialing Standards for Issuing Personal Identity Verification Cards under HSPD–12;" the Federal Acquisition Regulation; and the Defense Federal Acquisition Regulation.

(4) Develop guidance implementing the policy in this part.

(b) The Deputy Under Secretary of Defense (HUMINT, Counterintelligence & Security) DUSD(HCI&S), under the authority, direction, and control of USD(I) shall:

(1) Ensure that the program is consistent, cost-effective, efficient, and balances the rights of individuals with the interests of national security.

(2) Develop and publish revisions to 32 CFR part 154.

(3) Approve, coordinate, and oversee all DoD personnel security research initiatives and activities to improve the efficiency, effectiveness, and fairness of the DoD PSP.

(4) Ensure the Defense Security Service provides education, training, and awareness support to the DoD PSP.

(5) Serve as the primary contact between DoD, the Red Cross, United Service Organizations, and other organizations with direct DoD affiliation for all matters relating to the PSI policy and procedures prescribed herein.

(6) When appropriate, approve requests for exceptions to the DoD PSP for access to classified information except North Atlantic Treaty Organization (NATO) classified information. Requests for exceptions involving access to NATO classified information shall be sent to the Office of the Under Secretary of Defense for Policy.

(7) Issue policy guidance, interpretation, and clarification as needed.

(8) Conduct oversight inspections of the DoD Components for implementation and compliance with DoD personnel security policy and operating procedures.

(9) Develop a framework setting forth an overarching strategy identifying goals, performance measures, roles and responsibilities, a communications strategy, and metrics to measure the quality of security clearance investigations and adjudications to ensure a sound DoD PSP that will continue to meet the needs of DoD.

(c) The GC, DoD shall:

(1) Provide advice and guidance as to the legal sufficiency of procedures and standards involved in implementing the DoD PSP and exercise oversight of the established administrative due process procedures of the DoD PSP.

(2) Perform functions relating to the DoD PSP including the maintenance and oversight of the Defense Office of Hearings and Appeals.

(d) The Under Secretary of Defense for Policy shall approve requests for exceptions to the DoD PSP involving access to NATO classified information. Requests for exceptions involving access to any other classified information shall be sent to the DUSD(HCI&S).

(e) The Heads of the Office of the Secretary of Defense and DoD Components shall:

(1) Designate a senior agency official who shall direct and administer the DoD PSP consistent with this part.

(2) Comply with the policy and procedures regarding investigation and adjudication for CAC issuance and distribute this part to local and regional organizations.

(3) Provide funding to cover requirements for PSIs, adjudication, and recording of results to comply with the DoD PSP.

(4) Enforce requirements for prompt reporting of significant derogatory information, unfavorable administrative actions or adverse actions to the appropriate personnel security, human resources official(s), or counterintelligence official(s), as appropriate, within their respective Component.

(5) Provide requested information and recommendations, as appropriate, on any aspect of this part and the DoD PSP to the USD(I).

§ 156.6 Procedures—sensitive positions, duties, and classified access.

(a) *Procedures.* The objective of the personnel security program is to ensure persons deemed eligible for access to classified information, to hold a sensitive position, or perform a sensitive duty are and remain reliable and trustworthy. Duties considered sensitive and critical to national security do not always involve classified activities or classified matters. Personnel security procedures for sensitive positions or duties and classified access are set forth in E.O. 12968, as amended; 32 CFR 154; ICD 704; and DoD Regulation 5220.22–R.

(b) *Sensitive Compartmented Information (SCI) Eligibility.* Investigative and adjudicative requirements for SCI eligibility shall be executed in accordance with this part and ICD 704. Employees filling SCI designated positions within the IC must maintain eligibility for access to SCI as a mandatory condition of employment.

(c) *Adjudication.* (1) Personnel security criteria and adjudicative standards are described in E.O. 12968, as amended; parts 154 and 155 of 32 CFR; ICD 704, and DoD Regulation 5220.22–R in accordance with 32 CFR part 147.

(2) To ensure consistency and quality in determinations of eligibility for access to classified information and for sensitive positions or duties, adjudicators must successfully complete the full program of professional training provided by the Defense Center for Development of Security Excellence (or equivalent training) and be certified through the DoD Professional Certification Program for Adjudicators within two years of program implementation or, for new hires, within two years of eligibility for certification testing.

(d) *Appeal Procedures-Denial or Revocation of Eligibility.* Individuals may elect to appeal unfavorable personnel security determinations in accordance with the procedures set forth in E.O. 12968, as amended; parts 154 and 155 of 32 CFR; ICD 704, and DoD Regulation 5220.22–R or as otherwise authorized by law. Such procedures shall not be diminished but may be enhanced to achieve a common process to achieve efficiency from consolidation of functions.

(e) *Polygraph.* Under certain conditions, DoD Components are authorized to use polygraph examinations to facilitate national security information access decisions.

(f) *Continuous Evaluation.* All personnel determined to be eligible or who currently have access to classified information shall be subject to continuous evaluation consistent with E.O. 12968, as amended; E.O. 13467; 32 CFR 154; and the ICD 704.

(g) *Financial Disclosure.* DoD Component implementation of the electronic financial disclosure requirement shall be completed by the end of calendar year 2012 as described in E.O. 12968.

(h) *Reciprocal Acceptance of Eligibility Determinations* (1) DoD reciprocally accepts existing national security determinations or clearances from other government agencies in accordance with E.O. 13467, 5 CFR part 731, Office of Management Budget Memorandums "Reciprocal Recognition of Existing Personnel Security

Clearances" dated December 12, 2005 [7] and July 17, 2006.[8]

(2) Personnel who have been determined eligible for access to classified information or a sensitive position shall not be subject to additional security reviews or determinations unless potentially disqualifying conditions are present that have not been previously adjudicated. This does not preclude requirements for suitability determinations.

(3) Reciprocity for SCI eligibility shall be executed in accordance with the ICD 704.

(i) *National Security Agency (NSA)/ Central Security Service (CSS).* Employees, contractors, military assignees, and others with similar affiliations with the NSA/CSS must maintain SCI eligibility for access to sensitive cryptologic information in accordance with chapter 23 of 50 U.S.C.

(j) *Support of the Operation Warfighter Program.* PSIs in support of wounded warriors may be submitted and processed regardless of the time remaining in military service. Investigations will be accelerated through a special program code established by the Office of the USD(I) to ensure expedited service by the investigating and adjudicating agencies.

(1) Category 2 wounded, ill, or injured Uniformed Service personnel who expect to be separated with a medical disability rating of 30% or greater may submit PSIs for Top Secret clearance eligibility prior to medical separation provided they are serving in or have been nominated for a wounded warrior internship program.

(2) The investigations will be funded by the DoD sponsoring agency that is offering the internship. If the sponsoring agency does not have funds available, the owning Military Service may choose to fund the investigation.

§ 156.7 Procedures—common access card investigation and adjudication.

(a) A favorably adjudicated National Agency Check with Inquiries (NACI) is the minimum investigation required for the CAC.

(b) All final adjudicative determinations must be made by cleared and trained Government personnel. Automated adjudicative processes shall be used to the maximum extent practicable.

(c) Adjudication decisions of CAC investigations shall be incorporated into Central Adjudication Facility consolidation as directed by the Deputy Secretary of Defense.

(d) CAC applicants or holders may appeal CAC denial or revocation. No separate administrative appeal process is allowed when an individual has been denied a CAC as a result of a negative suitability determination under 5 CFR part 731, an applicable decision to deny or revoke a security clearance, or based on the results of a determination to disqualify the person from an appointment in the excepted service or from working on a contract for reasons other than eligibility for a Federal credential as described in the OPM Memorandum, "Final Credentialing Standards for Issuing Personal Identity Verification Cards under HSPD–12." If a later denial or revocation of a CAC results from an applicable denial or revocation of a security clearance, suitability decision or other action for which administrative process was already provided on grounds that support denial or revocation of a CAC, no separate appeal for CAC denial or revocation is allowed.

(1) Civilian applicants who have been denied a CAC, and for whom an appeal is allowed under this paragraph, may elect to appeal to a three member board containing one security and one human resources representative from the sponsoring activity.

(2) Contractor employees who have had their CAC revoked, and for whom an appeal is allowed under this paragraph, may appeal to the Defense Office of Hearings and Appeals under the established administrative process set out in 32 CFR part 155. Decisions following appeal are final.

(e) Reciprocity of CAC Determinations. (1) The sponsoring activity shall not readjudicate CAC determinations for individuals transferring from another Federal department or agency, provided:

(i) Possession of a valid PIV or CAC can be verified by the individual's former department or agency.

(ii) The individual has undergone the required NACI or other equivalent suitability, public trust, or national security investigation and received favorable adjudication from the former agency.

(2) Reciprocity may be granted as long as there is no break in service greater than 24 months and the individual has no actionable information since the date of the last completed investigation.

(3) Reciprocity shall be based on final adjudication only.

(4) Determinations for CACs issued on an interim basis are not eligible to be transferred.

Dated: January 14, 2011.

Patricia L. Toppings,

OSD Federal Register Liaison Officer, Department of Defense.

[FR Doc. 2011–2214 Filed 2–1–11; 8:45 am]

BILLING CODE 5001–06–P

[7] Copies available on the Internet at *http://www.whitehouse.gov/sites/default/files/omb/assets/omb/memoranda/fy2006/reciprocal121205.pdf.*

[8] Copies available on the Internet at *http://www.whitehouse.gov/sites/default/files/omb/assets/omb/memoranda/fy2006/m06-21.pdf.*

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 165

[Docket No. USCG–2011–0038]

RIN 1625–AA87

Security Zones; Cruise Ships, Port of San Diego, CA; Correction

AGENCY: Coast Guard, DHS.

ACTION: Notice of proposed rulemaking; correction.

SUMMARY: This document corrects the preamble to a proposed rule published in the **Federal Register** of January 27, 2011 (76 FR 4833), regarding security zones for cruise ships in the Port of San Diego, California. This correction clarifies when a preliminary environmental analysis checklist will be available in the docket.

DATES: This correction is effective February 2, 2011.

FOR FURTHER INFORMATION CONTACT: If you have questions on this document, call or e-mail Commander Michael B. Dolan, Prevention, Coast Guard Sector San Diego, Coast Guard; telephone 619–278–7261, e-mail *Michael.B.Dolan@uscg.mil.* If you have questions on viewing or submitting material to the docket, call Renee V. Wright, Program Manager, Docket Operations, telephone 202–366–9826.

Correction

In the notice of proposed rulemaking FR Doc. 2011–1804, beginning on page 4833 in the issue of January 27, 2011, make the following correction in the **SUPPLEMENTARY INFORMATION** section. On page 4835 in the 2nd column, remove the following sentence starting on line 9:

"A preliminary environmental analysis checklist supporting this determination is available in the docket where indicated under **ADDRESSES**."

And replace it with the following sentence:

"We intend to prepare a preliminary environmental analysis checklist and make it available in the docket where indicated under **ADDRESSES**."

Dated: January 27, 2011.

Kathryn A. Sinniger,

Chief, Office of Regulations and Administrative Law.

[FR Doc. 2011–2222 Filed 2–1–11; 8:45 am]

BILLING CODE 9110–04–P

DEPARTMENT OF VETERANS AFFAIRS

38 CFR Part 3

RIN 2900–AN64

Clothing Allowance

AGENCY: Department of Veterans Affairs.

ACTION: Proposed rule.

SUMMARY: The Department of Veterans Affairs (VA) proposes to amend its adjudication regulations regarding clothing allowances. The amendment would provide for annual clothing allowances for each qualifying prosthetic or orthopedic appliance worn or used by a veteran for a service-connected disability or disabilities that wears out or tears a distinct article of the veteran's clothing and for each physician-prescribed medication used by a veteran for a skin condition that is due to a service-connected disability that affects a distinct outergarment. The amendment would also provide two annual clothing allowances if a veteran wears or uses more than one qualifying prosthetic or orthopedic appliance, physician-prescribed medication for more than one skin condition, or an appliance and a medication for a service-connected disability or disabilities and the appliances(s) or medication(s) together cause a single article of clothing to wear out faster than if affected by a single appliance or medication.

DATES: VA must receive comments on or before April 4, 2011.

ADDRESSES: Written comments may be submitted through *http://www.Regulations.gov;* by mail or hand-delivery to Director, Regulations Management (02REG), Department of Veterans Affairs, 810 Vermont Ave., NW., Room 1068, Washington, DC 20420; or by fax to (202) 273–9026. (This is not a toll free number). Comments should indicate that they are submitted in response to "RIN 2900–AN64—Clothing Allowance." Copies of comments received will be available for public inspection in the Office of Regulation Policy and Management, Room 1063B, between the hours of 8 a.m. and 4:30 p.m., Monday through Friday (except holidays). Please call (202) 461–4902 for an appointment. (This is not a toll free number). In addition, during the comment period, comments may be viewed online through the Federal Docket Management System (FDMS) at *http://www.Regulations.gov.*

FOR FURTHER INFORMATION CONTACT: Tom Kniffen, Chief, Regulations Staff (211D), Compensation and Pension Service, Veterans Benefits Administration, Department of Veterans Affairs, 810 Vermont Avenue, NW., Washington, DC 20420, (202) 461–9725. This is not a toll-free number.

SUPPLEMENTARY INFORMATION: Section 1162 of title 38, United States Code, authorizes VA to pay an annual clothing allowance to each veteran who, because of a service-connected disability, wears or uses a prosthetic or orthopedic appliance (including a wheelchair) which VA determines tends to wear out or tear the veteran's clothing or uses prescription medication for a skin condition that is due to a service-connected disability which VA determines causes irreparable damage to the veteran's outergarments. VA had interpreted "a clothing allowance * * * because of a service-connected disability" in section 1162(1) and (2) and the word "or" between paragraphs (1) and (2) to mean that a veteran is entitled to only one annual clothing allowance, regardless of whether the veteran uses multiple qualifying appliances for more than one service-connected disability or uses a qualifying appliance for a service-connected disability and prescription medication for a skin condition resulting from a service-connected disability. In *Sursely* v. *Peake,* 551 F.3d 1351, 1356 (Fed. Cir. 2009), VA, based upon this statutory interpretation, rejected a claim for a second clothing allowance for "independently qualifying orthopedic appliances affecting different articles of clothing." The United States Court of Appeals for the Federal Circuit (Federal Circuit) disagreed with VA's interpretation and stated that, "by linking receipt of the benefit to a single qualifying appliance," Congress "require[s]" VA "to pay multiple clothing allowances to a veteran who * * * uses multiple qualifying appliances." *Id.* and 1356 n.4. The Federal Circuit also rejected the United States Court of Appeals for Veterans Claims' conclusion that it would be "irrational" to permit multiple clothing allowances for use of multiple prosthetic appliances affecting a single article of clothing because under such circumstances the garment may wear out faster than if affected by a single appliance. *Id.* at 1357–58 and 1358 n.6 (quoting 22 Vet. App. 21, 25–26 (2007)). However, the Federal Circuit noted that VA could promulgate regulations prohibiting multiple clothing allowances if "damage to a single garment resulting from multiple prosthetic appliances is 'overlapping.'" *Id.* at 1358 (quoting *Esteban* v. *Brown,* 6 Vet. App. 259, 262 (1994)).

VA proposes to amend 38 CFR 3.810(a) to implement *Sursely.* VA would amend current § 3.810(a)(1) so that it provides the criteria for entitlement to one annual clothing allowance currently set forth in § 3.810(a)(1) and (2). We would also make a technical change in § 3.810(a)(1)(i) by changing the reference to § 3.326(c) to § 3.326(b) to reflect a longstanding regulatory amendment. VA also would revise § 3.810(a)(2) to provide the criteria for more than one annual clothing allowance where distinct garments are affected. New § 3.810(a)(2) would state that a veteran is entitled to a clothing allowance for each prosthetic or orthopedic appliance or medication used by the veteran that satisfies the requirements of paragraph (1) of this subsection if each appliance or medication affects a distinct article of clothing or outergarment. This regulation is consistent with the *Sursely* holding that the veteran was entitled to a second clothing allowance "for his independently qualifying orthopedic appliances affecting different articles of clothing." 551 F.3d at 1356.

VA also recognizes, as the Federal Circuit did, that use of multiple qualifying appliances or medications may cause a single article of clothing to wear out faster, requiring replacement of the garment more frequently during the course of the year than if the garment were affected by only one appliance or medication. *Id.* at 1358 n.6. VA therefore also proposes to provide in § 3.810(a)(3) that a veteran is entitled to two annual clothing allowances if: (1) A veteran uses more than one qualifying prosthetic or orthopedic appliance, medication for more than one skin condition, or an appliance and a medication; and (2) the appliances(s) or medication(s) each satisfy the requirements of § 3.810(a)(1) and together tend to tear or wear a single article of clothing or irreparably damage an outergarment at a faster rate, requiring replacement sooner than if the article of clothing or outergarment was affected by a single qualifying appliance or medication. In such circumstances, VA would provide two annual clothing allowances, rather than an allowance for each appliance or medication, because we believe that the wear and tear or irreparable damage caused by three or

more appliances and/or medications will overlap the increased rate of damage caused by the second appliance and/or medication on the garment. *Id.* at 1358.

Paperwork Reduction Act

The collection of information under the Paperwork Reduction Act (44 U.S.C. 3501–3521) referenced in this proposed rule has an existing OMB approval as a form. The form is VA Form 10–8678, Application for Annual Clothing Allowance (Under 38 U.S.C. 1162), OMB approval number 2900–0198. No changes are made in this proposed rule to the collection of information.

Regulatory Flexibility Act

The Secretary hereby certifies that this proposed rule will not have a significant economic impact on a substantial number of small entities as they are defined in the Regulatory Flexibility Act, 5 U.S.C. 601–612. This proposed rule would not affect any small entities. Only VA beneficiaries could be directly affected. Therefore, pursuant to 5 U.S.C. 605(b), this proposed rule is exempt from the initial and final regulatory flexibility analysis requirements of sections 603 and 604.

Executive Order 12866

Executive Order 12866 directs agencies to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity). The Executive Order classifies a "significant regulatory action," requiring review by the Office of Management and Budget (OMB), as any regulatory action 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.

The economic, interagency, budgetary, legal, and policy implications of this proposed rule have been examined and it has been determined to be a not significant regulatory action under the Executive Order.

Unfunded Mandates

The Unfunded Mandates Reform Act of 1995 requires, at 2 U.S.C. 1532, that agencies prepare an assessment of anticipated costs and benefits before issuing any rule that may result in the expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of $100 million or more (adjusted annually for inflation) in any year. This proposed rule would have no such effect on State, local, and tribal governments, or on the private sector.

Catalog of Federal Domestic Assistance Numbers and Titles

The Catalog of Federal Domestic Assistance program numbers and titles for this proposed rule are 64.013, Veterans Prosthetic Appliances; and 64.109, Veterans Compensation for Service-Connected Disability.

Signing Authority

The Secretary of Veterans Affairs, or designee, approved this document and authorized the undersigned to sign and submit the document to the Office of the Federal Register for publication electronically as an official document of the Department of Veterans Affairs. John R. Gingrich, Chief of Staff, approved this document on January 19, 2011, for publication.

List of Subjects in 38 CFR Part 3

Administrative practice and procedure, Claims, Disability benefits, Health care, Pensions, Radioactive materials, Veterans, Vietnam.

Approved: January 26, 2011.

Robert C. McFetridge,

Director, Regulations Policy and Management, Department of Veterans Affairs.

For the reasons set out in the preamble, VA proposes to amend 38 CFR part 3 as follows:

PART 3—ADJUDICATION

Subpart A—Pension, Compensation, and Dependency and Indemnity Compensation

1. The authority citation for part 3, subpart A continues to read as follows:

Authority: 38 U.S.C. 501(a), unless otherwise noted.

2. Revise § 3.810(a) to read as follows:

§ 3.810 Clothing allowance.

(a) Except as provided in paragraph (d) of this section, a veteran who has a service-connected disability, or a disability compensable under 38 U.S.C. 1151 as if it were service connected, is entitled, upon application therefore, to an annual clothing allowance, which is payable in a lump sum, as specified in this paragraph.

(1) *One Clothing Allowance.* A veteran is entitled to one annual clothing allowance if—

(i) A VA examination or hospital or examination report from a facility specified in § 3.326(b) establishes that the veteran, because of a service-connected disability or disabilities due to loss or loss of use of a hand or foot compensable at a rate specified in § 3.350(a), (b), (c), (d), or (f), wears or uses one qualifying prosthetic or orthopedic appliance (including a wheelchair) which tends to wear or tear clothing; or

(ii) The Under Secretary for Health or a designee certifies that—

(A) A veteran, because of a service-connected disability or disabilities, wears or uses one qualifying prosthetic or orthopedic appliance (including a wheelchair) which tends to wear or tear clothing; or

(B) A veteran uses medication prescribed by a physician for one skin condition which is due to a service-connected disability and which causes irreparable damage to the veteran's outergarments.

(2) *More Than One Clothing Allowance; Distinct Garments Affected.*

A veteran is entitled to an annual clothing allowance for each prosthetic or orthopedic appliance or medication used by the veteran if each appliance or medication—

(i) Satisfies the requirements of paragraph (a)(1) of this section; and

(ii) Affects a distinct article of clothing or outergarment.

(3) *Two Clothing Allowances; Single Garment Affected.* A veteran is entitled to two annual clothing allowances if a veteran uses more than one prosthetic or orthopedic appliance, medication for more than one skin condition, or an appliance and a medication, and the appliance(s) or medication(s)—

(i) Each satisfy the requirements of paragraph (a)(1) of this section; and

(ii) Together tend to wear or tear a single article of clothing or irreparably damage an outergarment at a faster rate than if affected by one qualifying appliance or medication.

* * * * *

[FR Doc. 2011–2101 Filed 2–1–11; 8:45 am]

BILLING CODE 8320–01–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 26

[EPA–HQ–OPP–2010–0785; FRL–8862–7]

RIN 2070–AJ76

Revisions to EPA's Rule on Protections for Subjects in Human Research Involving Pesticides

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: EPA proposes to amend the portions of its rules for the protection of human subjects of research applying to third parties who conduct or support research with pesticides involving intentional exposure of human subjects and to persons who submit the results of human research with pesticides to EPA. The proposed amendments would broaden the applicability of the rules to cover human testing with pesticides submitted to EPA under any regulatory statute it administers. They would also disallow participation in third-party pesticide studies by subjects who cannot consent for themselves. Finally the proposed amendments would identify specific considerations to be addressed in EPA science and ethics reviews of proposed and completed human research with pesticides, drawn from the recommendations of the National Academy of Sciences (NAS). In seeking comments on these proposed amendments, EPA does not imply that the current Federal Policy for the Protection of Human Subjects (the "Common Rule"), which governs research with human subjects conducted or supported by EPA and many other Federal departments and agencies, is inadequate. Indeed, the amendments proposed here would make no changes to the Common Rule or EPA's codification of the Common Rule. Rather, EPA is proposing these amendments to other portions of its regulation as a result of a settlement agreement, and is now seeking comment on these proposed amendments. The settlement agreement makes clear that EPA retains full discretion concerning what amendments are proposed, and what, if any, amendments are finalized. Furthermore, no research has been identified that is outside the scope of EPA's current rule, but that would be within the scope of these proposed amendments. EPA seeks comments on the need for and value of the proposed changes.

DATES: Comments must be received on or before April 4, 2011.

ADDRESSES: Submit your comments, identified by docket identification (ID) number EPA–HQ–OPP–2010–0785, 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–2010–0785. 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 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 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: Kelly Sherman, Immediate Office of the Director (7501P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001; telephone number: (703) 305–8401; fax number: (703) 308–4776; e-mail address: *sherman.kelly@epa.gov.*

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this action apply to me?

You may be potentially affected by this action if you sponsor, conduct, review, or submit to EPA research with pesticides involving human subjects. Potentially affected entities may include, but are not limited to:

- Pesticide and other agricultural chemical manufacturers (NAICS code 325320) who sponsor or conduct human research with pesticides.
- Other entities (NAICS code 541710) that sponsor or conduct human research with pesticides, and Institutional Review Boards who review human research with pesticides to ensure it meets applicable standards of ethical conduct.

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 are 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 confidential business information (CBI)

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:

a. Identify the document by docket ID number and other identifying information (subject heading, **Federal Register** date and page number).

b. 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.

c. Explain why you agree or disagree; suggest alternatives and substitute language for your requested changes.

d. Describe any assumptions and provide any technical information and/or data that you used.

e. If you estimate potential costs or burdens, explain how you arrived at your estimate in sufficient detail to allow for it to be reproduced.

f. Provide specific examples to illustrate your concerns and suggest alternatives.

g. Explain your views as clearly as possible, avoiding the use of profanity or personal threats.

h. Make sure to submit your comments by the comment period deadline identified.

II. Background

A. What would the proposed amendments do?

The proposed amendments would change the 2006 rule, published in the **Federal Register** issue of February 6, 2006 (71 FR 6138) (FRL–7759–8), subsequently amended on June 23, 2006 (71 FR 36171) (FRL–8071–6), and codified at 40 CFR part 26, in the following substantive respects:

- By broadening the applicability of 40 CFR part 26, subparts K, L, M, and Q, so these subparts would apply not only to research submitted to or considered by EPA under the pesticide laws, but also to research involving a "pesticide" (as defined in the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) (7 U.S.C. 136(u)) which is submitted to or considered by EPA under any other regulatory statute it administers.
- By incorporating the definition of "pesticide" from FIFRA, as a substance or mixture of substances intended for pesticidal effect.
- By deleting from 40 CFR part 26, subpart K, all references to consent on behalf of a subject in research involving intentional exposure to a pesticide by a subject's "legally authorized representative."
- By incorporating into 40 CFR part 26, subparts P and Q, factors to be considered by EPA and the Human Studies Review Board (HSRB) in their review of proposed and completed research, derived from the recommendations of NAS in its 2004 Report to EPA, and from the Nuremberg Code.

The amendments proposed here would make no changes to the Federal Policy for the Protection of Human Subjects (the "Common Rule"), which governs research with human subjects conducted or supported by EPA and many other Federal departments and agencies. EPA's codification of the Common Rule appears as subpart A in 40 CFR part 26.

Subparts B, C, and D of 40 CFR part 26 would also be unchanged by these proposed amendments. These subparts categorically prohibit any EPA research involving intentional exposure to any substance of human subjects who are children or pregnant or nursing women (40 CFR part 26, subpart B), and provide extra protections for pregnant women and for children who are the subjects of observational research conducted or supported by EPA (40 CFR part 26, subparts C and D).

The proposed amendments would retain without substantive change the core provisions of the 2006 rule applying to the conduct of human pesticide research by third parties—*i.e.,* research neither conducted nor supported by EPA or another Common Rule Federal department or agency. These substantively unchanged provisions:

- Categorically prohibit new research involving intentional exposure of pregnant or nursing women or of children to a pesticide (40 CFR part 26, subpart L).
- Apply the provisions of the Common Rule to third-party human research involving intentional exposure of non-pregnant, non-nursing adults to a pesticide (40 CFR part 26, subpart K).
- Require submission to EPA of proposals for new covered research before it is initiated (40 CFR part 26, subpart K, § 26.1125).
- Require persons who submit to EPA reports of completed human research on pesticides to document the ethical conduct of that research (40 CFR part 26, subpart M).
- Establish an independent HSRB to review and advise EPA concerning both proposals for new human research involving intentional exposure to a pesticide and reports of completed research on which EPA proposes to rely in its actions (40 CFR part 26, subpart P).

The proposed amendments would make only minor editorial revisions to 40 CFR part 26, subpart O, which defines administrative actions available to EPA to address non-compliance with 40 CFR part 26, subparts A through L.

The proposed amendments would retain the essential structure of 40 CFR part 26, subpart P, which defines the processes of EPA and HSRB review of proposed and completed research. The amendments, however, would also add substantial new clarifying language to 40 CFR part 26, subpart P, as discussed in detail in Unit IV.C. of this document.

The proposed amendments would retain the essential structure of 40 CFR part 26, subpart Q, which defines the standards to be applied when EPA proposes to rely on data from completed research involving intentional exposure of human subjects to a pesticide. The amendments, however, would also add substantial new clarifying language to 40 CFR part 26, subpart Q, as discussed in detail in Unit IV.D. of this document.

The proposed amendments would not change the provision in 40 CFR part 26, subpart Q, forbidding EPA to rely on any otherwise unacceptable research involving intentional exposure of human subjects to a pesticide, except under extremely restrictive conditions. These conditions require a public review by HSRB, an opportunity for public comment, and a showing by EPA that to do so would result in a more protective regulatory standard than could be justified without reliance on the unethical research.

B. What is the agency's authority for taking this action?

The legal authority for the 2006 rule on human research is set forth in the preamble to that final rule (71 FR 6138, February 6, 2006) (FRL–7759–8). These proposed amendments to that rule rest upon the same legal authority. In particular, the legal authority for expanding the 2006 rule to cover research involving the intentional exposure of a human subject to a pesticide submitted under any EPA

regulatory statute is provided by section 201 of the Department of the Interior, Environment, and Related Agencies Appropriations Act, 2006, Public Law 109–54 (2006 Appropriations Act), and FIFRA.

The 2006 Appropriations Act directly mandates that EPA promulgate a rule on "third-party intentional dosing human toxicity studies for pesticides * * *" without limiting the rule to pesticide studies submitted under FIFRA or section 408 of the Federal Food, Drug, and Cosmetic Act (FFDCA) (21 U.S.C. 346a).

Additionally, under FIFRA, EPA has the authority to issue regulations as to both unregistered and registered pesticides used in research involving the intentional exposure of a human subject, whether or not that research is conducted for submission under FIFRA. Section 3(a) of FIFRA authorizes EPA to regulate the distribution, sale, or use of any unregistered pesticide in any State "[t]o the extent necessary to prevent unreasonable adverse effects on the environment" (defined at FIFRA section 2(bb), in pertinent part, as "any unreasonable risk to man or the environment, taking into account the economic, social, and environmental costs and benefits of the use of any pesticide"). EPA concludes that there would be an unreasonable risk to humans if unregistered pesticides were used in research involving intentional exposure of human subjects (or sold and distributed for such use) that is not already covered by the Common Rule absent compliance with the applicable rules in 40 CFR part 26, as proposed. The importance of these rules to the protection of human subjects is demonstrated in the 2004 Report from the National Research Council of the NAS, entitled "Intentional Human Dosing Studies for EPA Regulatory Purposes: Scientific and Ethical Issues" (2004 NAS Report) (*http://www.national-academies.org*).

Section 25(a) of FIFRA authorizes EPA to "prescribe regulations to carry out the provisions of [FIFRA]." (7 U.S.C. 136w(a)). Regulations protecting human subjects in research involving the intentional exposure of human subjects to registered pesticides fall within that purview. FIFRA provides that a pesticide may not be registered unless use of the pesticide under its labeling will not cause unreasonable risks to humans or the environment, that a pesticide may not be used inconsistent with its label, and that a pesticide may not be used in human testing unless the subjects are fully informed regarding the nature, purpose, and physical and mental health consequences of the testing and freely volunteer. (*See* 7 U.S.C. 136(bb), 136a(c)(5), 136j(a)(2)(G), 136j(a)(2)(P)). The 2006 rule and the amendments proposed in this document ensure that these provisions regarding use of registered pesticides in a manner that does not cause unreasonable risk and full and free consent in human testing with pesticides are effectuated.

III. EPA's Human Subjects Protection Rules

A. Overarching Principles

EPA is committed to relying on scientifically sound research that is ethically conducted, and to transparency in its review processes and decision-making. EPA issued the 2006 rule to further these commitments and nothing in the amendments proposed in this document will change that. These proposed amendments can be seen as increasing the transparency of EPA's decision-making process by clarifying the scope and applicability of the requirements in 40 CFR part 26, codifying the scope and approach used in EPA's science and ethics reviews of human research involving pesticides.

B. Appropriations Act of 2006

In August 2005, in the 2006 Appropriations Act, which appropriated funds for EPA and other Federal departments and agencies for FY 2006, Congress included at section 201 the following provision:

> None of the funds made available by this Act may be used by the Administrator of the Environmental Protection Agency to accept, consider or rely on third-party intentional dosing human toxicity studies for pesticides, or to conduct intentional dosing human toxicity studies for pesticides until the Administrator issues a final rulemaking on this subject. The Administrator shall allow for a period of not less than 90 days for public comment on the Agency's proposed rule before issuing a final rule. Such rule shall not permit the use of pregnant women, infants or children as subjects; shall be consistent with the principles proposed in the 2004 report of the National Academy of Sciences on intentional human dosing and the principles of the Nuremberg Code with respect to human experimentation; and shall establish an independent Human Subjects Review Board. The final rule shall be issued no later than 180 days after enactment of this Act.

In response, EPA published a proposed rule in the **Federal Register** issue of September 12, 2005 (70 FR 53838) (FRL–7728–2), accepted public comment until December 12, 2005, and promulgated on February 6, 2006, a final rule which took effect on April 7, 2006 (71 FR 6138) (FRL–7759–8). The 2006 rule, as subsequently amended on June 23, 2006, to extend special protections to nursing women as well (71 FR 36171) (FRL–8071–6), is discussed in Unit III.E. and is now being further amended by this proposed rule.

C. EPA's 2006 Rule

1. *Summary of contents.* The 2006 rule established a set of protections for people participating as subjects in third-party human research with pesticides. (In this context "third-party" research is research neither conducted ("first-party") nor supported ("second-party") by EPA or another Common Rule Federal department or agency.) The 2006 rule bans all third-party research on pesticides involving intentional exposure of children or of pregnant or nursing women. It further forbids EPA itself to conduct or support any research involving intentional exposure of pregnant or nursing women or of children to any substance. EPA was required to promulgate the 2006 rule by the 2006 Appropriations Act.

The 2006 rule also extends the ethical protections in the Common Rule to third-party studies of non-pregnant, non-nursing adult subjects intentionally exposed to pesticides. The key provisions of the 2006 rule include:

- Requiring pre-implementation submission to EPA of protocols and related information about proposed research to ensure any future studies meet high ethical standards.
- Establishing an independent HSRB to obtain expert peer review of both proposals for new research intended for submission to EPA and reports of completed human research involving intentional exposure on which EPA proposes to rely in an action taken under the pesticide laws.
- Prohibiting EPA from relying on the results of research in its actions under the pesticide laws unless EPA determines that the research meets acceptance standards derived from the recommendations in the 2004 NAS Report.

2. *Research with pesticides since promulgation of the 2006 rule.* Contrary to some predictions, the 2006 rule has not led to an upsurge in human research with pesticides for submission to EPA under FIFRA or FFDCA. Since promulgation of the 2006 rule EPA has received no proposals at all for research on the toxicity of a pesticide to human subjects, and has received significantly fewer than were projected proposals for new research of other kinds (*e.g.,* insect repellent studies). In the analyses supporting the 2006 rule, EPA estimated 33 new intentional exposure studies would be submitted each year; in fact, only 26 proposals for new research on pesticides for submission to EPA under

FIFRA and FFDCA have been submitted over a span of approximately 5 years, or just over 5 per year.

3. *Overview of HSRB reviews.* EPA's experience in implementing the 2006 rule is critical to understanding the amendments proposed in this document. The public meetings of HSRB have served as key milestones in the implementation of the 2006 rule, and the implementation of the 2006 rule can be best characterized by summarizing what HSRB has been called upon to review. HSRB met for the first time in April 2006, immediately after the 2006 rule became effective, and has met 14 times since then, most recently in October 2010. At these meetings, HSRB has reviewed both reports of completed research and proposals for new research. Specifically, HSRB has reviewed:

- Completed reports of pre-2006 rule research reporting toxic endpoints. These have included intentional exposure toxicity tests initiated both before and after passage of the Food Quality Protection Act (FQPA) in 1996, as well as therapeutic trials of substances used both as drugs and as pesticides, reporting side effects relevant to EPA pesticide risk assessments.
- Proposals for and reports of new research involving intentional exposure to materials used in the research as pesticides.

a. *Pre-rule research reporting toxic endpoints.* At its first two meetings in April and May 2006, HSRB reviewed 28 reports of pre-rule research conducted with 11 substances. At all its subsequent meetings combined the Board has reviewed 14 more such reports. Half of these 42 reports were published; the rest were unpublished reports submitted directly to EPA by pesticide companies. Of the 42 reports, 37 reported non-therapeutic research, and 5 were published reports of therapeutic trials that described side effects relevant to pesticide risk assessments. We summarize the disposition of each of the 42 studies in the following paragraphs, and additional details may be accessed in the study specific reports available on the HSRB Web site at *http://www.epa.gov/hsrb/index.htm.*

Twenty-nine of the 37 non-therapeutic studies reviewed by HSRB were initiated before the passage of FQPA in 1996; all reported toxic endpoints. EPA conducted both science and ethic reviews of these studies prior to submission of the studies to HSRB. EPA science reviewers proposed to rely on 17 of these 29 studies. HSRB found 13 of these 17 studies scientifically acceptable under the applicable standards of the 2006 rule. EPA ethics reviewers found 5 of the 17 clearly acceptable, and deferred to HSRB concerning whether the shortcomings noted in the conduct of the remaining 12 studies rose to the level of "significant" deficiencies relative to prevailing standards of ethical research conduct. HSRB found 15 of those 17 studies ethically acceptable under the applicable standards of the 2006 rule—§ 26.1703 and § 26.1704. HSRB found 1 study ethically unacceptable because of deficiencies in risk minimization procedures that could have led to serious harm to subjects, and another unacceptable because incomplete information provided to subjects concerning previous studies seriously impaired their informed consent. These 2 studies found by HSRB to be ethically unacceptable were among those also found by HSRB to be scientifically unacceptable. EPA has not subsequently relied on any studies deemed either scientifically or ethically unacceptable by HSRB.

The 12 remaining pre-FQPA studies that EPA science reviewers had proposed to reject concerned dichlorvos (DDVP). These reports on the effects of dichlorvos had been submitted by the registrant to support a proposal to reduce the inter-species uncertainty factor in EPA's DDVP risk assessment. EPA reviewers found all 12 to be scientifically unacceptable to reduce the inter-species factor since a dose response could not be calculated due to numerous technical weaknesses. HSRB concurred. Because the reported research was deemed scientifically unacceptable for the proposed use, neither EPA nor HSRB explicitly reviewed its ethical conduct. EPA has not relied on any of these 12 studies.

Turning to the 8 post-FQPA toxicity studies that EPA presented to HSRB, we note that they were among a group of about 20 studies at the center of controversy before promulgation of the 2006 rule. Other post-FQPA human toxicity studies were deemed by EPA science reviewers to be irrelevant to EPA's risk assessments, and have not been considered further.

Of the eight relevant post-FQPA toxicity studies, EPA science reviewers found six scientifically acceptable and proposed to rely on them, found one more to be clearly scientifically unacceptable to set a point of departure because no effect was measured from the single dose level tested [1], and deferred to HSRB with respect to the scientific acceptability of the last one. HSRB concurred that the first six studies were scientifically acceptable, and found both the others unacceptable. EPA ethics reviewers found four of the eight studies clearly acceptable, one clearly unacceptable, and deferred to HSRB's judgment whether the shortcomings noted in the conduct of the remaining three rose to the level of "significant" deficiencies relative to prevailing standards of ethical conduct. HSRB found all but one of these eight studies ethically acceptable under the applicable standards in the 2006 rule. Studies found either scientifically or ethically unacceptable by HSRB have not subsequently been relied on by EPA in any actions.

EPA also proposed to rely on five published reports of therapeutic trials of materials that may be used as either drugs or as pesticide active ingredients. In these studies the reported toxic endpoints relevant to EPA pesticide risk assessments were not the main objective of the research, they were reported side effects of treatment when a test material (which is sometimes used as a pesticide) was administered as a medication. HSRB concurred with the EPA science reviews that these four studies were scientifically unacceptable, but found one study scientifically unacceptable for the purpose EPA proposed. EPA ethics reviewers and HSRB both found all five of these studies to be ethically acceptable under the standards of the 2006 rule.

In summary, EPA and HSRB worked through the backlog of pre-rule studies of pesticide toxicity awaiting review when the 2006 rule was promulgated. EPA and HSRB agreed about the acceptability of these studies in most cases; when there was disagreement, EPA has accepted HSRB recommendation. Some pre-rule studies that met the scientific and ethical standards defined in the 2006 rule have been relied upon by EPA in actions under the pesticide laws, although EPA has not relied on any studies found unacceptable by HSRB. Meanwhile, as EPA completed the reassessment of tolerances mandated by FQPA, it found human toxicity testing to be relevant to only a handful of those assessments.

b. *New research involving intentional exposure of human subjects.* In addition to reviewing pre-2006 rule research, HSRB has reviewed proposals for new research involving intentional exposure of human subjects. EPA developed a detailed "framework" for its reviews of these proposals (*see* the HSRB Web site at *http://www.epa.gov/hsrb/index.htm*). This framework has been used to guide all subsequent EPA reviews, and has

[1] For more details on this finding, *see* the study report available on the HSRD Web site at *http://www.epa.gov/hsrb/index.htm.*

been refined in detail to incorporate suggestions from HSRB. A completed framework addressing concerns identified in the 2004 NAS Report and subsequently by HSRB has been attached to each EPA review of a proposal for new research under the 2006 rule.

Since promulgation of the 2006 rule EPA has received no proposals at all for new research concerning pesticide toxicity or metabolism in human subjects. All submitted proposals for new research have been for research involving intentional exposure of human subjects to registered pesticides used for pesticidal purposes in the research itself. This has included proposals for research to measure the duration of effectiveness of skin-applied repellents intended to keep mosquitoes, ticks, and other pests away from the treated skin of human subjects, and for research monitoring occupational exposure of pesticide handlers as they mix, load, or apply pesticides in a variety of agricultural and non-agricultural use scenarios.

Close scrutiny by both EPA and HSRB of proposals for new repellent performance testing and worker exposure monitoring studies has led to steady and substantial improvement both in the scientific design of these studies and in their provision for ethical treatment of subjects. These reviews have led to some delays in field research costly to the study sponsors, but the sponsors and investigators proposing these studies have learned how to design and execute them efficiently and in full compliance with the standards of the 2006 rule. These studies provide essential information about repellent performance and worker exposure that is not available except from well designed, ethically conducted research involving intentional exposure of human subjects to pesticides.

i. *Repellent performance studies.* Repellent performance studies using human subjects have been required by EPA for many years to support registration of pesticide products bearing claims to keep mosquitoes, ticks, or other pests away from treated human skin. Since 2006, HSRB has reviewed proposals for 13 new repellent performance studies testing a total of 29 repellent formulations. EPA and HSRB identified enough scientific and ethical deficiencies in their initial review of the first 2 such proposals that a second review was required. After they were revised and resubmitted, both proposals were reviewed favorably by EPA and HSRB. All subsequent proposals for new repellent performance studies have been found acceptable, with identified needed refinements, upon their first review by EPA and HSRB.

Five of the 13 proposals have been for laboratory research with caged insects or ticks reared in the laboratory and known to be disease-free. The remaining studies have been for field studies of repellency against wild populations of insects. Three of the 13 studies have measured the duration of tick repellency in the laboratory—2 of them concurrently testing repellency to 2 species of ticks. Two more have measured the duration of repellency to biting flies—1 in the laboratory with laboratory-reared stable flies, and another in the field measuring repellency against black flies. The remaining 8 studies have measured the duration of repellency against mosquitoes—7 of them in the field, in areas where previous monitoring has not found evidence of infection of potential disease vectors among the wild insects present, and 1 in the laboratory with laboratory-reared, pathogen-free mosquitoes.

In all these cases, HSRB has concurred with the EPA science and ethics reviews, in some cases recommending further refinements. One proposal was abandoned by its sponsor after a favorable HSRB review; 11 more have been amended consistent with EPA and HSRB recommendations and executed. Reports of these 11 have been submitted to EPA and reviewed by EPA and HSRB. The most recent proposal is expected to be executed in the field in 2011.

In one case EPA and HSRB found the execution of a completed field mosquito repellency test to have been non-compliant with 40 CFR part 26, subparts A–L. This study protocol was subsequently revised and re-executed; the report of the re-executed study was found acceptable by EPA and HSRB.

Reports of all the other ten completed repellent performance studies were found both scientifically and ethically acceptable by EPA and HSRB as first submitted.

ii. *Studies of occupational exposure of pesticide handlers.* All other proposals for new research submitted to EPA since promulgation of the 2006 rule have been for research monitoring exposure of professional pesticide handlers as they mix, load, or apply pesticides in well-defined agricultural and non-agricultural use scenarios. In such research, experienced workers performing their usual tasks are typically monitored at different sites, representing the range of variation in use practices, equipment, and other factors likely to affect exposure. Potential dermal exposure of the workers is measured by analyzing residues in special "long underwear" worn under their normal work clothing, and by rinsing their hands, face and neck. Potential inhalation exposure is measured with a portable air sampler worn in the breathing zone of each worker. This type of research has also long been required by EPA to support its assessments of worker risk.

Five proposals for field monitoring of worker exposure submitted to EPA by an industry consortium were presented to HSRB in June 2006. These proposals were from the Agricultural Handlers Exposure Task Force (AHETF). HSRB review was highly critical, and called for substantially greater information from both the consortium and from EPA concerning the overall design of the research program, the statistical design of the proposed studies, the uses to which the resulting data would be put by EPA, and many other aspects of the proposed research. All five of these proposals were subsequently withdrawn so that HSRB criticisms could be addressed prior to resubmission.

Since that initial review, the overall designs of the umbrella monitoring programs of AHETF and the designs from the Antimicrobial Exposure Assessment Task Force (AEATF II) have been fully documented and presented to HSRB. HSRB continues to review the design of individual monitoring studies, but the soundness of the overall approaches of both the AEATF II and AHETF programs have been established.

Monitoring studies for four antimicrobial exposure scenarios submitted by the AEATF II have been presented to HSRB and approved with suggestions for refinements by both EPA and HSRB. These four scenarios involve common methods of application of antimicrobial pesticide products, including mopping, wiping down surfaces with a pre-soaked ready-to-use wipe, spraying surfaces with a pump spray and wiping them down with a cloth, and spraying surfaces with an aerosol product that does not need to be wiped off. For each scenario, monitoring of workers at three distinctive locations was proposed. After amendment of the protocols consistent with EPA and HSRB recommendations, the first three of these four studies have been executed; the first complete scenario report was submitted to EPA and reviewed by HSRB in October 2010. The remaining reports of completed AEATF II exposure research were submitted to EPA in the fall of 2010, and are scheduled for presentation to HSRB in early 2011.

Monitoring studies for four agricultural exposure scenarios

submitted by the AHETF have been presented to HSRB and approved, again with suggestions for refinements by both EPA and HSRB. These scenarios involve application of liquid pesticides to trellis and orchard crops using "air-blast" spray equipment with closed cabs, application of liquid pesticides using air-blast spray equipment with open cabs, mixing and loading pesticides sold in water-soluble packaging into a wide variety of application equipment, and application of herbicides to rights-of-way. Each of these scenarios calls for monitoring workers in five different regions of the United States, working with different kinds of equipment and crops. The first two of these four studies have been executed; the first complete scenario report was submitted to EPA and reviewed by HSRB in October 2010. Reports of the remaining research scenarios will be submitted to EPA and presented to HSRB in 2011.

D. Legal Challenge to the 2006 Rule

In early 2006, the Natural Resources Defense Council, Inc., Pesticide Action Network North American, Pineros y Campesinos Unido Del Noroeste, Physicians for Social Responsibility—San Francisco, Farm Labor Organizing Committee, ALF–CIO, and Migrant Clinicians Network petitioned for review of the 2006 rule in the United States Court of Appeals for the Second Circuit (Second Circuit Court of Appeals). (*NRDC* v. *EPA,* No. 06–0820-ag (2d Cir.)). The Petitioners argued that the 2006 rule violated the 2006 Appropriations Act because it did not bar all pesticide research with pregnant women and children, was inconsistent with the 2004 NAS Report, and was inconsistent with the Nuremburg Code. The following paragraphs describe the Petitioner's arguments in greater detail.

1. *Inadequate bar against research with pregnant women and children.* Petitioners argued that the scope of the 2006 rule's ban on research with pregnant women and children was unlawfully narrow because it was limited to studies intended for submission to EPA under FIFRA or FFDCA—the pesticide regulatory laws EPA administers. Petitioners argued that Congress's direction to EPA in the Appropriations Act to "not permit the use of pregnant women, infants, or children as subjects" in "intentional dosing human toxicity studies for pesticides" did not allow EPA to distinguish between studies originally intended for publication and those intended for submission to EPA, or between studies with pesticides conducted for consideration under FIFRA or FFDCA and those conducted for consideration under the Safe Drinking Water Act or any other regulatory statute. Petitioners argued that EPA's 2006 rule violated the plain language of the 2006 Appropriations Act on this point.

2. *Inconsistency with the 2004 NAS Report.* The 2006 Appropriations Act required EPA's rule to be consistent with the principles proposed in the 2004 NAS Report. Petitioners argued that in citing the "principles" of the 2004 NAS Report, Congress was referring to the 17 recommendations in that report. Petitioners further argued that the 2006 rule was inconsistent with several specific recommendations in the 2004 NAS Report.

First, Petitioners argued that the 2006 rule did not incorporate Recommendations 3–1 and 5–1 from the 2004 NAS Report, which recommend factors to be considered in the scientific evaluation of human research, including that such studies should have "adequate statistical power" and involve "representative populations for the endpoint in question."

Second, Petitioners argued that the 2006 rule did not incorporate Recommendations 4–1 and 4–2 from the 2004 NAS Report, which suggest ethical considerations relevant to evaluation of human studies.

Third, Petitioners argued that by adding qualifying language to the acceptance standard for pre-rule research suggested in Recommendation 5–7 from the 2004 NAS Report, EPA made it inconsistent with the 2004 NAS Report. Petitioners argued that EPA's addition of the word "significantly" to the recommended acceptance standard, which permits EPA to rely on research not "significantly" deficient relative to prevailing standards, made the criterion in the 2006 rule unlawfully inconsistent with the recommendations in the 2004 NAS Report.

Finally, Petitioners argued that the 2006 rule unlawfully failed to require provision of medical care for study participants, as suggested by Recommendation 5–5 from the 2004 NAS Report.

3. *Inconsistency with the Nuremberg Code.* The 2006 Appropriations Act also required EPA's rule to be consistent with the principles in the Nuremberg Code pertaining to human experimentation. Petitioners argued that the 2006 rule was inconsistent with several principles in the Nuremburg Code.

First, Petitioners argued that although the Nuremberg Code specifies that consent must be given by the human subject, the 2006 rule permits consent to be given in certain situations by a legally authorized representative of the subject.

Second, Petitioners argued that the 2006 rule was inconsistent with the Nuremberg Code principle that a test subject "should have sufficient knowledge and comprehension of the elements of the subject matter involved as to enable him to make an understanding and enlightened decision." Petitioners argued that the 2006 rule consent requirements were inadequate to ensure fully informed consent in the context of research involving pesticides.

Third, Petitioners argued that the 2006 rule failed to address adequately the Nuremberg Code principle that a subject must be "so situated as to be able to exercise free power of choice, without the intervention of any element of force, fraud, deceit, duress, over-reaching, or other ulterior form of constraint or coercion." Petitioners argued that the requirement of the 2006 rule that consent should only be sought in circumstances that "minimize the possibility of coercion or undue influence" did not address the potential for fraud, deceit, over-reaching, or constraint. Petitioners asserted that constraint was a particular problem when prisoners are used as subjects in human studies, and the 2006 rule did not specifically address research with prisoners.

Fourth, Petitioners argued that the 2006 rule was inconsistent with the Nuremberg Code because it did not explicitly impose the Nuremburg Code's requirement that human studies be "designed and based on the results of animal experimentation."

Finally, Petitioners argued that the 2006 rule was inconsistent with the Nuremberg Code principle that human testing "should be such as to yield fruitful results * * * unprocurable by other methods or means of study, and not random and unnecessary in nature." Petitioners argued that the 2006 rule requires no inquiry into whether human testing is necessary given other methods of research.

E. Settlement of the Litigation

After briefing and argument, but before a decision was rendered by the Second Circuit Court of Appeals, EPA and Petitioners began negotiations to settle the litigation. In the settlement agreement finalized on November 3, 2010, EPA agreed to conduct notice-and-comment rulemaking on the issue of whether the 2006 rule should be amended. EPA also agreed to propose, at a minimum, amendments to the 2006 rule that are substantially consistent with language negotiated between the

parties and attached to the settlement agreement as Exhibit A. This agreement, including Exhibit A, is available in the docket for this action as described under **ADDRESSES**.

The settlement agreement further provides that EPA will propose the negotiated amendments no later than January 18, 2011, and that EPA will take final action on the amendments no later than December 18, 2011. The settlement agreement, however, makes clear that EPA retains full discretion concerning what amendments are proposed, and what, if any, amendments are finalized.

Although the wording of the amendments proposed in this document differs in a few details of construction and wording, they are substantially consistent with the regulatory language negotiated with Petitioners, and EPA considers these amendments to address the Petitioners' major arguments outlined in Unit III.D. Specifically:

- The proposed amendments would retain the scope of the 2006 rule to cover research submitted to EPA under FIFRA or FFDCA, and extend that scope to cover as well research involving intentional exposure to a pesticide, intended for submission to EPA under any other regulatory statute administered by EPA.
- The proposed amendments incorporate language from each of the recommendations from the 2004 NAS Report cited by Petitioners in their challenge to the 2006 rule, as well as other pertinent recommendations from the 2004 NAS Report.
- The proposed amendments address Petitioners' arguments concerning the Nuremberg Code by dropping from 40 CFR part 26, subpart K, all provisions for consent by a representative, and by requiring EPA to consider whether subjects gave their "free and fully informed consent" to participate in a study, whether the design of proposed new human research takes into account the knowledge gained in earlier animal testing, and whether proposed new human research is necessary.

Although these proposed amendments emerged from a settlement agreement, EPA believes that proposing these amendments is consistent with the language and purposes of the applicable statutes and because they further the 2006 rule's goal of ensuring that EPA does not rely on research involving intentional exposure of human subjects to pesticides that is not ethically conducted or that is not scientifically sound. EPA believes that many of the changes proposed in this document are codifications of the manner in which EPA and HSRB have interpreted and implemented the 2006 rule, but welcomes comment on these interpretations. EPA will fully re-evaluate the appropriateness of the proposed amendments in light of all comments received in response to this proposed rule before making a final determination. In particular, EPA seeks comment on the relative merits of the proposed changes compared to retaining the current scope and content (*i.e.,* current wording) of the 2006 rule.

IV. Proposed Amendments, Rationale, and Request for Comment

This unit provides a description of each proposed change, the rationale for the proposed change, and the anticipated effects of each change relative to the current regulatory text (*i.e.,* the 2006 rule). EPA specifically requests comment on each of these proposed changes, as well as on the changes in the aggregate. In particular, EPA asks for comment on its conclusions regarding the effect of these proposed changes, including the effect of these proposed changes on the volume of studies covered by the rule, the likely statutes under which studies may be submitted, and the impact on activities covered by those other statutes, relative to the scope of the 2006 rule.

A. Redefining the Scope and Applicability of 40 CFR Part 26, Subparts K, L, M, P, and O

1. *Summary of proposed changes.* EPA is proposing amendments that would modify the scope and applicability of several subparts of the 2006 rule. The proposed changes would modify the criteria defining the types of research covered by 40 CFR part 26, subparts K, L, and M—most notably the criteria relating to the intentions of the sponsor or investigator in conducting the research or the intentions of the person submitting the research to EPA.

The specific changes proposed to the scope and applicability sections of 40 CFR part 26, subparts K, L, M, P, and Q, are explained here. Although EPA does not propose to change the text of the 2006 rule defining the scope of 40 CFR part 26, subpart O, concerning "Administrative Actions for Noncompliance," the scope of that subpart would change nonetheless, because its applicability depends on the scope provisions in other subparts that EPA is proposing to change. More specifically, these changes alter the scope as follows: instead of covering substances under FIFRA, the proposed amendments would cover pesticides under all statutes.

In general, the proposed amendments would shift the focus from whether the research on the substance was intended for EPA's consideration and use under the pesticide laws, FIFRA and FFDCA, to whether the research was conducted with a pesticide and was intended for EPA's consideration and use in connection with an action under any regulatory statute administered by EPA. The proposed amendments also would add a new section to 40 CFR part 26, subpart P, defining its scope and would change the scope and applicability of 40 CFR part 26, subpart Q, to parallel the changes in 40 CFR part 26, subpart K.

2. *Summary of anticipated effects.* Although almost all studies with pesticides are conducted and submitted to EPA for consideration under FIFRA or FFDCA, it is possible that some pesticide studies may be considered by EPA only under other regulatory authorities and not be considered under FIFRA and FFDCA. If studies involving intentional exposure of humans to a pesticide are submitted or considered under other EPA regulatory statutes, with the proposed amendment, such studies would be subject to the same requirements that would have applied had they been submitted or considered under FIFRA or FFDCA. In proposing these amendments, EPA finds that these changes in scope are consistent with the focus in the 2006 Appropriations Act on intentional dosing human toxicity studies with pesticides.

In sum, EPA does not believe that the several changes to the "scope" sections of 40 CFR part 26, subparts K and L—§ 26.1101 and § 26.1201—and a new definition of "pesticide" at § 26.1102(c), that expand the range of human research to which these two subparts apply, will result in a significant increase in the number of studies reviewed under the rule. However, EPA recognizes that this is a possibility and requests comment on whether these proposed changes are clear about which studies would fall under the scope of the rule. EPA knows of no third-party research involving intentional exposure of a human subject to a pesticide that has ever been proposed, conducted, or submitted to EPA under regulatory authorities other than the pesticide laws. The proposed expansion of the scope of these subparts, however, would mean that any such studies that are proposed, conducted, or submitted to EPA will be governed by the same standards as pesticide studies submitted under FIFRA or FFDCA section 408.

3. *40 CFR part 26, subparts K and L—basic ethical requirements and prohibitions applying to third-party research involving intentional exposure of human subjects to a pesticide.*

a. *Current rule.* Subpart K of 40 CFR part 26 extends the basic protections of the Common Rule to subjects in certain third-party human research; subpart L of 40 CFR part 26 forbids new third-party research involving intentional exposure of children or of pregnant or nursing women. In the 2006 rule these two subparts apply to "research with a human subject" which meets four criteria. First, it was initiated after April 7, 2006 (the effective date of the 2006 rule). Second, it is "research involving intentional exposure of a human subject" as defined at § 26.1102(i). Third, it was conducted or supported by a "person" as defined at § 26.1102(j). Fourth, it was intended by any person conducting or supporting the research to be submitted to EPA, or to be held for later inspection by EPA, under the pesticide laws (FIFRA or FFDCA).

The two cited definitions are critical to understanding the scope and applicability of subparts K and L of 40 CFR part 26. "Research involving intentional exposure of a human subject," is defined at § 26.1102(i) as "a study of a substance in which the exposure to the substance experienced by a human subject participating in the study would not have occurred but for the human subject's participation in the study." In applying this definition, EPA considers whether a test subject would have experienced equivalent exposure to a test material had the subject not participated in the research. If not, the research is deemed to involve intentional exposure of the subject. Notably this definition encompasses all classes of test substances—not only pesticides.

A "person" is defined at § 26.1102(j) to have the same meaning as in FIFRA section 2(s) (7 U.S.C. 136(s)), except that it excludes Federal agencies subject to the Common Rule and any person when performing research supported by a Common Rule Federal department or agency. This exclusion is appropriate because that research is covered by the Common Rule, which provides necessary and appropriate protections for the research subjects. Thus, research already covered by the standards of the Common Rule is not also subject to subparts K and L. These subparts, in short, apply only to "third-party research"—research that is neither conducted ("first-party") nor supported ("second-party") by EPA or another Common Rule Federal department or agency.

Finally, § 26.1101(g) explains how EPA will approach determination of the intent of sponsors or investigators to submit research to EPA under the pesticide laws, or hold it for inspection by EPA under the pesticide laws.

b. *Proposed amendments, rationale, and anticipated effect.* The amendments proposed in this document would not change the definitions of "research involving intentional exposure of a human subject" or of "person." They would add a new definition of "pesticide" at § 26.1102(c), and would modify the applicability provisions in § 26.1101, as explained later in this Unit of the document.

The first of the four criteria for application of 40 CFR part 26, subpart K, will change to incorporate the effective date of a final rule amending the 2006 rule. EPA believes it would be inappropriate to apply these proposed amendments retroactively. For example, if post-2006 research newly covered by an amended rule as proposed in this document were submitted to EPA, its acceptability should not be judged by its compliance with a rule promulgated after it was conducted. Until the 2006 rule is amended by a final rule, its provisions continue to apply fully to new research. Hence no sponsor or investigator subject to the 2006 rule would be relieved by the change in the effective date of any obligation to comply with 40 CFR part 26, subparts K and L, for research initiated between April 7, 2006, and the effective date of any subsequent amendments.

The proposal would modify the second of the four criteria so that 40 CFR part 26, subparts K and L, would apply to research involving intentional exposure of a human subject "to a pesticide" when the research is intended for submission to EPA under any regulatory statute other than FIFRA or FFDCA. The definition of "research involving intentional exposure of a human subject" would not change, nor would the applicability of these subparts to all new third-party research involving intentional exposure of human subjects which is intended for submission to EPA under FIFRA or FFDCA.

In determining whether research involves intentional exposure to a pesticide, EPA will focus, as does the FIFRA definition of a "pesticide," on the intended use of the substance. EPA expects that application of this standard will nearly always be straightforward. However, EPA recognizes that there may be cases where making such a determination may not be as straightforward. EPA will apply this criterion as follows.

Initially, EPA will examine the study on its face. If the study states that it involves the testing of a pesticide, or if the tested substance is used for pesticidal effect in the study, as it is in insect repellent efficacy testing or in monitoring exposure of pesticide applicators, there can be little question that the study involves exposure to a pesticide. If on the other hand the study reports testing of another type of substance, such as an industrial chemical, waste product, or air pollutant, then absent compelling evidence to the contrary, EPA will not treat the study as involving exposure to a pesticide.

If it is not clear from the face of the study whether it involves exposure to a pesticide, EPA will look to other objective factors to determine whether a substance is being tested as a pesticide. Intent to test a substance as a pesticide could be indicated by evidence that the testing was conducted or supported by an entity regulated under FIFRA or section 408 of FFDCA; the testing was conducted for the purpose of attaining a FIFRA registration or FFDCA tolerance; there are not significant commercial uses for the substance other than as a pesticide; or human exposure to the substance occurs primarily from its use as a pesticide. Absent any such evidence, EPA will generally treat the study as not involving exposure to a pesticide.

EPA expects that in most cases, the question of whether the study involves exposure to a pesticide will be quickly resolvable without looking to other objective factors such as the four identified in the previous paragraph. EPA believes that this would be true even for multiple-use substances that may be used as a pesticide and may also result in human exposure from other commercial uses or as a result of deposition in the environment as a waste product.

A good example of how EPA will determine if studies on multi-use substances are studies on a pesticide is presented by sulfur dioxide (SO_2)—a registered pesticide active ingredient used as a fungicide in grape culture, and also a common air pollutant. Thousands of tons of SO_2 are released yearly into the atmosphere by burning of coal and other fossil fuels. In promulgating National Ambient Air Quality Standards (NAAQS) for SO_2 under the Clean Air Act (CAA) in 2010, EPA relied on numerous human studies involving intentional exposure of subjects to SO_2. Most of these studies on their face indicate clearly that they tested SO_2 as an industrial air pollutant and not as a pesticide. The few that do not expressly state they tested SO_2 as an air pollutant are, nonetheless, easily classified as not involving exposure to a pesticide, because the testing was not conducted

or sponsored by a pesticide registrant, the studies do not indicate they were performed in support of FIFRA registration, and there are clearly other major sources of human exposure to SO_2 in addition to whatever pesticide exposure occurs. Thus, these studies would not come within the scope of the 2006 rule if the scope is modified as proposed.

EPA specifically requests comment on the implications of this change for the volume of studies that may need to be reviewed under such a proposed amendment.

The amendments proposed in this document would not change the applicability of 40 CFR part 26, subparts K and L, to "persons" or the definition of that term at § 26.1102(j). Thus the third of the four criteria would not be affected by these proposed amendments.

The fourth criterion would be broadened by the amendments proposed in this document beyond the scope of the 2006 rule. The 2006 rule applies to research with any substance, conducted with intent to submit its results to EPA under FIFRA or FFDCA; as proposed here, the rule would apply as well to research with a pesticide, conducted with intent to submit its results to EPA "for consideration in connection with any action that may be performed under any regulatory statute administered by EPA" other than FIFRA or FFDCA.

The new element in this fourth criterion, putting aside the proposed amendment to refer to "pesticides," is the reference to actions taken "under any regulatory statute administered by EPA." Research intended for submission under FIFRA or FFDCA is covered by the 2006 rule and would continue to be covered under proposed § 26.1101(a)(1). Proposed § 26.1101(a)(2) would broaden the scope of subparts K and L of 40 CFR part 26 to apply as well to research involving intentional exposure of a human subject to a pesticide which is intended for submission to EPA for consideration in connection with any action that may be performed under any regulatory statute other than FIFRA or FFDCA. Such submission could be made under CAA, the Safe Drinking Water Act (SDWA), the Clean Water Act (CWA), the Resource Conservation and Recovery Act (RCRA), the Comprehensive Environmental Response, Compensation and Liability Act (CERCLA, or the Superfund law), or other similar statutes. EPA specifically seeks comment on the scope of this proposed change (*i.e.,* the frequency with which it might be triggered, including other statutes to which the proposed change would apply) and the implications of the proposed changes on the activities governed by those other regulations. EPA seeks comment on the relative merits of this change compared to retaining the current scope of the 2006 rule. As noted, EPA does not expect that these wording changes will result in any substantive changes to the number or manner in which studies are currently reviewed.

As an example, EPA's Office of Water has, in the past, set Maximum Contaminant Levels (MCLs) under the SDWA with pesticides found in drinking water. Under the proposed amendment to the scope of 40 CFR part 26, subpart K, any new third-party study involving intentional exposure of a human to a pesticide, and intended for submission to the Office of Water for consideration in setting a MCL, would now be subject to 40 CFR part 26, subpart K, including the requirement of § 26.1125 for submission of the proposal for prior review by EPA and HSRB. EPA would note that this is a theoretical example in that it is unaware of any such study having been submitted with regard to a MCL.

EPA actions not taken under the authority of regulatory statutes would not satisfy this fourth criterion. For example, an EPA comment on another Federal department's or agency's Environmental Impact Statement would not constitute an action taken under a regulatory statute, and research intended for submission solely for consideration in such a context would not be subject to 40 CFR part 26, subparts K and L.

EPA interprets the word "action" in this context broadly, embracing both regulatory and non-regulatory actions. Regulatory actions include, for example, cancellation or registration of a pesticide, establishment of a tolerance for a pesticide residue in food, or establishing a MCL for a pesticide active ingredient under SDWA. Non-regulatory actions include, for example, risk assessments of pesticide active ingredients, recommended (non-binding) safe levels of exposure such as Health Advisory Limits when these pertain to pesticides, or clean-up standards for pesticides at a Superfund site.

The amendments proposed in this document include two additional editorial revisions to clarify the scope sections of 40 CFR part 26, subparts K and L. One change would clarify the applicability of 40 CFR part 26, subpart K, by moving the exposition of how EPA will determine intent to submit from § 26.1101(g), where it appears in the 2006 rule, to § 26.1101(b), immediately following the presentation of the four criteria. The other would amend § 26.1201, the scope section of 40 CFR part 26, subpart L, to state simply that 40 CFR part 26, subpart L applies to all research subject to 40 CFR part 26, subpart K.

4. *40 CFR part 26, subpart M—requirement for documentation of the ethical conduct of completed human research submitted to EPA.*

a. *Current rule.* Subpart M of 40 CFR part 26 requires those who submit the results of human research to EPA for consideration under the pesticide laws to submit information documenting the ethical conduct of the completed research. Under the 2006 rule, 40 CFR part 26, subpart M, applies when a "person" as defined at § 26.1102(j) submits after the effective date of the 2006 rule a report containing the results of any human research to EPA for consideration under the pesticide laws.

These criteria differ from those defining coverage by 40 CFR part 26, subparts K and L, in important ways. First, unlike other subparts of the 2006 rule, subpart M applies to submissions after the effective date of the rule of any and all human research, without regard to who conducted it, when, or for what purpose, or whether or not the reported research involved intentional exposure of a human subject. Second, subpart M applies only when a person (other than a Federal department or agency subject to the Common Rule) submits the results of human research to EPA. Subpart M does not apply when EPA, on its own initiative, retrieves published articles or otherwise obtains information derived from human research.

b. *Proposed amendments and rationale.* EPA proposes to broaden the applicability of 40 CFR part 26, subpart M, by amending § 26.1301, while leaving the substantive requirements of subpart M unchanged. Specifically, EPA proposes to include submissions of reports of human research on pesticides for consideration by EPA under regulatory statutes other than FIFRA or FFDCA. Under the proposed amendments, subpart M would apply when a "person" as defined at § 26.1102(j) submits after the effective date of the amended rule a report containing the results of any human research to EPA for consideration under FIFRA or FFDCA, or a report containing the results of any human research on or with a pesticide for consideration under any other regulatory statute administered by EPA.

The proposed amendments to 40 CFR part 26, subpart M, attempt to balance the need for full information on ethical issues with a concern that the public not be deterred from submitting scientific data relevant to EPA information

requests. Section 26.1303 requires a submitter to provide "information concerning the ethical conduct" of the human research, including copies of relevant IRB records, and copies of records relevant to the key ethical considerations outlined in § 26.1117 and § 26.1125(a). This requirement is qualified by the provision that such records need only be provided "[t]o the extent [the records] are available to the submitter and not previously provided to EPA," but any submitter not providing the information required must "describe the efforts made to obtain the information."

To minimize the potential burden on commenters, EPA considered excluding from the coverage of 40 CFR part 26, subpart M, submissions of published scientific journal articles reporting human research, or of citations to such articles. In some circumstances, however, EPA believes it is important for submitters of even published human research to bear the burden of gathering the information required by § 26.1303. Specifically, EPA believes a submitter of published human research who is seeking action under a regulatory statute from EPA that would directly benefit the submitter should be obliged to gather records bearing on the conduct of the research, even if the research is described in the public literature. For example, an applicant for a pesticide registration or a party petitioning for a pesticide tolerance should have to exercise reasonable efforts to obtain records of the ethical conduct of research relied on to support the EPA action sought, whether or not the research happens to be described in a scientific journal. Reasonable efforts in these circumstances may include seeking relevant records from the research administrator or the overseeing IRB. On the other hand, if a member of the public responds to an EPA request for information on a pesticide by citing or submitting a published study, EPA believes that certification that the submitter did not sponsor, participate in, or otherwise have personal knowledge of or responsibility for the referenced research would satisfy the submitter's obligation under 40 CFR part 26, subpart M.

c. *Anticipated effect.* EPA's concern for the potential burden of 40 CFR part 26, subpart M, on the public is tempered by its experience under the 2006 rule. Since promulgation of the 2006 rule EPA has received very few submissions of reports of human research on or with a pesticide for consideration under FIFRA or FFDCA, and EPA expects submissions of such studies to EPA for consideration only under other regulatory statutes will be even less common.

EPA specifically requests comments on this approach to and interpretation of the requirements in 40 CFR part 26, subpart M. Such comments should address whether the proposed rule language is adequate to implement EPA's interpretation.

5. *40 CFR part 26, subpart P—EPA and HSRB review of proposed and completed human research.*

a. *Current rule.* Subpart P of 40 CFR part 26 applies to EPA and HSRB reviews of proposals for new research involving intentional exposure of a human subject, and EPA and HSRB reviews of reports of completed research involving intentional exposure of a human subject and on which EPA proposes to rely in an action under the pesticide laws. Unlike other subparts of the 2006 rule, subpart P does not include a "scope" section; its applicability is defined only indirectly by references to other subparts.

b. *Proposed amendments and rationale.* EPA proposes to make explicit the applicability of 40 CFR part 26, subpart P, in a new § 26.1601. This proposed new section provides that 40 CFR part 26, subpart P, applies to EPA and HSRB reviews of (1) "proposed research subject to 40 CFR § 26.1125," and (2) "reviews by EPA after [effective date of the amended rule] and, to the extent required by § 26.1604, by the Human Studies Review Board, of reports of completed research subject to 40 CFR 26.1701."

c. *Anticipated effect.* Since 40 CFR 26.1125 is in subpart K and 40 CFR 26.1701 is in subpart Q, the broadened scope of these subparts as proposed in these amendments would indirectly broaden the scope of 40 CFR part 26, subpart P.

6. *40 CFR part 26, subpart Q—ethical standards for assessing whether to rely on the results of human research in EPA actions.*

a. *Current rule.* Subpart Q of 40 CFR part 26 defines ethical standards that must be met for EPA to rely on the results of human research in actions taken under the pesticide laws. Specifically, 40 CFR part 26, subpart Q, applies to EPA decisions to rely on data from completed studies involving intentional exposure of a human subject, when EPA regards the data as scientifically valid and relevant to an action taken under the pesticide laws.

b. *Proposed amendments and rationale.* For the same reasons it is proposing to broaden the applicability of 40 CFR part 26, subpart K (discussed in Unit IV.A.1.), EPA proposes to amend § 26.1701 to broaden the applicability of 40 CFR part 26, subpart Q. Proposed § 26.1701(a) would retain without change the applicability of 40 CFR part 26, subpart Q, to research involving intentional exposure of human subjects to any substance, in the context of EPA actions taken under FIFRA or FFDCA. Proposed § 26.1701(b) would extend the applicability of 40 CFR part 26, subpart Q, to research involving intentional exposure of human subjects to a pesticide, in the context of EPA actions taken under any other regulatory statute administered by EPA.

EPA intends to interpret "action" and "regulatory statute administered by EPA" in 40 CFR part 26, subpart Q, just as these terms would be interpreted for 40 CFR part 26, subpart K. To make this scope provision consistent with the other scope provisions in this proposal, EPA proposes to depart from the language negotiated in the settlement agreement and define the scope of 40 CFR part 26, subpart Q, in terms of the "research" covered rather than the "decisions" covered.

c. *Anticipated effect.* EPA expects this change in the scope of 40 CFR part 26, subpart Q, to affect few, if any, EPA actions. Although such actions may occur in the future, EPA cannot identify any actions taken since 2006 under any regulatory statute other than FIFRA or FFDCA that relied on research involving intentional exposure of a human subject to a pesticide.

As explained previously, EPA is authorized to propose this change because it is consistent with the 2006 Appropriations Act. This proposal would mean that all intentional human studies involving pesticides submitted to EPA would be reviewed under the same ethical and scientific criteria. On the other hand, EPA has also noted that it expects this change will affect few additional studies and may create some uncertainty as to what studies are covered by the rule.

EPA specifically invites comment on the value of making this change and whether there are additional factors to be considered in evaluating the appropriateness of the change, such as the frequency with which it might be triggered, including other statutes to which the proposed change would apply, and on the clarity of the proposed changes.

B. Disallowing Consent by a Surrogate (40 CFR Part 26, Subpart K)

1. *Current rule.* In the 2004 NAS Report to EPA, the NAS recommended use of the Common Rule as the starting point for protecting human subjects in research involving intentional exposure. Consistent with this recommendation,

EPA incorporated much of the text of the Common Rule into subpart K of 40 CFR part 26, including language providing for consent for a subject's participation in research by the subject's "legally authorized representative" when the subject lacks the capacity to consent for himself or herself. The Common Rule, drafted to protect subjects in a wide variety of research settings, included these provisions to permit research in various situations, including, for example, research into emergency procedures to save lives of unconscious patients, into improved care for people suffering psychosis or schizophrenia, and to collect valuable data from research with other subjects who lacked the legal capacity to provide fully informed, fully voluntary consent.

2. *Proposed amendments and rationale.* EPA proposes to amend 40 CFR part 26 by deleting from subpart K all references permitting consent by a subject's legally authorized representative. The sections affected are the definition of "legally authorized representative" at § 26.1102(c); the "Criteria for IRB approval of research" at § 26.1111; the "General requirements for informed consent" at § 26.1116; and the requirements for "Documentation of informed consent" at § 26.1117.

EPA proposes to disallow consent by a representative in third-party studies because the types of research that are conducted on pesticides would not use subjects for whom such a procedure is needed. (The research covered by 40 CFR part 26, subpart K includes research involving intentional exposure of non-pregnant, non-nursing adults to a pesticide or research involving intentional exposure of non-pregnant, non-nursing adults intended for submission under FIFRA or FFDCA.)

3. *Anticipated effect.* EPA has never seen, and cannot envision, any such research in which it could be justified to enroll subjects lacking the capacity to consent for themselves. EPA does not propose to modify the provisions of 40 CFR part 26, subpart A, EPA's codification of the Common Rule. 40 CFR part 26, subpart A, applies to a much broader range of research with human subjects conducted or supported by EPA including research for which consent by a legally authorized representative may be appropriate.

C. Revised Standards for EPA and HSRB Reviews (40 CFR Part 26, Subpart P)

1. *Current rule.* 40 CFR part 26, subpart P, defines in largely procedural terms how EPA evaluates proposals for new research submitted under § 26.1125 of 40 CFR part 26, subpart K, and how EPA is to review reports of completed research. Subpart P of 40 CFR part 26 also defines the membership and responsibilities of HSRB.

2. *Proposed amendments and rationale.*

a. *Revisions to 40 CFR part 26, subpart P, generally.* The proposed amendments to 40 CFR part 26, subpart P, include:

- A proposed new § 26.1601 explicitly defining the applicability of 40 CFR part 26, subpart P, to EPA and HSRB reviews of proposals for new research submitted under § 26.1125 of subpart K and to EPA and HSRB reviews of reports of completed research covered by subpart Q. This change is discussed in Unit IV.A.3.
- A proposed new § 26.1602 references the definitions in 40 CFR part 26, subpart K.
- A proposal to expand the discussion of EPA reviews of proposed research in § 26.1603, retaining all elements of § 26.1601 from the 2006 rule, and including a new § 26.1603(b) listing considerations to be addressed by EPA in its science reviews of proposed research, and a new § 26.1603(c) listing considerations to be addressed by EPA in its ethics reviews of proposed research.
- A proposal to slightly revise discussion of EPA reviews of completed research, redesignating § 26.1602 in 40 CFR part 26 as § 26.1604, and revising paragraph (a) to emphasize the required thoroughness of EPA's reviews and to extend its applicability to reviews of completed human research on pesticides considered under regulatory statutes other than FIFRA or FFDCA.
- The unchanged text of § 26.1603 in the 2006 rule would be redesignated as § 26.1605, defining the membership and responsibilities of HSRB.
- A proposed new § 26.1606 requiring HSRB in its reviews of proposed research to consider the same range of scientific, ethical, and other topics addressed by EPA in its reviews under § 26.1603.
- A proposed new § 26.1607 requiring HSRB in its reviews of completed research to consider both the scientific and ethical merits of the research, and to apply the appropriate acceptance standards in 40 CFR part 26, subpart Q.

As indicated previously and again throughout this discussion, EPA requests comment on each of these proposed changes, as well as on the changes in the aggregate. EPA also seeks comments on particular points as provided in the discussion.

b. *Section 26.1603—EPA Review of proposed human research.* Because the most significant changes proposed are the new lists in § 26.1603(b) and (c) of considerations to be addressed in EPA reviews of proposed new research, those proposed changes will be discussed in greater detail here. These proposed lists were derived primarily from the following recommendations in the 2004 NAS Report (reproduced verbatim here and referenced in the subsequent discussions):

Recommendation 3–1: Scientific Validity of Intentional Human Dosing Studies

EPA should issue guidelines for determining whether intentional human dosing studies have been:

a. Justified, in advance of being conducted, as needed and as scientifically appropriate, in that they could contribute to addressing an important scientific or policy question that cannot be resolved on the basis of animal data or human observational data;

b. Designed in accordance with current scientific standards and practices to (i) address the research question, (ii) include representative study populations for the endpoint in question, and (iii) meet requirements for adequate statistical power;

c. Conducted in accordance with recognized good clinical practices, including appropriate monitoring for safety; and

d. Reported comprehensively to EPA, including the full study protocol, all data produced in the study (including adverse events), and detailed analyses of the data.

Recommendation 4–1: Value of Studies That Seek to Improve the Accuracy of EPA's Decisions But Do Not Provide a Public Health or Environmental Benefit

EPA should consider a human dosing study intended to reduce the interspecies uncertainty factor (for example, a study of a biomarker such as cholinesterase inhibition) as conferring a societal benefit only if it was designed and conducted in a manner that would improve the scientific accuracy of EPA's extrapolation from animal to human data. Because the anticipated benefit would not be as great as that conferred by studies intended to provide a public health or environmental benefit, the study could be justified ethically only if the participants' exposure to the pesticide could reliably be anticipated to pose no identifiable risk or present a reasonable certainty of no harm to study participants.

Recommendation 5–1: Criteria for Scientific and Ethical Acceptability

Studies that do not meet the highest scientific and ethical standards should not be carried out or accepted by EPA as input to the regulatory decision-making process. Necessary conditions for scientifically and ethically acceptable intentional human dosing studies include:

a. Prior animal studies and, if available, human observational studies;

b. A demonstrated need for the knowledge to be obtained from intentional human dosing studies;

c. Justification and documentation of a research design and statistical analysis that are adequate to address an important scientific or policy question, including adequate power to detect appropriate effects;

d. An acceptable balance of risks and benefits and minimization of risks to participants;

e. Equitable selection of participants;

f. Free and informed consent of participants; and

g. Review by an appropriately constituted IRB or its foreign equivalent.

Recommendation 5–2: Participant Selection Criteria

IRBs reviewing intentional human dosing studies should ensure that the following conditions are met in selecting research participants:

a. Selection should be equitable.

b. Selection of persons from vulnerable populations must be convincingly justified in the protocol, which also must justify the measures to be taken to protect those participants.

c. Selection of individuals with conditions that put them at increased risk for adverse effects in such studies must be convincingly justified in the protocol, which also must justify the measures that investigators will use to decrease the risks to those participants to an acceptable level.

Recommendation 5–3: Payment for Participation

IRBs, all relevant review boards, investigators, and research sponsors should ensure that payments to participants in intentional human dosing studies are neither so high as to constitute undue inducement nor so low as to be attractive only to individuals who are socioeconomically disadvantaged. Proposed levels of and purposes for remuneration (*e.g.,* time, inconvenience, and risk) should be scrutinized in light of the principles of justice and respect for persons. Moreover, EPA, in conjunction with other Federal agencies, should consider developing further guidance on remuneration for participation in intentional human dosing studies, including guidance regarding whether remuneration should reflect the level of risk as well as the time and inconvenience involved.

Recommendation 5–5: Compensation for Research-Related Injuries

At a minimum, sponsors of or institutions conducting intentional human dosing studies should ensure that participants receive needed medical care for injuries incurred in the study, without cost to the participants. In addition, EPA should study whether broader compensation for research-related injuries should be required.

Recommendation 6–1: IRB Review of All Studies

EPA should require that all human research conducted for regulatory purposes be approved in advance by an appropriately constituted IRB or an acceptable foreign equivalent. Research conducted by EPA scientists should be reviewed by an EPA-authorized IRB.

[Taken from pages 7–14 of the 2004 NAS Report (*http://www.national-academies.org*).]

c. *Science Reviews—§ 26.1603(b).* The provisions in proposed § 26.1603(b) include considerations that EPA must take into account when conducting its science reviews of proposed research that would be covered by the rule. In developing this list of considerations, EPA relied on recommendations 3–1 and 5–1 from the 2004 NAS Report to identify specific items that would be relevant to evaluating the scientific merit of proposed human research. How EPA developed the specific language for each provision follows.

• *Proposed § 26.1603(b)(1): Whether the research would be likely to produce data that address an important scientific or policy question that cannot be resolved on the basis of animal data or human observational research.*

This language is a combination of recommendations 3–1(a) and 5–1(b) and (c) from the 2004 NAS Report (*see* verbatim text provided in Unit IV.C.2.b.). The language "address an important scientific or policy question" reflects excerpts taken from recommendation 5–1(c). The language "that cannot be resolved on the basis of animal data or human observation research" is taken from recommendation 3–1(a). These recommendations are intended to avoid unnecessary exposure for human subjects. If animal data or human observational research were available to address an important scientific or policy question, then there would be no scientific need for additional human research. EPA relied primarily on recommendation 5–1 in formulating the proposed language because that recommendation addresses criteria for EPA acceptance of human research, whereas recommendation 3–1describes topics that should be covered in EPA guidelines.

Based on recommendation 5–1, EPA has phrased the proposed language as whether the research "addresses" an important scientific question rather than use the phraseology "contributes to addressing" in recommendation 3–1. The Agency believes its formulation is clearer and intends to interpret this as meaning that the research needs to be designed to obtain data likely to provide significant insight into important research questions.

EPA requests comment on whether its reliance primarily on the language of recommendation 5–1(c) is appropriate here, or whether it should have used the "contributes to" language from recommendation 3–1(a).

• *Proposed § 26.1603(b)(2): Whether the proposed research is designed in accordance with current scientific standards and practices to: Address the research question, include representative study populations for the endpoint in question, and have adequate statistical power to detect appropriate effects.*

Again, this language is a combination of recommendations 3–1(b) and 5–1(c) from the 2004 NAS Report (*see* verbatim text provided in Unit IV.C.2.b.). The recommendations highlight the need for adequate statistical power and appropriate representative study populations to ensure the scientific validity and reliability (and thus ethical conduct) of human research. To accommodate these recommendations, EPA is proposing to adopt language from the recommendations 3–1(b) and 5–1(c).

For the reason stated in the previous discussion on proposed § 26.1603(b)(1), EPA placed primary reliance on recommendation 5–1. The Agency notes that the proposed § 26.1603(b)(2)(iii), which reflects the language in 5–1(c), differs from the language in 3–1(b), which says "meets requirements for adequate statistical power." The Agency prefers to propose the language as contained in 5–1(c) because it does not believe that there is one specific set of "requirements" with which to evaluate statistical power. The Agency intends to evaluate the statistical power of a study while focusing on the ultimate goal of ensuring that appropriate effects are detected rather than on some arbitrary and undefined set of "requirements."

EPA requests comment on whether the proposed language is clear and specifically on this language as compared to using the language directly from the recommendation in the 2004 NAS Report.

• *Proposed § 26.1603(b)(3): Whether the investigator proposes to conduct the research in accordance with recognized good research practices, including, when appropriate, good clinical practice guidelines and monitoring for the safety of subjects.*

This provision reflects excerpts taken from recommendation 3–1(c) from the 2004 NAS Report (*see* verbatim text provided in Unit IV.C.2.b.). Although the NAS focused on good clinical practice guidelines, the Agency is proposing to apply a broader standard "recognized good research practices", which may include good clinical practice guidelines when appropriate. The rationale for this is that some human research—in fact, all human research proposed to EPA to be conducted since promulgation of the 2006 rule—is not conducted in clinical settings (*e.g.,* field testing of repellents or worker exposure) and thus good clinical practice guidelines would be inappropriate to apply. However, there may be other general good research practices that the research community

employs to ensure scientific integrity of their studies and safety of the subjects that would be relevant for the Agency to consider. One such practice that has currently been developed is the Guidelines for Performance Testing of Skin-Applied Insect Repellent issued in October 2008, and incorporated into the OCSPP harmonized test guidelines library in July 2010, entitled "Product Performance Test Guidelines No. 810.3700: Insect Repellents to be Applied to Human Skin" (*http://www.epa.gov/ocspp/pubs/frs/publications/Test_Guidelines/series810.htm*).

EPA requests comment on this expansion and also welcomes suggestions for other good research practice documents that could be cited here as well.

d. *Ethics Reviews—§ 26.1603(c).* The provisions in proposed § 26.1603(c) address many important ethical concerns, including, among other things, identification and minimization of risks to participants, equitable selection of participants, and provision of medical care for participants. In developing this list of considerations, EPA relied on several recommendations from the 2004 NAS Report, including 4–1, 5–1, 5–2, 5–3, and 5–5 (*see* verbatim text provided in Unit IV.C.2.b.), to identify specific considerations that would be relevant to evaluating the ethics of proposed human research. Each proposed consideration is discussed below.

• *Proposed § 26.1603(c)(1): Whether adequate information is available from prior animal studies or from other sources to assess the potential risks to subjects in the proposed research.*

This provision reflects excerpts taken from recommendation 5–1(a) from the 2004 NAS Report (*see* verbatim text provided in Unit IV.C.2.b.), which recommends that animal studies be available prior to conducting human studies. This NAS recommendation also suggests consideration of human observational studies if available. When EPA conducts its ethics reviews, it does and will continue to consider whether there is adequate information from prior animal and human observational studies to understand the level of risk that may be presented to subjects of the proposed research. Although the NAS does not specify in its recommendation the specific purpose that the information from prior animal studies or from other sources, including human observational studies if available, serves, EPA believes its use of these studies to assess potential risks in evaluating the ethics of a human research proposal subject to this rule is reasonable and an integral part of determining whether the benefits of the research outweigh the risks of the research. The proposed language refers to "information * * * from prior animal studies or from other sources." EPA intends the reference to "other sources" to include human observational studies, consistent with recommendation 5–1.

EPA requests comment on whether the proposed language is clear and specifically on this language as compared to using the language directly from the recommendation in the 2004 NAS Report.

• *Proposed § 26.1603(c)(2): Whether the research proposal adequately identifies anticipated risks to human subjects and their likelihood of occurrence, minimizes identified risks to human subjects, and identifies likely benefits of the research and their distribution.*

This provision is based on recommendation 5–1(d) from the 2004 NAS Report (*see* verbatim text provided in Unit IV.C.2.b.), which states that the necessary conditions for human research include "an acceptable balance of risks and benefits and minimization of risks to participants." EPA has separated these two conditions and addresses minimization of risk in this paragraph and the balance of risks and benefits in proposed § 26.1603(c)(3). In this paragraph, EPA also proposes to include a consideration of whether the research proposal adequately identifies anticipated risks to human subjects and their likelihood of occurrence and the likely benefits of the research and their distribution. These additional considerations are important in understanding the overall risk/benefit picture of proposed human research covered by this rule. EPA does not believe that adding these considerations will impose any additional burden on stakeholders since this information is typically provided with research proposals that are submitted to IRBs and to the Agency. EPA currently reviews human research proposals submitted to it under the 2006 rule with these considerations in mind.

EPA requests comment on whether it is appropriate to address minimization of risk and the risk-benefit balance in separate paragraphs. EPA has chosen this approach because it interprets recommendation 5–1(d) as setting forth separate and independent considerations and, given this interpretation, believes that repeating the risk-benefit balance language in this paragraph would be duplicative and confusing. EPA also recognizes an alternative view of recommendation 5–1(d) is that separating the minimization of risk consideration from the risk-benefit balance consideration alters the collective context intended by recommendation 5–1(d) of the 2004 NAS Report. As such, EPA requests comments on both approaches as they apply to the proposed §§ 26.1603(c)(2) and 26.1603(c)(3).

• *Proposed § 26.1603(c)(3): Whether the proposed research presents an acceptable balance of risks and benefits. In making this determination for research intended to reduce the interspecies uncertainty factor in a pesticide risk assessment, the Administrator must consider Recommendation 4–1 in the 2004 Report from the National Research Council of the National Academy of Sciences (NAS), entitled "Intentional Human Dosing Studies for EPA Regulatory Purposes: Scientific and Ethical Issues."*

This provision reflects excerpts taken from recommendations 5–1(d) and 4–1 from the 2004 NAS Report (*see* verbatim text provided in Unit IV.C.2.b.). For each human research proposal submitted to the Agency that is covered by this rule, in addition to considering whether a study proposal minimizes risks to the human subjects, EPA is proposing to consider whether the proposed research presents an acceptable balance of risks and benefits based on, among other things, the information it considers under the proposed paragraphs (c)(1) and (c)(2) in § 26.1603.

Recommendation 5–1(d) also refers to "the minimization of risks to participants." EPA addressed that consideration in proposed § 26.1603(c)(2). The Agency requests comment on whether another reference to minimization of risk is nonetheless needed in this paragraph for consistency with the 2004 NAS Report.

For research that is intended specifically to reduce the interspecies uncertainty factor in a pesticide risk assessment, the Agency is proposing to consider whether that study presents an acceptable balance of risks and benefits in accordance with process laid out for evaluating that type of study in recommendation 4–1 and the attendant discussion in the 2004 NAS report that informs the application of that recommendation. EPA lacks experience in reviewing proposals for research intended to reduce the interspecies uncertainty factor. Since the promulgation of the 2006 rule, EPA has received no proposals for such research and, as noted in Unit IV.A.2. and A.3., EPA knows of no third-party research involving intentional exposure of a human subject to a pesticide that has ever been proposed, conducted, or

submitted to EPA under regulatory authorities other than the pesticide laws. However, EPA recognizes that this is a possibility in the future.

The Agency asks for comment on how it should consider NAS recommendation 4–1, if this proposed amendment were finalized and EPA received a study proposal for that purpose, and, given the context of the proposed expansion to the scope of the 2006 rule as discussed in Unit IV.A., whether the proposed § 26.1603(c)(3) is clear about how NAS recommendation 4–1 might apply to future studies.

• *Proposed § 26.1603(c)(4): Whether subject selection will be equitable.*

This provision is taken directly from recommendations 5–1(e) and 5–2(a) from the 2004 NAS Report (*see* verbatim text provided in Unit IV.C.2.b.).

• *Proposed § 26.1603(c)(5): Whether subjects' participation would follow free and fully informed consent.*

This provision reflects excerpts taken from recommendations 5–1(f) from the 2004 NAS Report (*see* verbatim text provided in Unit IV.C.2.b.), which mentions free and informed consent, and the Nuremberg Code.[2]

Key aspects or indicators of free and fully informed consent or legally effective consent are set out in detail in § 26.1116. They include that information be provided in a form understandable to the subject, including information on the purposes and duration of the research as well as on the procedures, risks, and any compensation involved in the research. Further, the subject must be made aware that participation in the research is voluntary, that there is no penalty for not participating, and that the subject may withdraw from the research at any time. The reference in § 26.1603(c)(5) to "free and fully informed consent" emphasizes the centrality of this concept to the ethics evaluation process.

• *Proposed § 26.1603(c)(6): Whether an appropriately constituted Institutional Review Board or its foreign equivalent has approved the proposed research.*

This provision reflects excerpts taken from recommendations 5–1(g) and 6–1 from the 2004 NAS Report (*see* verbatim text provided in Unit IV.C.2.b.). Section 26.1125 already requires third-parties covered by the 2006 rule to obtain IRB approval before submitting proposals to EPA under subpart P, and section 26.1601(c) of the current rule allows the Agency to consider whether foreign proposed research has undergone equivalent protective procedures.

• *Proposed § 26.1603(c)(7): If any person from a vulnerable population may become a subject in the proposed research, whether there is a convincing justification for selection of such a person, and whether measures taken to protect such human subjects are adequate.*

This provision reflects excerpts taken from recommendation 5–2(b) from the 2004 NAS Report (*see* verbatim text provided in Unit IV.C.2.b.). EPA recognizes that some individuals who may become subjects in human research may be more vulnerable to coercion or undue influence, for example, prisoners, persons with mental disabilities, or economically or educationally disadvantaged persons. As such, for proposals in which such individuals may become a subject of the research, EPA is proposing to consider whether the proposal contains a convincing justification for the selection of those persons as well as whether any measures taken to protect those persons are adequate. The specific language of recommendation 5–2(b) states that "IRBs * * * should ensure that the following conditions met in selecting research participants * * * (b) Selection of persons from vulnerable populations must be convincingly justified in the protocol, which also must justify the measures to be taken to protect the participants." In drafting this provision EPA rephrased recommendation 5–2(b) to convert it to regulatory language. In doing so, EPA first made this provision conditional (the "if" clause) because EPA does not expect that vulnerable populations will often be included in human research and there is no reason to impose a burden on researchers to justify a situation when it is inapplicable. EPA also substituted the requirement that measures taken to protect such human subjects be "adequate" instead of requiring a "convincing justification" for them.

EPA requests comment on whether the proposed language is clear and specifically on this language as compared to using the language directly from recommendation 5–2(b) in the 2004 NAS Report.

• *Proposed § 26.1603(c)(8): If any person with a condition that would put them at increased risk for adverse effects may become a subject in the proposed research, whether there is a convincing justification for selection of such a person, and whether measures taken to protect such human subjects are adequate.*

This provision reflects excerpts taken from recommendation 5–2(c) from the 2004 NAS Report (*see* verbatim text provided in Unit IV.C.2.b.). Although EPA anticipates that persons with conditions that put them at increased risk for adverse effects would likely be screened from participating in human research subject to this rule, there may be circumstances when an exception is warranted. In those instances where such persons may become subjects in research covered by this rule, EPA is proposing to consider whether the research contains a convincing justification for the selection of those persons as well as whether any measures taken to protect those persons are adequate to decrease risks to an acceptable level. The specific language of recommendation 5–2(b) states that "IRBs * * * should ensure that the following conditions met in selecting research participants * * * (c) Selection of individuals with conditions that put them at increased risk for adverse effects in such studies must be convincingly justified in the protocol, which also must justify the measures that investigators will use to decrease the risks to those participants to an acceptable level." For this provision, EPA followed a similar path in converting the NAS recommendation into regulatory language as it did with proposed § 26.1603(c)(7), *i.e.,* EPA made the provision conditional and used an adequacy test rather than a convincing justification as to evaluating the measures to protect the subjects.

EPA requests comment on whether the proposed language is clear and specifically on this language as compared to using the language directly from recommendation 5–2(c) in the 2004 NAS Report.

• *Proposed § 26.1603(c)(9): Whether any proposed payments to subjects are consistent with the principles of justice and respect for persons, and whether they are so high as to constitute undue inducement or so low as to be attractive only to individuals who are socioeconomically disadvantaged.*

This provision reflects excerpts taken from recommendation 5–3 from the 2004 NAS Report (*see* verbatim text provided in Unit IV.C.2.b.). Although this provision overlaps slightly with proposed §§ 26.1603(c)(4) and § 26.1603(c)(7), EPA is proposing to enumerate a specific consideration for whether the level of remuneration for

[2] The Nuremburg Code states the importance of free and fully informed consent and describes the elements of such consent: "The voluntary consent of the human subject is absolutely essential. This means that the person involved should have legal capacity to give consent; should be so situated as to be able to exercise free power of choice, without the intervention of any element of force, fraud, deceit, duress, over-reaching, or other ulterior form of constraint or coercion; and should have sufficient knowledge and comprehension of the elements of the subject matter involved as to enable him to make an understanding and enlightened decision * * *" *http://ohsr.od.nih.gov/guidelines/nuremberg.html.*

participation in any proposal for human research covered by this rule is appropriate, *i.e.,* consistent with the principles of justice and respect for persons, and whether it is likely to induce participation from individuals from vulnerable populations and affect the equitable selection of subjects. In converting the affirmative statement in recommendation 5–3 into a "whether" statement for regulatory language, EPA dropped the recommendation's "neither—nor" phrasing because it is potentially confusing. EPA believes that, as drafted, this provision requires consideration of whether payments are either too high or too low but requests comment on this point.

EPA requests comment on whether the proposed language is clear and specifically on this language as compared to using the language directly from recommendation 5–3 in the 2004 NAS Report.

• *Proposed § 26.1603(c)(10): Whether the sponsor or investigator would provide needed medical care for injuries incurred in the proposed research, without cost to the human subjects.*

This provision reflects excerpts taken from recommendation 5–5 from the 2004 NAS Report (*see* verbatim text provided in Unit IV.C.2.b.). EPA is proposing to consider in its ethics review of proposed human research subject to this rule whether medical care resulting from participation in the research will be provided without cost to the human subjects.

As noted throughout this section, EPA requests comment on whether the provisions of proposed § 26.1603 are consistent with the recommendations from the 2004 NAS Report and whether the regulatory language chosen by EPA adequately captures EPA's intended goal and is otherwise clear and easily understood.

D. Revised Acceptance Standards for Completed Research (40 CFR part 26, subpart Q)

1. Overview

a. *Current rule.* 40 CFR part 26, subpart Q, establishes standards governing reliance by EPA under the pesticide laws on "scientifically valid and relevant data from research involving intentional exposure of human subjects." Section 26.1703 forbids EPA to rely on any research involving intentional exposure of a subject who was a pregnant woman, a nursing woman, or a child. Section 26.1704 forbids EPA to rely on research initiated before the effective date of the 2006 rule in the face of clear and convincing evidence that "the conduct of the research was fundamentally unethical (*e.g.,* the research was intended to seriously harm participants or failed to obtain informed consent), or was significantly deficient relative to the ethical standards prevailing at the time the research was conducted." Section 26.1705 forbids EPA to rely on research initiated after the effective date of the 2006 rule unless EPA has "adequate information to determine that the research was conducted in substantial compliance with subparts A through L * * *" Section 26.1706 permits EPA to rely on the results of human research unacceptable under the standards of §§ 26.1703–26.1705 only if EPA determines, after public notice and comment and consultation with HSRB, that reliance on the research is necessary to support "a more stringent regulatory restriction that would improve protection of public health * * * than could be justified without relying on the data." The Agency is not proposing to amend the substance of § 26.1706.

b. *Summary of proposed changes.* In addition to broadening the scope of 40 CFR part 26, subpart Q, to apply to research relied on by EPA under regulatory statutes other than FIFRA or FFDCA, EPA proposes to amend the substantive standards in §§ 26.1703, 26.1704, and 26.1705 for determining the acceptability of completed research involving intentional exposure of a human subject to a pesticide. As noted throughout this document, EPA requests comment on each of these proposed changes, as well as on the changes in the aggregate. In particular, EPA seeks comment on its conclusions regarding the effect of these proposed changes relative to the scope of the 2006 rule, including the effect of these proposed changes on the volume of studies covered by the rule, the likely statutes under which studies may be submitted, and the impact on activities covered by those other statutes.

c. *Anticipated effects.* If a covered study does not meet the applicable standards in 40 CFR part 26, subpart Q, EPA would be prohibited from relying on the data in any action it takes under any of its regulatory authorities except under the extremely restrictive conditions defined in § 26.1706.

2. § 26.1703: Standards Applicable to all Covered Research

a. *Proposed changes and rationale.* Consistent with the changes proposed in 40 CFR part 26, subpart P, and discussed in Unit IV.C., EPA proposes to add in § 26.1703(a) an explicit prohibition against reliance on data from completed research "unless EPA determines that the data are relevant to a scientific or policy question important for EPA decision-making, that the data were derived in a manner that makes them scientifically valid and reliable, and that it is appropriate to use the data for the purpose proposed by EPA."

In making this determination, EPA would be required to assess these four aspects of the research:

• Whether the research was designed and conducted according to "appropriate scientific standards and practices prevailing at the time the research was conducted."

• The extent to which the test subjects represent the population whose response the data will be used to predict.

• The statistical power of the data to support the scientific conclusions drawn by EPA.

• Whether, in a study that reports a No Observed Effect Level (NOEL) or a No Observed Adverse Effect Level (NOAEL), some dose level elicited a biological effect.

These four aspects of the research are derived from Recommendations 3–1 and 5–1 from the 2004 NAS Report. They do not establish fixed criteria for acceptance or rejection of a study, but they identify specific aspects of a study that EPA must consider in determining that it is relevant, scientifically valid and reliable, and appropriate for a particular use.

b. *Anticipated effect.* As noted previously, 40 CFR part 26, subpart Q, applies to EPA decisions to rely on "scientifically valid and relevant data" from covered research. Since 2006, EPA's practice in reviewing reports of covered human research has been to examine carefully the scientific merit of the reported studies and to refuse to use research deemed invalid or irrelevant. EPA proposes to delete these factors from the scope of 40 CFR part 26, subpart Q, as defined in § 26.1701, and to codify them as factors in § 26.1703(a) to ensure that they remain central to determinations of scientific validity and relevance. If this proposed amendment is finalized, EPA would likely make minor revisions to its internal review procedures to highlight the consideration given to these four aspects of the research.

3. § 26.1704: Acceptance Standards for Research not Subject to § 26.1705

a. *Proposed changes and rationale.* The Agency based the ethical acceptability standard in § 26.1704 on Recommendation 5–7 from the 2004 NAS Report, which states in relevant part:

EPA should accept scientifically valid studies conducted before its new rules are implemented unless there is clear and convincing evidence that the conduct of those studies was fundamentally unethical (*e.g.,* the studies were intended to seriously harm participants or failed to obtain informed consent) or that the conduct was deficient relative to then-prevailing standards.

Section 26.1704 provides in relevant part (emphasis added):

* * * EPA shall not rely on data from any research initiated before [the effective date of the 2006 rule], if there is clear and convincing evidence that the conduct of the research was fundamentally unethical (*e.g.,* the research was intended to seriously harm participants or failed to obtain informed consent), or was *significantly* deficient relative to the ethical standards prevailing at the time the research was conducted.

EPA adopted the recommendation from the 2004 NAS Report nearly verbatim, with the notable insertion of the word "significantly" before "deficient." EPA explained in the preamble to the 2006 rule (at 71 FR 6161) that this was to allow it the flexibility to consider the impact on subjects of any ethical shortcomings in the conduct of the research. EPA stated in that preamble (at 71 FR 6161) that "EPA expects [the meaning of "significantly"] to acquire greater clarity over time, through HSRB and public review of Agency decisions concerning reliance on completed human research."

EPA believes that greater clarity has, indeed, been achieved through the application of the 2006 rule by EPA and HSRB. EPA now proposes to revise § 26.1704 by deleting the word "significantly," proposing instead to characterize explicitly the kinds of deficiencies that would make a study unacceptable.

This language is derived from the advice of HSRB as they have applied the standard of § 26.1704 in the 2006 rule. *See,* for example, their comments on studies involving aldicarb, methomyl, oxamyl, azinphos-methyl, DDVP, ethephon, sodium cyanide, and amitraz at: *http://www.epa.gov/osa/hsrb/files/meeting-materials/apr-4-6-2006-public-meeting/april2006mtgfinalreport62606.pdf.* For each study they found ethically acceptable, HSRB found "no evidence of significant deficiencies in the ethical procedures that could have resulted in serious harm (based on the knowledge available at the time the study was conducted) nor that information provided to participants seriously impaired their informed consent."

Finally, EPA proposes to redefine the applicability of § 26.1704 in a new paragraph (a) as the complement of the more detailed scope of § 26.1705, thereby eliminating any gaps or overlap in the applicability of the two standards.

b. *Anticipated effect.* Proposed § 26.1704 would forbid EPA to rely on research not covered by 40 CFR part 26, subpart K, or the Common Rule in the face of clear and convincing evidence that its conduct "placed participants at increased risk of harm (based on knowledge available at the time the study was conducted) or impaired their informed consent." EPA specifically requests comment on the incremental value of this change as well as the extent to which this change might inappropriately reduce EPA's access to human research.

4. § 26.1705: Standards for Completed Research Conducted Under 40 CFR Part 26 or Another Codification of the Common Rule

a. *Proposed changes and rationale.* The standard in 40 CFR part 26 applying to completed research initiated after the effective date of the rule is § 26.1705, based on Recommendation 5–6 from the 2004 NAS Report, which states in relevant part (italics in the original; footnote omitted):

EPA should operate on the strong presumption that data obtained in studies conducted *after* implementation of the new rules that do not meet the ethical standards described in this report will not be considered in its regulatory decisions.

EPA adapted this recommendation in its drafting of § 26.1705, which provides in relevant part:

EPA shall not rely on data from any research initiated after [the effective date of the 2006 rule] unless EPA has adequate information to determine that the research was conducted in substantial compliance with subparts A through L of this part, or if conducted in a foreign country, under procedures at least as protective as those in subparts A through L of this part.

EPA now proposes to amend both the applicability of § 26.1705 and the substance of the standard itself. In the 2006 rule, § 26.1705 applies to any scientifically valid and relevant research involving intentional exposure of human subjects and initiated after the effective date of the rule. EPA proposes now to limit application of the § 26.1705 standard to research subject, at the time it was conducted, either to subparts A through L of 40 CFR part 26 or to another Federal department or agency's codification of the Common Rule.

EPA recognizes that it could in the future wish to rely on data from third-party research conducted after 2006 but which fell outside the scope of 40 CFR part 26, subpart K, and for which EPA therefore would not have conducted a protocol review under 40 CFR part 26, subpart P, before the research was conducted. For example, as discussed in Unit IV.A., 40 CFR part 26, subpart K, as now proposed would not apply to a new clinical trial evaluating the therapeutic efficacy of a drug that was also a pesticide. Because this research would fall outside the scope of 40 CFR part 26, subpart K, investigators would not have submitted the protocol to EPA under 40 CFR part 26, subpart K, and EPA and HSRB would not have reviewed it under 40 CFR part 26, subpart P. Yet, if data from such research were to be relied on by EPA, the standards of subpart Q would apply. As § 26.1705 is currently worded in 40 CFR part 26, such a study could only be relied on if "EPA has adequate information to determine that the research was conducted in substantial compliance with subparts A through L." But because the protocol would not have been submitted for review by EPA and HSRB, the research in this example would not have been conducted in substantial compliance with 40 CFR part 26, subpart K.

EPA believes that it would be inappropriate to reject otherwise meritorious and ethical research for failure to comply with provisions in 40 CFR part 26, subparts A–L that did not apply when the research was conducted. Thus EPA proposes to make § 26.1705 applicable only to studies that were initiated after the effective date of the 2006 rule and that were subject to EPA's rules for the protection of human subjects (40 CFR part 26, subparts A through L) or another codification of the Common Rule. A companion change in § 26.1704(a) would apply the standard of § 26.1704 to all other completed research considered by EPA under 40 CFR part 26, subpart Q, without regard to when the research was initiated.

EPA proposes further changes to § 26.1705 to help make this clear. Proposed § 26.1705(b)(1) defines the applicable standard as either 40 CFR part 26, subparts A through L, or another Federal department or agency's codification of the Common Rule, whichever set of rules covered the research when it was conducted. In proposed § 26.1705(b)(2), corresponding changes are made applicable to research conducted in foreign countries.

Finally, in a new paragraph (c) in § 26.1705, EPA proposes to require substantial compliance of covered research with its protocol. A study reviewed as a proposal under subpart P of 40 CFR part 26 could be relied on only if it had been conducted in substantial compliance with the

protocol found acceptable by EPA, and if the investigator did not further amend or deviate from the protocol in ways that placed participants at increased risk of harm (based on knowledge available at the time the study was conducted) or impaired their informed consent. If a completed study was not reviewed as a proposal under 40 CFR part 26, subpart P, the study could only be relied on if it had been conducted in substantial compliance with a protocol that would have been found acceptable, and if the investigator did not amend or deviate from the protocol in ways that placed participants at increased risk of harm (based on knowledge available at the time the study was conducted) or impaired their informed consent.

b. *Anticipated effect.* Taken together, these proposed changes in § 26.1705 reflect the interpretations and methods used by EPA and HSRB since 2006 in reviewing completed, post-rule research. Codifying these interpretations will ensure consistency and transparency in future decision-making and is consistent with the 2006 Appropriations Act.

E. Request for Public Comment on Possible Re-Codification of 40 CFR Part 26, Subparts K–Q

1. *Current rule.* Subparts A–D of 40 CFR part 26 all apply to research with human subjects which is conducted or supported by EPA in its role as a research agency. Subparts K–Q of 40 CFR part 26 apply to pesticide research with human subjects that is conducted by regulated third parties, and to EPA's regulatory oversight of that research. Some stakeholders have suggested that this important distinction would be clearer if 40 CFR part 26 contained only those subparts applying to EPA as a research agency, and if 40 CFR part 26, subparts K–Q, were moved to a different section of EPA's regulations, within the range where other pesticide-specific regulations are found.

2. *Proposed amendments and rationale.* EPA is not now proposing such a re-codification, but invites public comment on the idea. Although it would necessitate many non-substantive revisions—mainly of internal cross-references—re-codification would not be difficult to accomplish. 40 CFR part 26 would retain current 40 CFR part 26, subparts A–D, and at least parts of current 40 CFR part 26, subpart O. A previously unused part within 40 CFR, within the numerical range of parts 150–180 where other pesticide-related regulations appear, would include current 40 CFR part 26, subparts K, L, M, O, P, and Q. 40 CFR part 26, subpart O, potentially applies to both EPA research and to third-party research and would need to be adapted to fit into both parts of a separated codification in 40 CFR.

3. *Anticipated effect.* Although this proposed re-codification may better distinguish those requirements applying to EPA as a research agency, and those applying to third-party studies, it would only change the location of the regulation within 40 CFR, and would not otherwise have any effect on the requirements.

V. FIFRA Review Requirements

In accordance with FIFRA section 25(a), EPA has submitted a draft of the proposed rule to the FIFRA Scientific Advisory Panel (SAP), the Secretary of Agriculture (USDA), and appropriate Congressional Committees. The FIFRA SAP waived its review of this proposal on October 12, 2010, because the significant scientific issues involved have already been reviewed by the SAP and additional review is not necessary. USDA responded without comments, but participated in the interagency review process under Executive Order 12866.

VI. Statutory and Executive Order Reviews

A. Regulatory Planning and Review

Under Executive Order 12866, entitled *Regulatory Planning and Review* (58 FR 51735, October 4, 1993), this has been identified as a "significant regulatory action." Accordingly, EPA submitted the draft proposed rule to the Office of Management and Budget (OMB) for review under Executive Order 12866 and any changes made in response to OMB recommendations have been documented in the docket for this rulemaking as required by the Executive Order.

The incremental costs of these proposed amendments both to industry and to EPA are expected to be negligible. EPA has not, therefore, prepared a new economic analysis for this rulemaking. Because no research has been identified that is outside the scope of the 2006 rule but that would be within the scope of these proposed amendments, EPA has no basis on which to revise the cost estimates that were provided in the economic analysis for the 2006 rulemaking or those most recently provided in the 2008 renewal of the Information Collection Request (ICR) for the existing regulation at 40 CFR part 26. The recent estimates included in the ICR are summarized in Unit VI.B. and a copy of the ICR is available in the docket.

B. Paperwork Reduction Act

This action does not impose any new information collection burden that would require additional review or approval by OMB under the Paperwork Reduction Act (PRA), 44 U.S.C. 3501 *et seq.* OMB previously approved the information collection requirements contained in the existing regulations at 40 CFR part 26 under OMB Control No. 2070–0169 (EPA ICR No. 2195). Burden is defined at 5 CFR 1320.3(b).

In its 2008 analysis supporting the most recent renewal of this ICR, EPA estimated that respondents would submit to the Agency some 34 proposals for or reports of research involving intentional exposure of human subjects each year. EPA estimated that preparation of information required by the 2006 rule would require about 598 hours per study at a cost of $45,927 per study, for a total estimated annual burden for affected entities of 20,332 hours at an estimated cost of $1,561,518. In addition, EPA estimated annual submission of 20 reports of research requiring only documentation of ethical conduct at a cost of 12 hours/$879 per report, or 240 hours/$17,580 per year. The total estimate of the annual respondent burden and cost was the sum of these two estimates, or 2,572 hours/$1,579,098.

These paperwork burden and cost estimates include activities related to initial rule familiarization, as well as activities that researchers would have to perform even without the Agency's rulemaking in this area, such as developing a protocol and maintaining records.

The average annual burden on EPA for reviewing each of the 34 study submissions was estimated to be 178 hours/$16,850 per study, or 6,052 hours/$572,900 per year. The average annual burden on EPA for reviewing each of the 20 additional submissions was estimated to be 44 hours/$3,158 per study, or 880 hours/$63,160 per year. The total estimate of the annual burden on EPA was the sum of these two estimates, or 6,932 hours/$636,000 per year.

In no year since promulgation of the 2006 rule have more than 7 protocols been submitted to EPA by industry; the average annual rate has been just over 5 for the 5-year period of 2006–2010. Somewhat fewer completed reports have been submitted during this period, so the average of new protocols and finished studies has been about 11 per year, less than a third of the projected 34 per year covered by the ICR. There is no evidence to suggest an upward trend, and nothing in these amendments

is believed likely to lead to a significant change in the rate of protocol and study submissions.

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 40 CFR are listed in 40 CFR part 9.

C. Small Entity Impacts

Pursuant to section 605(b) of the Regulatory Flexibility Act (RFA), 5 U.S.C. 601 *et seq.,* the Agency hereby certifies that this action will not have a significant adverse economic impact on a substantial number of small entities. Under RFA, small entities include small businesses, small organizations, and small governmental jurisdictions. For purposes of assessing the impacts of this proposed rule on small entities, small entity is defined in accordance with RFA section 601 as:

1. A small business as defined by the Small Business Administration's (SBA) regulations at 13 CFR 121.201.

2. A small governmental jurisdiction that is a government of a city, county, town, school district or special district with a population of less than 50,000.

3. A small organization that is any not-for-profit enterprise which is independently owned and operated and is not dominant in its field.

Because no small entities have been identified that are directly regulated by these proposed amendments, EPA has not attempted to reduce the impact of this proposed rule on small entities. Comments are invited on all aspects of the proposal and its impacts on small entities.

D. Unfunded Mandates

This action does not impose any enforceable duty, contain any unfunded mandate, or otherwise have any effect on small governments subject to the requirements of sections 202, 203, 204, or 205 of the Unfunded Mandates Reform Act (UMRA), 2 U.S.C. 1531–1538. These amendments are unlikely to affect State, local, and tribal governments at all, and are likely to affect the private sector only trivially. The action does not contain a Federal mandate that may result in expenditures of $100 million or more for State, local, and tribal governments, in the aggregate, or the private sector in any 1 year.

E. Federalism

This action does not have federalism implications because it is not expected to have substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government, as specified in Executive Order 13132, entitled *Federalism* (64 FR 43255, August 10, 1999). It makes marginal changes in the scope of an existing rule applying to sponsors and investigators conducting certain kinds of research involving human subjects, and refines the standards for EPA oversight of and reliance on such research.

In the spirit of Executive Order 13132, and consistent with EPA policy to promote communications between EPA and State and local governments, EPA specifically requests comments on this proposed action from State and local officials.

F. Tribal Implications

This action does not have tribal implications as specified in Executive Order 13175, entitled *Consultation and Coordination with Indian Tribal Governments* (65 FR 67249, November 9, 2000). This action is not expected to have substantial direct effects on Indian Tribes, will not significantly or uniquely affect the communities of Indian Tribal governments, and does not involve or impose any requirements that affect Indian Tribes. Thus, Executive Order 13175 does not apply to this action.

G. Children's Health Protection

EPA interprets Executive Order 13045, entitled *Protection of Children from Environmental Health Risks and Safety Risks* (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 does not establish an environmental standard intended to mitigate health or safety risks, nor is it an "economically significant regulatory action" as defined in Executive Order 12866. The 2006 rule applies to the conduct and review of research involving intentional exposure of human subjects, and prohibits the conduct of or EPA reliance on any such research involving subjects who are children, or pregnant or nursing women. These provisions would not be affected by the proposed amendments.

H. Affect on Energy Supply, Distribution, or Use

This action is not a "significant energy action" as defined in Executive Order 13211, entitled *Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use* (66 FR 28355, May 22, 2001), because this action is not likely to have any affect on the supply, distribution, or use of energy.

I. Technical Standards

Because this action does not involve any technical standards, section 12(d) of the National Technology Transfer and Advancement Act of 1995 (NTTAA) (15 U.S.C. 272 note), does not apply to this action.

J. Environmental Justice

This action does not entail special considerations of environmental justice related issues as delineated by Executive Order 12898, entitled *Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations* (59 FR 7629, February 16, 1994). The strengthened protections for human subjects participating in covered research established in the 2006 rule would not be altered by these proposed amendments.

List of Subjects in 40 CFR Part 26

Environmental protection, Administrative practice and procedures, Human research, Pesticides and pests.

Dated: January 18, 2011.

Lisa P. Jackson,

Administrator.

Therefore, it is proposed that 40 CFR chapter I be amended as follows:

PART 26—[AMENDED]

1. The authority citation for part 26 is revised to read as follows:

Authority: 5 U.S.C. 301; 7 U.S.C. 136a(a) and 136w(a)(1); 21 U.S.C. 346a(e)(1)(C); sec. 201, Pub. L. 109–54, 119 Stat. 531; and 42 U.S.C. 300v–1(b).

2. Amend § 26.1101 as follows:

a. Remove paragraphs (a), (c), and (g);

b. Redesignate paragraph (b) as (c), (f) as (g), (e) as (f), and (d) as (e); and

c. Add new paragraphs (a), (b), and (d) to read as follows.

§ 26.1101 To what does this subpart apply?

(a) Except as provided in paragraph (c) of this section, this subpart applies to all research initiated on or after [effective date of final rule] involving intentional exposure of a human subject to:

(1) Any substance if, at any time prior to initiating such research, any person who conducted or supported such research intended either to submit results of the research to EPA for consideration in connection with any action that may be performed by EPA under the Federal Insecticide,

Fungicide, and Rodenticide Act (FIFRA) (7 U.S.C. 136–136y) or section 408 of the Federal Food, Drug, and Cosmetic Act (FFDCA) (21 U.S.C. 346a), or to hold the results of the research for later inspection by EPA under FIFRA (7 U.S.C. 136–136y) or section 408 of FFDCA (21 U.S.C. 346a); or

(2) A pesticide if, at any time prior to initiating such research, any person who conducted or supported such research intended either to submit results of the research to EPA for consideration in connection with any action that may be performed by EPA under any regulatory statute administered by EPA other than those statutes designated in paragraph (a)(1) of this section, or to hold the results of the research for later inspection by EPA under any regulatory statute administered by EPA other than those statutes designated in paragraph (a)(1) of this section.

(b) For purposes of determining a person's intent under paragraph (a) of this section, EPA may consider any available and relevant information. EPA must rebuttably presume the existence of intent if:

(1) The person or the person's agent has submitted or made available for inspection the results of such research to EPA; or

(2) The person is a member of a class of people who, or whose products or activities, are regulated by EPA and, at the time the research was initiated, the results of such research would be relevant to EPA's exercise of its regulatory authority with respect to that class of people, products, or activities.

* * * * *

(d) The Administrator retains final judgment as to whether a particular activity is covered by this subpart.

* * * * *

3. In § 26.1102, revise paragraphs (a) and (c) and add paragraph (k) to read as follows:

§ 26.1102 Definitions.

(a) *Administrator* means the Administrator of the Environmental Protection Agency (EPA) and any other officer or employee of EPA to whom authority has been delegated.

* * * * *

(c) *Pesticide* means any substance or mixture of substances meeting the definition in 7 U.S.C. 136(u) [Federal Insecticide, Fungicide, and Rodenticide Act, section 2(u)].

* * * * *

(k) *Common Rule* refers to the Federal Policy for the Protection of Human Subjects that was established in 1991 by the Office of Science and Technology Policy and codified in 1991 by EPA and 14 other federal departments and agencies (*see* 56 FR 28003, June 18, 1991) and subsequently codified by other Federal departments and agencies. The Common Rule contains a widely accepted set of standards for conducting ethical research with human subjects, together with a set of procedures designed to ensure that the standards are met. Once codified by a Federal department or agency, the requirements of the Common Rule apply to research conducted or sponsored by that Federal department or agency. EPA's codification of the Common Rule currently appears in 40 CFR part 26, subpart A.

§ 26.1111 [Amended]

4. In § 26.1111, remove from paragraph (a)(4) the phrase "or the subject's legally authorized representative".

5. In § 26.1116, revise the introductory text of the section to read as follows:

§ 26.1116 General requirements for informed consent.

No investigator may involve a human being as a subject in research covered by this subpart unless the investigator has obtained the legally effective informed consent of the subject. An investigator must seek such consent only under circumstances that provide the prospective subject sufficient opportunity to consider whether or not to participate and that minimize the possibility of coercion or undue influence. The information that is given to the subject must be in language understandable to the subject. No informed consent, whether oral or written, may include any exculpatory language through which the subject is made to waive or appear to waive any of the subject's legal rights, or releases or appears to release the investigator, the sponsor, the institution or its agents from liability for negligence.

* * * * *

6. Revise § 26.1117 to read as follows:

§ 26.1117 Documentation of informed consent.

(a) Informed consent must be documented by the use of a written consent form approved by the IRB and signed by the subject. A copy shall be given to the subject.

(b) The consent form may be either of the following:

(1) A written consent document that embodies the elements of informed consent required by § 26.1116. This form may be read to the subject, but in any event, the investigator must give the subject adequate opportunity to read it before it is signed; or

(2) A short form written consent document stating that the elements of informed consent required by § 26.1116 have been presented orally to the subject. When this method is used, there must be a witness to the oral presentation. Also, the IRB shall approve a written summary of what is to be said to the subject. Only the short form itself is to be signed by the subject. However, the witness must sign both the short form and a copy of the summary, and the person actually obtaining consent must sign a copy of the summary. A copy of the summary must be given to the subject, in addition to a copy of the short form.

7. Revise the heading for subpart L to read as follows:

Subpart L—Prohibition of Third-Party Research Involving Intentional Exposure to a Pesticide of Human Subjects Who Are Children or Pregnant or Nursing Women

8. Revise § 26.1201 to read as follows:

§ 26.1201 To what does this subpart apply?

This subpart applies to any research subject to subpart K of this part.

9. Revise § 26.1301 to read as follows:

§ 26.1301 To what does this subpart apply?

This subpart applies to any person who submits to EPA after [effective date of final rule] either of the following:

(a) A report containing the results of any human research for consideration in connection with an action that may be performed by EPA under FIFRA (7 U.S.C. 136–136y) or section 408 of FFDCA (21 U.S.C. 346a).

(b) A report containing the results of any human research on or with a pesticide for consideration in connection with any action that may be performed by EPA under any regulatory statute administered by EPA.

§ 26.1302 [Amended]

10. In § 26.1302 remove the word "shall".

§ 26.1502 [Amended]

11. Amend § 26.1502 as follows:

a. In the first sentence of paragraph (a) remove the period after the phrase "during an inspection." and add in its place a comma; and

b. In the second sentence of paragraph (a) remove the phrase "The agency" and add in its place "EPA".

c. In the last sentence of the introductory text of paragraph (b) remove the phrase "the Agency" and add in its place "EPA".

§ 26.1505 [Amended]

12. In § 26.1505 remove from the last sentence, the phrase "§ 26.1502(c)" and add in its place "§ 26.1502(b)(4)".

§ 26.1507 [Amended]

13. In § 26.1507 remove from the last sentence, the phrase "The Agency" and add in its place "EPA".

§§ 26.1601 through 26.1603 [Redesignated as §§ 26.1603 through 26.1605]

14. Amend subpart P by redesignating §§ 26.1601 through 26.1603 as §§ 26.1603 through 26.1605.

15. Add new §§ 26.1601 and 26.1602 to read as follows:

§ 26.1601 To what does this subpart apply?

This subpart applies to both of the following:

(a) Reviews by EPA and by the Human Studies Review Board of proposals to conduct new research subject to 40 CFR 26.1125.

(b) Reviews by EPA after [effective date of the final rule] and, to the extent required by § 26.1604, by the Human Studies Review Board of reports of completed research subject to 40 CFR 26.1701.

§ 26.1602 Definitions.

The definitions in § 26.1102 apply to this subpart as well.

16. Amend newly redesignated § 26.1603 as follows:

a. Remove paragraphs (a) and (e).

b. Redesignate paragraphs (b) through (d) as (e) through (g).

c. Add new paragraphs (a), (b), (c), (d), and (h) to read as follows.

§ 26.1603 EPA review of proposed human research.

(a) EPA must review all proposals for new human research submitted under § 26.1125 in a timely manner.

(b) In reviewing proposals for new human research submitted under § 26.1125, the EPA Administrator must consider and make determinations regarding the proposed research, including:

(1) Whether the research would be likely to produce data that address an important scientific or policy question that cannot be resolved on the basis of animal data or human observational research.

(2) Whether the proposed research is designed in accordance with current scientific standards and practices to:

(i) Address the research question.

(ii) Include representative study populations for the endpoint in question.

(iii) Have adequate statistical power to detect appropriate effects.

(3) Whether the investigator proposes to conduct the research in accordance with recognized good research practices, including, when appropriate, good clinical practice guidelines and monitoring for the safety of subjects.

(c) In reviewing proposals for new research submitted under § 26.1125, the EPA Administrator must consider and make determinations regarding ethical aspects of the proposed research, including:

(1) Whether adequate information is available from prior animal studies or from other sources to assess the potential risks to subjects in the proposed research.

(2) Whether the research proposal adequately identifies anticipated risks to human subjects and their likelihood of occurrence, minimizes identified risks to human subjects, and identifies likely benefits of the research and their distribution.

(3) Whether the proposed research presents an acceptable balance of risks and benefits. In making this determination for research intended to reduce the interspecies uncertainty factor in a pesticide risk assessment, the Administrator must consider Recommendation 4–1 in the 2004 Report from the National Research Council of the National Academy of Sciences (NAS), entitled "Intentional Human Dosing Studies for EPA Regulatory Purposes: Scientific and Ethical Issues."

(4) Whether subject selection will be equitable.

(5) Whether subjects' participation would follow free and fully informed consent.

(6) Whether an appropriately constituted IRB or its foreign equivalent has approved the proposed research.

(7) If any person from a vulnerable population may become a subject in the proposed research, whether there is a convincing justification for selection of such a person, and whether measures taken to protect such human subjects are adequate.

(8) If any person with a condition that would put them at increased risk for adverse effects may become a subject in the proposed research, whether there is a convincing justification for selection of such a person, and whether measures taken to protect such human subjects are adequate.

(9) Whether any proposed payments to subjects are consistent with the principles of justice and respect for persons, and whether they are so high as to constitute undue inducement or so low as to be attractive only to individuals who are socioeconomically disadvantaged.

(10) Whether the sponsor or investigator would provide needed medical care for injuries incurred in the proposed research, without cost to the human subjects.

(d) With respect to any research or any class of research, the EPA Administrator may recommend additional conditions which, in the judgment of the EPA Administrator, are necessary for the protection of human subjects.

* * * * *

(h) EPA must provide the submitter of the proposal copies of the EPA and Human Studies Review Board reviews.

17. Amend newly redesignated § 26.1604 by revising paragraph (a) to read as follows:

§ 26.1604 EPA review of completed human research.

(a) When considering, under any regulatory statute it administers, data from completed research involving intentional exposure of humans to a pesticide, EPA must thoroughly review the material submitted under § 26.1303, if any, and other available, relevant information and document its conclusions regarding the scientific and ethical conduct of the research.

* * * * *

18. Add §§ 26.1606 and 26.1607 to read as follows:

§ 26.1606 Human Studies Review Board review of proposed human research.

In commenting on proposals for new research submitted to it by EPA, the Human Studies Review Board must consider the scientific merits and ethical aspects of the proposed research, including all elements listed in § 26.1603(b) and (c) and any additional conditions recommended pursuant to § 26.1603(d).

§ 26.1607 Human Studies Review Board review of completed human research.

In commenting on reports of completed research submitted to it by EPA, the Human Studies Review Board must consider the scientific merits and ethical aspects of the completed research, and must apply the appropriate standards in subpart Q of this part.

19. Revise the heading for subpart Q to read as follows:

Subpart Q—Standards for Assessing Whether To Rely on the Results of Human Research in EPA Actions

20. Revise §§ 26.1701 through 26.1705 to read as follows:

* * * * *

Sec.

26.1701 To what does this subpart apply?

26.1702 Definitions.
26.1703 Prohibitions applying to all research subject to this subpart.
26.1704 Prohibition of reliance on unethical human research with non-pregnant, non-nursing adults which is not subject to § 26.1705.
26.1705 Prohibition of reliance on unethical human research with non-pregnant, non-nursing adults initiated after April 7, 2006, and subject to subparts A through L of this part, or the codification of the Common Rule by another Federal department or agency.

* * * * *

§ 26.1701 To what does this subpart apply?

(a) For decisions under FIFRA (7 U.S.C. 136–136y) or section 408 of FFDCA (21 U.S.C. 346a), this subpart applies to research involving intentional exposure of human subjects to any substance.

(b) For decisions under any regulatory statute administered by EPA other than those statutes designated in paragraph (a) of this section, this subpart applies to research involving intentional exposure of human subjects to a pesticide.

§ 26.1702 Definitions.

The definitions in § 26.1102 and § 26.1202 apply to this subpart as well.

§ 26.1703 Prohibitions applying to all research subject to this subpart.

(a) Prohibition of reliance on scientifically invalid research. EPA must not rely on data from research subject to this subpart unless EPA determines that the data are relevant to a scientific or policy question important for EPA decisionmaking, that the data were derived in a manner that makes them scientifically valid and reliable, and that it is appropriate to use the data for the purpose proposed by EPA. In making such determinations, EPA must consider:

(1) Whether the research was designed and conducted in accordance with appropriate scientific standards and practices prevailing at the time the research was conducted.

(2) The extent to which the research subjects are representative of the populations for the endpoint or endpoints in question.

(3) The statistical power of the data to support the scientific conclusion EPA intends to draw from the data.

(4) In a study that reports only a No Observed Effect Level (NOEL) or a No Observed Adverse Effect Level (NOAEL), whether a dose level in the study gave rise to a biological effect, thereby demonstrating that the study had adequate sensitivity to detect an effect of interest.

(b) Prohibition of reliance on research subject to this subpart involving intentional exposure of human subjects who are pregnant women (and therefore their fetuses), nursing women, or children. Except as provided in § 26.1706, EPA must not rely on data from any research subject to this subpart involving intentional exposure of any human subject who is a pregnant woman (and therefore her fetus), a nursing woman, or a child.

§ 26.1704 Prohibition of reliance on unethical human research with non-pregnant, non-nursing adults which is not subject to § 26.1705.

(a) This section applies to research subject to this subpart that is not subject to § 26.1705.

(b) Except as provided in § 26.1706, EPA must not rely on data from any research subject to this section if there is clear and convincing evidence that:

(1) The conduct of the research was fundamentally unethical (*e.g.,* the research was intended to seriously harm participants or failed to obtain informed consent); or

(2) The conduct of the research was deficient relative to the ethical standards prevailing at the time the research was conducted in a way that placed participants at increased risk of harm (based on knowledge available at the time the study was conducted) or impaired their informed consent.

(c) The prohibition in this section is in addition to the prohibitions in § 26.1703.

§ 26.1705 Prohibition of reliance on unethical human research with non-pregnant, non-nursing adults initiated after April 7, 2006, and subject to subparts A through L of this part, or the codification of the Common Rule by another Federal department or agency.

(a) This section applies to research subject to this subpart, that:

(1) Was initiated after April 7, 2006.

(2) Was subject, at the time it was conducted, either to subparts A through L of this part, or to the codification of the Common Rule by another Federal department or agency.

(b) Except as provided in § 26.1706, EPA must not rely on data from any research subject to this section unless EPA determines that the research was conducted in substantial compliance with either:

(1) All applicable provisions of subparts A through L of this part, or the codification of the Common Rule by another Federal department or agency; or

(2) If the research was conducted outside the United States, with procedures at least as protective of subjects as those in subparts A through L of this part, or the codification of the Common Rule by another Federal department or agency.

(c) Except as provided in § 26.1706, EPA must not rely on data from any research subject to this section unless EPA determines that the research was conducted in substantial compliance with either:

(1) A proposal that was found to be acceptable under § 26.1603(c), and no amendments to or deviations from that proposal placed participants at increased risk of harm (based on knowledge available at the time the study was conducted) or impaired their informed consent. If EPA discovers that the submitter of the proposal materially misrepresented or knowingly omitted information that would have altered the outcome of EPA's evaluation of the proposal under § 26.1603(c), EPA must not rely on that data.

(2) A proposal that would have been found to be acceptable under § 26.1603(c), if it had been subject to review under that section, and no amendments to or deviations from that proposal placed participants at increased risk of harm (based on knowledge available at the time the study was conducted) or impaired their informed consent.

(d) The prohibition in this section is in addition to the prohibitions in § 26.1703.

§ 26.1706 [Amended]

21. In paragraph (d) of § 26.1706 remove the word "publishes" and add in its place the phrase "has published".

[FR Doc. 2011–1629 Filed 2–1–11; 8:45 am]

BILLING CODE 6560–50–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Parts 416, 418, 482, 483, 484, 485, 486, and 491

[CMS–3225–P]

RIN 0938–AP94

Medicare and Medicaid Programs; Patient Notification of Right To Access State Survey Agencies and Medicare Beneficiary Notification of the Right To Access Quality Improvement Organizations

AGENCY: Centers for Medicare & Medicaid Services (CMS), HHS.

ACTION: Proposed rule.

SUMMARY: This proposed rule would set forth new requirements for Medicare certified providers and suppliers. This proposed rule would require that the Medicare certified providers and suppliers make available to their Medicare beneficiaries information about their right to file a written complaint with the Quality Improvement Organization (QIO) in the State where healthcare services are being or were provided about the quality of care they are receiving or have received. The Medicare certified providers and suppliers would be required to provide their Medicare beneficiaries with written notice of the QIO's contact information. In addition, we are proposing new requirements for certain Medicare providers and suppliers that would require facilities to inform all patients about State agency contact information.

DATES: To be assured consideration, comments must be received at one of the addresses provided below, no later than 5 p.m. on April 4, 2011.

ADDRESSES: In commenting, please refer to file code CMS–3225–P. Because of staff and resource limitations, we cannot accept comments by facsimile (FAX) transmission.

You may submit comments in one of four ways (please choose only one of the ways listed):

1. *Electronically.* You may submit electronic comments on this regulation to *http://www.regulations.gov.* Follow the instructions under the "More Search Options" tab.

2. *By regular mail.* You may mail written comments to the following address ONLY: Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS–3225–P, P.O. Box 8010, Baltimore, MD 21244–8010.

Please allow sufficient time for mailed comments to be received before the close of the comment period.

3. *By express or overnight mail.* You may send written comments to the following address ONLY: Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS–3225–P, Mail Stop C4–26–05, 7500 Security Boulevard, Baltimore, MD 21244–1850.

4. *By hand or courier.* If you prefer, you may deliver (by hand or courier) your written comments before the close of the comment period to either of the following addresses:

a. For delivery in Washington, DC—Centers for Medicare & Medicaid Services, Department of Health and Human Services, Room 445–G, Hubert H. Humphrey Building, 200 Independence Avenue, SW., Washington, DC 20201.

(Because access to the interior of the Hubert H. Humphrey Building is not readily available to persons without Federal government identification, commenters are encouraged to leave their comments in the CMS drop slots located in the main lobby of the building. A stamp-in clock is available for persons wishing to retain a proof of filing by stamping in and retaining an extra copy of the comments being filed.)

b. For delivery in Baltimore, MD—Centers for Medicare & Medicaid Services, Department of Health and Human Services, 7500 Security Boulevard, Baltimore, MD 21244–1850.

If you intend to deliver your comments to the Baltimore address, please call telephone number (410) 786–9994 in advance to schedule your arrival with one of our staff members.

Comments mailed to the addresses indicated as appropriate for hand or courier delivery may be delayed and received after the comment period.

Submission of comments on paperwork requirements. You may submit comments on this document's paperwork requirements by following the instructions at the end of the "Collection of Information Requirements" section in this document.

For information on viewing public comments, see the beginning of the **SUPPLEMENTARY INFORMATION** section.

FOR FURTHER INFORMATION CONTACT: Jacqueline Morgan, (410) 786–4282.

SUPPLEMENTARY INFORMATION: *Inspection of Public Comments:* All comments received before the close of the comment period are available for viewing by the public, including any personally identifiable or confidential business information that is included in a comment. We post all comments received before the close of the comment period on the following Web site as soon as possible after they have been received: *http://www.regulations.gov.* Follow the search instructions on that Web site to view public comments.

Comments received timely will also be available for public inspection as they are received, generally beginning approximately 3 weeks after publication of a document, at the headquarters of the Centers for Medicare & Medicaid Services, 7500 Security Boulevard, Baltimore, Maryland 21244, Monday through Friday of each week from 8:30 a.m. to 4 p.m. To schedule an appointment to view public comments, phone 1–800–743–3951.

I. Legislative and Regulatory Background

Various sections of the Social Security Act (the Act) define the terms used for each Medicare provider and supplier. In some cases, those definitions describe requirements that Medicare certified providers and suppliers must meet for purposes of the Medicare program. Some of those provisions also specify that the Secretary of the Department of Health and Human Services (DHHS) (the Secretary) may establish other requirements as necessary in the interest of health and safety of patients. The Public Health Service (PHS) Act also specifies additional requirements that some Medicare certified providers and suppliers must meet.

The Secretary has established in regulation the requirements that each provider and supplier must meet in order to participate in the Medicare and Medicaid programs. These requirements are called the Conditions of Participation (CoPs), or Requirements (for Long Term Care Facilities) for providers and the Conditions for Coverage (CfCs) for suppliers. The CoPs and CfCs establish health and safety measures that are intended to ensure that a minimum level of quality care is furnished to all Medicare patients.

To assist with improving the quality of health care for Medicare patients, we propose to establish a new standard for the following 10 Medicare certified providers and suppliers:

- Ambulatory Surgical Centers (ASCs).
- Hospices.
- Hospitals.
- Long Term Care (LTC) Facilities.
- Home Health Agencies (HHAs).
- Comprehensive Outpatient Rehabilitation Facilities (CORFs).
- Critical Access Hospitals (CAHs).
- Clinics and Rehabilitation Agencies.
- Portable X-Ray Services.
- Rural Health Clinics (RHCs) and Federally Qualified Health Centers (FQHCs).

II. Quality Improvement Organizations

Section 142 of the Peer Review Improvement Act of 1982 (Title I, Subtitle C of the Tax Equity and Fiscal Responsibility Act (TEFRA) of 1982 (Pub. L. 97–248)) amended section 1862 of the Act by adding new subsection (g), which requires that the Secretary enter into contracts with utilization and quality control peer review organizations (PROs). These organizations make determinations about whether care is reasonable and medically necessary, or is custodial in

nature. They also promote the effective, efficient, and economical delivery of care, and promote the quality of that care. In 2002, CMS began referring to these Peer Review Organizations as Quality Improvement Organizations (QIOs). (*See* 67 FR 36539.) The national Quality Improvement Organization (QIO) Program was established to improve the efficiency, effectiveness, economy and quality of services delivered to Medicare beneficiaries. CMS contracts with 53 QIOs (one in each State, Puerto Rico, the District of Columbia, and the U.S. Virgin Islands) for a term of 3 years.

Section 143 of TEFRA added sections 1151 through 1163 in Part B of Title XI of the Act, which established the Utilization and Quality Control Peer Review Program. Section 1151 of the Act sets out the purpose of Part B of title XI of the Act. Section 1152 of the Act defines the entities that can qualify as QIOs, including the requirement that the QIO must be composed of a substantial number of the "licensed doctors of medicine and osteopathy engaged in the practice of medicine or surgery" in the QIO's area of responsibility. Alternatively, the QIO must have available the services of a sufficient number of licensed doctors of medicine or osteopathy engaged in the practice of medicine or surgery in its area to assure adequate peer review of the services provided by the various medical specialties and subspecialties. Section 1153 of the Act provides specific requirements regarding how contracts between the QIOs and CMS must be structured. Section 1154(a)(1) of the Act describes the QIOs' responsibility to determine whether a provider's or practitioner's services and items are reasonable and medically necessary, provided in the appropriate setting, and whether the quality of services meets "professionally recognized standards" of care. QIOs also have the specific responsibility under section 1154(a)(14) of the Act to conduct an "appropriate review of all written complaints about the quality of services (for which payment may otherwise be made under title XVIII) not meeting professionally recognized standards of health care. * * *" A complaint can only be reviewed and resolved by the QIO if filed by an individual entitled to benefits for such services under Medicare (or a person acting on the individual's behalf). The QIO's review responsibility applies to any beneficiary's complaint, even if the issues raised do not appear to the QIO to involve serious or substantial quality violations.

As part of the effort to evaluate the QIO program, section 109(d)(1) of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) mandated the Institute of Medicine (IOM) to conduct a review of the program and to recommend how its impact could be enhanced. IOM published the final report on March 9, 2006 and it can be found at *http://www.iom.edu/Reports/2006/Medicares-Quality-Improvement-Organization-Program-Maximizing-Potential.aspx.* One of the issues the report highlighted was that QIOs perform few beneficiary complaint reviews.

We believe that a factor contributing to the low volume of beneficiary complaint reviews is that beneficiaries are unaware of their right to voice complaints to the QIO in their State. CMS, in the past, has instituted efforts to inform beneficiaries of their right to report to their respective QIOs, concerns they have about the quality of care they receive. These efforts have included the incorporation of a specific provision in the Hospital CoPs at § 482.13(a)(2) that includes a requirement that the grievance process must include a mechanism for timely referral to the appropriate Utilization and Quality Control Quality Improvement Organization of beneficiary concerns regarding quality of care. In accordance with section 1866(a)(1)(M) of the Act, hospitals and critical access hospitals (CAHs) must deliver, at or about the time of patient admission, the "Important Message from Medicare" (IM) to all inpatient Medicare beneficiaries which explains their Medicare rights, including appeal rights. The IM informs beneficiaries of their right to report to the QIO any concerns about the quality of care they received. It also requires that the hospital provide the name of the QIO and the QIO's contact information. The current data shows that QIO utilization rates are higher among in-patient Medicare beneficiaries than among Medicare beneficiaries who receive care in other settings. Under the current QIO 9th Statement of Work (8/1/2008 through 7/31/11), the QIOs have received 6,379 inpatient and 4,116 outpatient requests for complaint reviews.

III. Provisions of the Proposed Rule

Over the past decade, quality of health care has been of increasing concern. CMS recognizes this concern and has started revising patient health and safety regulations to include quality assessment and performance improvement requirements.

Currently, Medicare beneficiaries receiving hospital in-patient services are informed of their right to communicate health care concerns to a QIO. We believe that this requirement should also be provided to Medicare out-patient beneficiaries and to those beneficiaries receiving care in other healthcare settings. To further assist in improving quality of health care, we are proposing to include a new standard for 10 specific Medicare certified providers and suppliers (that is, CoPs or CfCs). The new standard would inform Medicare beneficiaries of their right to communicate health care concerns to a QIO. These standards are applicable only to Medicare beneficiaries because QIOs are only authorized to review the health care quality complaints of Medicare beneficiaries.

As part of this effort, we propose that Medicare beneficiaries be informed by written notice at the start of care (or, for some providers or suppliers, at the time of inpatient admission or at an initial assessment visit in advance of furnishing care) of their right to voice concerns about the quality of care they are receiving (or, once services have been furnished, have received) to the QIO in the State where services are being or have been provided. We also propose that the facility document that it presented written notice to the beneficiary or the beneficiary's representative or a surrogate selected by the beneficiary, such as a family member or friend of the beneficiary. This person may act as a liaison between the beneficiary and the provider/supplier to help the beneficiary communicate, understand, remember and cope with the interactions that take place during their visit/stay, and explain any instructions to the beneficiary that are delivered by the provider or supplier. If a patient is unable to fully communicate directly with the provider or supplier, then the provider or supplier may give written information to the beneficiary's representative or surrogate. Patient representatives or surrogates are not intended to serve as interpreters for limited English proficient (LEP) or deaf/hard of hearing persons. Under regulations issued pursuant to Title VI of the Civil Rights Act of 1964 (Title VI), recipients of Federal funds such as health care providers must take reasonable steps to provide LEP persons with meaningful access to programs and activities. Further, under Section 504 of the Rehabilitation Act of 1973, recipients must ensure effective communication with persons with disabilities, including those who are deaf or hard of hearing. Under both laws, interpreters necessary for

meaningful access and effective communication are to be provided free of charge. If a patient wishes his or her representative or surrogate to serve in the capacity of interpreter, the provider or supplier can obtain a signed waiver from the patient documenting that a free interpreter was offered and declined in favor of using the representative or surrogate. In any case, the provider or supplier continues to be responsible for ensuring the language access and effective communication. Where necessary for compliance with Title VI, providers and suppliers should provide written translations for LEP persons, particularly for languages that are commonly used by non-English-speaking beneficiaries, such as Spanish.

These proposed requirements are based on the provisions that are already established for those Medicare beneficiaries receiving care in a hospital setting. At this time, we are not proposing to require that a specific format be utilized. Entities will have the flexibility to design their own notice and documentation process.

This proposed rule would affect the following Medicare certified providers and suppliers: (1) Ambulatory Surgical Centers (ASCs); (2) Hospices; (3) Hospitals; (4) Long Term Care Facilities (LTCs); (5) Home Health Agencies (HHAs); (6) Comprehensive Outpatient Rehabilitation Facilities (CORFs); (7) Critical Access Hospitals (CAHs); (8) Clinics and Rehabilitation Agencies; (9) Portable X-ray Services; and (10) Rural Health Clinics (RHCs) and Federally Qualified Health Centers (FQHCs).

In addition to informing Medicare beneficiaries about QIO contact information, we have also included a proposed requirement for seven out of the ten providers and suppliers that requires each of them to inform all patients, including Medicare beneficiaries, about State agency contact information. We wanted to be sure patients also had information about filing a complaint with the State survey agency. As we mentioned previously, CMS is continually updating the health and safety standards of various providers and suppliers and, as a result, Ambulatory Surgical Centers, Long Term Care Facilities, and Home Health Agencies already have existing regulations that require them to provide patients with State survey agency contact information. We propose to add the State agency contact information requirement to the following seven types of providers and suppliers: Hospices, Hospitals, CORFs, CAHs, Clinics and Rehabilitation Agencies, Portable X-ray Services and RHCs and FQHCs.

Medicare health and safety standards are in place to protect patients. All patients receiving care at Medicare-certified facilities have the right to file a complaint or grievance with the State agency against a Medicare provider or supplier for improper care or treatment. The State survey agency and CMS work together to make sure providers and suppliers meet Federal standards. Medicare beneficiaries can file a complaint with the State agency and/or a QIO. It is our intent to ensure that, as part of patient rights, patients receive complete information about filing a complaint in the event they have a healthcare concern or complaint about the care they received from a Medicare certified facility. In the event that a QIO received a complaint from a non-Medicare beneficiary, we expect that the QIO would explain that complaints are covered only for Medicare beneficiaries and the individual should contact the facility directly for procedures for filing a complaint and information on contacting the appropriate State survey agency.

Some Medicare certified providers and suppliers were determined not to be appropriate for inclusion in this proposed rule for various reasons. For example, End Stage Renal Disease (ESRD) facilities are excluded from this proposed requirement because they already have a specific complaint process built into the ESRD Network System that is similar to the QIO complaint process. At this time, we would also like to solicit comments on whether this QIO notice should also be given at the end of a Medicare beneficiary's treatment, service or hospitalization. Another option may be to only require that the QIO notice be given upon completion of treatment or discharge (in addition to the notification upon admission) if the Medicare beneficiary has experienced an adverse event.

CMS Data Resource

The data regarding the number of Medicare certified providers and suppliers that would be affected by this proposed rule would be generated by CMS' Online Survey, Certification, and Reporting (OSCAR) data system as of December 31, 2008. We note that the OSCAR system is updated frequently by individual States. Thus, the figures may not always total 100 percent.

A. Ambulatory Surgical Centers (§ 416.50)

Section 42 CFR 416.2 defines an ambulatory surgical center (ASC) as any distinct entity that operates exclusively for the purpose of providing surgical services to patients not requiring hospitalization, in which the expected duration of services would not exceed 24 hours following an admission.

The surgical services performed at ASCs are scheduled, primarily elective, non-life-threatening procedures that can be safely performed in an ambulatory setting. Patients are examined immediately before surgery to evaluate the risk of anesthesia and of the procedure to be performed. Patients are also evaluated before discharge from the ASC to ensure that there has been proper anesthesia recovery. Currently, there are 5,174 Medicare certified ASCs in the United States. Most ASCs are small physician-owned entities.

The ASC CfCs are located at § 416.40 through § 416.52. Currently, the patient rights standard for ASCs specifies that the ASC must inform the patient or the patient's representative of the patient's rights, and must protect and promote the exercise of such rights. In addition, it states that the ASC must provide the patient or the patient's representative with verbal and written notice of the patient's rights in advance of the date of the procedure, in a language and manner that the patient or the patient's representative understands. To further assist with improving the quality of health care, we are proposing to revise the ASC patient rights requirement at § 416.50 by redesignating paragraph (c) as paragraph (d) and paragraph (d) as paragraph (e) and adding a new standard at paragraph (c). The proposed standard would require the ASC to inform all Medicare beneficiaries by written notice, at the time of admission, of their right to file a written complaint with the QIO in the State where services are being or were provided about the quality of care they are receiving or have received. In addition, the new standard would require that the ASC provide Medicare beneficiaries with the name, telephone number, electronic mail address, and mailing address of the QIO, as well as require that the ASC document in the beneficiary's record that it has presented the written notice to the beneficiary or beneficiary's representative or surrogate.

B. Hospice Care (§ 418.52)

Section 122 of TEFRA, Public Law 97–248, added section 1861(dd) to the Act to provide coverage for hospice care to terminally ill Medicare beneficiaries who elect to receive care from a Medicare-participating hospice. Under section 1861(dd) of the Act, the Secretary has established the CoPs that a hospice must meet in order to participate in the Medicare and Medicaid programs or both programs.

Under section 1861(dd) of the Act, the Secretary is responsible for ensuring that the CoPs and their enforcement are adequate to protect the health and safety of individuals under hospice care. The hospice care CoPs at § 418.52 through § 418.116 apply to a hospice as an entity, as well as to the services furnished to each individual under hospice care.

Hospice care provides palliative care rather than traditional medical care and curative treatment to terminally ill individuals. Palliative care improves the quality of life of patients and their families facing the problems associated with life-threatening illness through the prevention and relief of suffering by means of early identification, assessment, and treatment of pain and other issues. Hospice care allows the patient to remain at home as long as possible by providing support to the patient and family, and by keeping the patient as comfortable as possible while maintaining his or her dignity and quality of life. A hospice uses an interdisciplinary approach to deliver medical, social, physical, emotional, and spiritual services through the use of a broad spectrum of caregivers. Currently, there are 3,346 hospice agencies nationally.

The patient's rights standard for hospice care currently states that the patient has the right to be informed of his or her rights, and that the hospice must protect and promote the exercise of these rights. However, it does not state that the patient is to receive State survey agency information to report complaints or to be informed of his or her right to communicate health care quality concerns to a QIO. Therefore, we are proposing to include these requirements by revising the hospice patient's rights requirements at § 418.52 by adding a new requirement at proposed paragraph (c)(9). We are also proposing to add a new standard at proposed paragraph (d). At proposed paragraph (c)(9), we are proposing that the hospice provide patients with the mailing address, electronic mail address, and telephone number of the State survey agency in the event they wish to report a grievance. The proposed new standard at paragraph (d) would require the hospice to inform all Medicare beneficiaries by written notice, during the initial assessment visit in advance of furnishing care, of their right to file a written complaint about the quality of care they are receiving or have received to the QIO in the State where services are being provided or were provided. In addition, the proposed standard would require the hospice to provide Medicare beneficiaries with the name, telephone number, electronic mail address, and mailing address of the QIO, as well as require that the hospice document in the beneficiary's records that it presented the written notice to the beneficiary or beneficiary's representative or surrogate.

C. Hospitals (§ 482.13)

Section 1861(e)(1) through (8) of the Social Security Act (the Act) defines the term "hospital" and lists the requirements that a hospital must meet to be eligible for Medicare participation. Section 1861(e)(9) of the Act specifies that a hospital must also meet such other requirements as the Secretary finds necessary in the interest of the health and safety of the hospital's patients. Under the authority of 1861(e), the Secretary has established in regulations at 42 CFR part 482 the requirements that a hospital must meet to participate in the Medicare program.

Section 1905(a) of the Act provides that Medicaid payments may be applied to hospital services. Regulations at § 440.10(a)(3)(iii) require hospitals to meet the Medicare conditions of participation (CoPs) to qualify for participation in Medicaid. The hospital CoPs are found at § 482.1 through § 482.66.

We are proposing to amend the patient's rights requirements at § 482.13 by adding a new requirement at subparagraph (a)(1)(i). To remain consistent among providers and suppliers, we are proposing to require that hospitals provide patients with the address and telephone number of the State survey agency to report complaints. Currently, our patient's rights regulation at § 482.13(a)(2) already requires hospitals to provide all patients with a grievance process. This regulation also includes the timely referral, for Medicare beneficiaries, to a QIO about complaints regarding the quality of care and discharges, similar to the proposals we are making here for other providers and suppliers. We are also proposing to add new standards at § 482.13(a)(1)(ii) which would require that the hospital inform all Medicare beneficiaries by written notice, at the time of inpatient admission or outpatient service, of their right to file a written complaint about the quality of care they are receiving or have received to the QIO in the State where services are being or were provided. In addition, the new standard would require the hospital to provide beneficiaries with the name, telephone number, electronic mail address, and mailing address of the QIO, as well as require that the hospital document in the beneficiary's record that it has presented the written notice to the beneficiary or beneficiary's representative or surrogate.

D. Requirements for Long Term Care Facilities (§ 483.10)

Section 1819(a) of the Act defines a skilled nursing facility (SNF) for Medicare purposes as an institution or a distinct part of an institution that is primarily engaged in providing skilled nursing care and related services to residents that require medical or nursing care or rehabilitation services due to an injury, disability, or illness. Section 1919(a) of the Act defines a nursing facility (NF) for Medicaid purposes as an institution or a distinct part of an institution that is primarily engaged in providing to residents: Skilled nursing care and related services for residents who require medical or nursing care; rehabilitation services due to an injury, disability, or illness; or, on a regular basis, health-related care and services to individuals who, due to their mental or physical condition, require care and services (above the level of room and board) that are available only through an institution.

To participate in the Medicare and Medicaid programs, long-term care (LTC) facilities, that is, SNFs and NFs, must meet certain Federal requirements specified at § 483.1 through § 483.75. SNFs must be certified as meeting the requirements of section 1819(a) through section (d) of the Act. NFs must be certified as meeting the requirements in section 1919(a) through section (d) of the Act.

LTC facilities provide a substantial amount of care to Medicare beneficiaries and Medicaid recipients, as well as "dual eligibles," who qualify for both Medicare and Medicaid. As of December 2008, there were 15,727 LTC facilities and each year they provided care for about 1.7 million individuals. In 2007, SNFs and NFs accounted for more than 10 and 15 percent, respectively, of Medicare and Medicaid expenditures.

The current regulation for LTC facilities contains specific requirements that address resident rights. However, it does not require LTC facilities to inform beneficiaries of their right to communicate with a QIO. Therefore, we are proposing to revise the resident rights requirements at § 483.10 by redesignating paragraphs (c) through (o) as paragraphs (d) through (p). We are proposing to add a new standard at paragraph (c). The proposed new standard would require the LTC facility to inform all Medicare beneficiaries by written notice, at the time of admission, of their right to file a written complaint with the QIO in the State where services

are being or were provided about the quality of care they are receiving or have received. In addition, the proposed new standard would require the LTC facility to provide the beneficiary with the name, telephone number, electronic mail address, and mailing address of the QIO, as well as require that the LTC facility document in the beneficiary's record that it has presented the written notice to the beneficiary or his or her representative or surrogate.

E. Home Health Agencies (§ 484.10)

Under sections 1861(m), 1861(o), and 1891 of the Act, the Secretary has established in regulations the requirements that a Home Health Agency (HHA) must meet in order to participate in the Medicare program. Home health services are covered for the elderly and disabled under the Hospital Insurance (Part A) and Supplemental Medical Insurance (Part B) benefits of the Medicare program. These services must be furnished by, or under arrangement with, a HHA that participates in the Medicare program and, as a general rule, must be provided on a visiting basis in the beneficiary's home.

As of December 2008, there were 9,787 HHAs participating in the Medicare program. Medicare-certified HHAs provided home health services to 3.2 million patients nationwide in FY 2006. The effective delivery of quality home health services is essential to the care and prevention of recurrent illness and hospitalizations.

The home health services CoPs requirements are located at § 484.1 through § 484.55. Currently the patient rights standard for HHAs specifies that the HHA must provide the patient with a written notice of the patient's rights in advance of furnishing care to the patient or during the initial evaluation visit before the initiation of treatment. To further assist with improving quality of health care, we are proposing to revise the HHA patient rights requirement at § 484.10 by redesignating paragraphs (c) through paragraphs (f) as paragraphs (d) through paragraphs (g). We are also proposing to add a new standard at paragraph (c). The proposed new standard would require the HHA to inform all Medicare beneficiaries by written notice, at the time of initiation of treatment, of their right to file a written complaint about the quality of care they are receiving or have received to the QIO in the State where services are being or were provided. In addition, the proposed standard would require the HHA to provide the beneficiary with the name, telephone number, electronic mail address, and mailing address of the QIO, and to document in the beneficiary's record that the written notice was presented to the beneficiary or beneficiary's representative or surrogate.

F. Comprehensive Outpatient Rehabilitation Facilities (§ 485.56)

Section 1861(cc) of the Act defines the term "comprehensive outpatient rehabilitation facility" (CORF) and lists the requirements that a CORF must meet to be eligible for Medicare participation. By definition, under 42 CFR 485.51(a), a CORF is a non-residential facility that is established and operated exclusively for the purpose of providing diagnostic, therapeutic, and restorative services to outpatients for the rehabilitation of injured, disabled, or sick persons, at a single fixed location, by or under the supervision of a physician. As of December 2008, there were 476 Medicare-certified CORFs in the United States.

Section 1861(cc)(2)(J) of the Act also states that the CORF must meet other requirements that the Secretary finds necessary in the interest of the health and safety of a CORF's patients. Under this authority, the Secretary has established requirements at § 485.50 through § 485.74, that a CORF must meet to participate in the Medicare program.

We are proposing to amend the governing body and administration requirements at § 485.56 by adding a new requirement at paragraph (e)(11). We are also proposing to add a new standard by adding a new paragraph (g). At proposed paragraph (e)(11), we are proposing to require that CORFs provide patients with the mailing address, electronic mail address, and telephone number of the State survey agency to report complaints. The proposed new standard in paragraph (g) would require the CORF to inform all Medicare beneficiaries by written notice, at the time of initiation of treatment, of their right to file a written complaint about the quality of care they are receiving or have received to the QIO in the State where services are being or were provided. In addition, the proposed standard would require the CORF to provide the beneficiary with the name, telephone number, electronic mail address, and mailing address of the QIO, and document in the beneficiary's record that it has presented the written notice to the beneficiary or beneficiary's representative or surrogate.

G. Critical Access Hospitals (§ 485.627)

Sections 1820 and 1861(mm) of the Act provide that critical access hospitals participating in Medicare and Medicaid meet certain specified requirements. CMS has implemented these provisions in 42 CFR part 485, subpart F, Conditions of Participation for Critical Access Hospitals (CAHs). There are 1,305 CAHs that must meet the CAH CoPs. CAHs are small, generally rural, limited-service facilities with low patient volume. The intent of designating facilities as "critical access hospitals" is to preserve access to primary care and emergency services that meet community needs. A CAH designation is a core component of the State's Medicare Rural Hospital Flexibility Program (Flex Program). To be designated as a CAH, a facility must be located in a State that has established a Flex program, be located in a rural area or be treated as rural in accordance with existing § 485.610(b), which, among other things, allows qualified hospital providers in urban areas to be treated as rural for purposes of becoming a CAH. Facilities that are so designated and meet the CAH conditions of participation (CoPs) under 42 CFR part 485, subpart F, will be certified as CAHs by CMS.

The current regulations at § 485.601 through § 485.647 do not contain patient rights requirements. Therefore, we are proposing to revise the organizational structure requirements by adding two new standards at § 485.627(c) and (d). The first proposed standard would require the CAH to provide CAH patients with the mailing address, electronic mail address, and telephone number of the State survey agency if the patient wishes to report complaints. The second proposed standard would require the CAH to inform all Medicare beneficiaries by written notice, at the time of service, of their right to file a written complaint with the QIO in the State where services are being or were provided about the quality of care they are receiving or have received. In addition, the new standard would require the CAH to provide the beneficiary with the name, telephone number, electronic mail address, and mailing address of the QIO, and to document in the beneficiary's record that the CAH has presented the written notice to the beneficiary or beneficiary's representative or surrogate.

H. Clinics and Rehabilitation Agencies, and Public Health Agencies as Providers of Outpatient Physical Therapy and Speech-Language Pathology Services (§ 485.709)

Under section 1861(p) of the Act, the Secretary has established CoPs that clinics and rehabilitation agencies must meet when they provide outpatient physical therapy (OPT) and speech-

language pathology services. Section 1861(p) of the Act describes "outpatient physical therapy services" to mean physical therapy services furnished by a provider of services, a clinic or rehabilitation agency, or by others under an arrangement with, and under the supervision of, such provider, clinic or rehabilitation agency to an individual as an outpatient. The patient must also be under the care of a physician.

The term also includes speech-language pathology services furnished by a provider of services, a clinic, or a rehabilitation agency, or by others under an arrangement. There are 2,781 Medicare certified clinics and rehabilitation agencies that provide outpatient physical therapy and speech-language pathology services.

The current regulations at § 485.701 through § 485.729 do not contain patient rights requirements, therefore, we are proposing to revise the administrative management requirements by adding two new standards at § 485.709(e) and § 485.709(f). The first proposed standard would require that the clinic or rehabilitation agency provide all patients with the mailing address, electronic mail address, and telephone number of the State survey agency in order to permit patients to report complaints. The second proposed standard would require the clinics or rehabilitation agencies to inform all Medicare beneficiaries by written notice, at the time of initiation of treatment, of their right to file a written complaint with the QIO in the State where services are being or were provided about the quality of care they are receiving or have received. In addition, the new standard would require the facility to provide the beneficiary with the name, telephone number, electronic mail address, and mailing address of the QIO, and would require that clinics or rehabilitation agencies document in the beneficiary's record that they have presented the written notice to the beneficiary or beneficiary's representative or surrogate.

I. Portable X-Ray Services (§ 486.100)

The Conditions for Coverage (CfC) for portable x-ray services are specified under section 1861(s)(3) of the Act and were adopted in January 1969. X-ray services are provided under the supervision of a qualified physician. Diagnostic x-ray services furnished by a portable x-ray supplier are covered under Medicare when furnished in a place of residence used as the patient's home. Suppliers of portable x-ray services must conform to the requirements specified at § 486.100 through § 486.110.

We are proposing to amend the requirements at § 486.106 by adding new standards at § 486.106(d) and (e). The first proposed new standard would require suppliers of portable x-ray services to provide patients with the mailing address, electronic mail address, and telephone number of the State survey agency to report complaints. The second proposed standard would require the suppliers to inform all Medicare beneficiaries by written notice, at the time services are provided, of their right to file a written complaint with the QIO in the State where services are being or were provided about the quality of care they are receiving or have received. In addition, the new standard would require the supplier to provide beneficiaries with the name, telephone number, electronic mail address, and mailing address of the QIO, and to document in the beneficiary's record that they presented written notice to the beneficiary or beneficiary's representative or surrogate.

J. Rural Health Clinics: Conditions for Certification; and FQHCs Conditions for Coverage (§ 491.9)

Rural Health Clinics (RHCs) and Federally Qualified Health Centers (FQHCs) under section 1861(aa) of the Act were established to improve and maintain primary care for rural and underserved communities. To qualify as an RHC, a facility must be located in a medically underserved area (MUA), a health professional shortage area (HPSA) either by population or geographic area or location, or a State Governor-designated shortage area. To qualify as an FQHC, a facility may be located in either an urban or rural area. The distinction between urban and rural is based on whether or not the area in which a clinic is located is part of a Metropolitan Statistical Area.

Primary health care services for RHCs and FQHCs are defined as the treatment of acute or chronic medical problems which usually brings a patient to a physician's office. An RHC may be any primary care practice (for example, family practice, pediatric, obstetrics, gynecology, or internal medicine). An FQHC must provide primary care for all life-cycle ages. Therefore, primary care specialty practices are not eligible for FQHC status unless they provide primary care for all life-cycles. The FQHC program is funded under Section 330 of the Public Health Service Act.

RHCs and FQHCs improve access to primary health care in rural or underserved communities and promote a collaborative model of health care delivery using physicians and non-physician practitioners. Currently, there are 3,758 Medicare-approved RHCs and approximately 4,384 FQHCs. To qualify for Medicare reimbursement, RHCs and FQHCs must comply with conditions for certification and CfCs, respectively, at CFR part 491, subpart A. The current conditions for RHCs and FQHCs, are located at § 491.1 through § 491.11.

We are proposing to revise the provision of services condition at § 491.9 by adding two new standards at § 491.9(e) and (f). The first proposed new standard would require the clinic or center to provide all patients with the mailing address, electronic mail address, and telephone number of the State survey agency in order to allow patients to report complaints. The second proposed standard would require RHCs and FQHCs to inform all Medicare beneficiaries by written notice, at the time of service, of their right to file a written complaint with the QIO in the State where services are being or were provided about the quality of care they are receiving or have received. In addition, the RHC or FQHC would be required to provide beneficiaries with the name, telephone number, electronic mail address, and mailing address of the QIO, and to document in the beneficiary's record that they have presented the written notice to the beneficiary or beneficiary's representative or surrogate.

IV. Collection of Information Requirements

Under the Paperwork Reduction Act of 1995 (PRA), we are required to provide 60-day notice in the **Federal Register** and solicit public comment before a collection of information requirement is submitted to the Office of Management and Budget (OMB) for review and approval. In order to fairly evaluate whether an information collection should be approved by OMB, section 3506(c)(2)(a) of the PRA requires that we solicit comment on the following issues:

- The need for the information collection and its usefulness in carrying out the proper functions of our agency.
- The accuracy of our estimate of the information collection burden.
- The quality, utility, and clarity of the information to be collected.
- Recommendations to minimize the information collection burden on the affected public, including automated collection techniques.

We are soliciting public comment on each of these issues for the following sections of this document:

A. ICRs Regarding Condition for Coverage: Patient Rights—Ambulatory Surgical Centers (ASCs) (§ 416.50)

Proposed § 416.50(c)(1) would require that at the time of admission, an ASC must inform all Medicare beneficiaries by written notice of their right to file a written complaint with the QIO in the State where services are being or were provided about the quality of care they are receiving or have received. Proposed § 416.50(c)(3) would require the ASC to document that the written notice was presented to the beneficiary, beneficiary's representative or surrogate. The burden associated with these requirements is the time and effort associated with developing and distributing a standard written notice and documenting receipt of the notice.

We believe 5,174 ASCs must comply with these requirements. We estimate that proposed § 416.50 will impose a one-time 2 hour burden for the development of a standard written notice containing the name, address, and telephone number of the QIO. The total burden associated with this task is 10,348 hours. Similarly, we estimate that each ASC will distribute approximately 1,224 notices per year for a total of 6,332,976 annual notices. We estimate that it will take a total of 5 minutes to notify the beneficiary, beneficiary's representative or surrogate and to document distribution of the notification. The estimated annual burden for this requirement is 527,748 hours. The total estimated annual burden associated with all of the requirements in proposed § 416.50 is 538,096 hours. The total cost associated with this requirement is $18,978,232.

B. ICRs Regarding Condition of Participation: Patient's Rights—Hospices (§ 418.52)

Proposed § 418.52(c)(9) would require that hospices provide patients with the address and telephone number of the State survey agency to report complaints. Proposed § 418.52(d)(1) would require that at the time of admission, a hospice must inform all Medicare beneficiaries by written notice of their right to file a written complaint to the QIO in the State where services are being or were provided about the quality of care they are receiving or have received. Proposed § 418.52(d)(3) would require the hospice to document that the written notice was presented to the beneficiary, the beneficiary's representative or surrogate. The burden associated with these requirements is the time and effort associated with developing and distributing a standard written notice and documenting the receipt of the notice.

We believe 3,346 hospice facilities must comply with these requirements. We estimate that proposed § 418.52 will impose a one-time 2-hour burden for the development of a standard written notice containing the address and telephone number of the State survey agency and the name, address, and telephone number of the QIO. The total burden associated with this task is 6,692 hours. Similarly, we estimate that each hospice will distribute approximately 314 notices per year for a total of 1,050,644 annual notices. We estimate that it will take a total of 5 minutes to notify the beneficiary, the beneficiary's representative or surrogate and to document the distribution of the notice. The estimated annual burden for this requirement is 87,554 hours. The total estimated annual burden associated with all of the requirements in proposed § 418.52 is 94,246 hours. The total cost associated with this requirement is $3,392,298.

C. ICRs Regarding Patients Rights—Hospitals (§ 482.13)

Proposed § 482.13(a)(1)(i) would require that hospitals provide patients with the address and telephone number of the State survey agency to report complaints. We believe a total of 4,859 hospitals must comply with this requirement. We estimate that proposed § 482.13 will impose a one-time one hour burden for the development of a standard written notice containing the address and telephone number of the State survey agency. The total burden associated with this task is 4,859 hours at a cost of $238,091. This notice can be incorporated into existing admission paperwork documents that are already required and given to the beneficiary, beneficiary's representative or surrogate, therefore we are not assigning additional burden hours.

Proposed § 482.13(a)(1)(ii) would require that at the time of inpatient admission or outpatient service, the hospital must inform all Medicare beneficiaries by written notice of their right to file a written complaint with the QIO in the State where services are being or were provided about the quality of care they are receiving or have received.

Proposed § 482.13(a)(1)(ii) would also require the hospital to document that the written notice was presented to the beneficiary, beneficiary's representative or surrogate. The burden associated with these requirements is the time and effort associated with developing and distributing a standard written notice and documenting the distribution of the notice.

We believe 4,859 hospitals must comply with these requirements. We estimate that proposed § 482.13 will impose a one-time two hour burden for the development of a standard written notice containing the name, address, and telephone number of the QIO. The total burden associated with this task is 9,718 hours. Similarly, we estimate that each hospital will distribute approximately 228 notices per year for a total of 1,107,852 annual notices. We estimate that it will take a total of 5 minutes to notify the beneficiary, the beneficiary's representative or surrogate and to document the distribution of the notice. The estimated annual burden for this requirement is 92,321 hours at a cost of $3,231,235. The total estimated annual burden associated with all of the requirements in proposed § 482.13 is 102,039 hours. The total cost associated with this requirement is $3,707,417.

D. ICRs Regarding Resident Rights—Long Term Care Facilities (§ 483.10)

Proposed § 483.10(c)(1) would require that at the time of admission, a LTC facility must inform all Medicare beneficiaries by written notice of their right to file a written complaint with the QIO in the State where services are being or were provided about the quality of care they are receiving or have received. Proposed § 483.10(c)(3) would require the LTC facility to document that the written notice was presented to the beneficiary, beneficiary's representative or surrogate. The burden associated with these requirements is the time and effort associated with developing and distributing a standard written notice and documenting the distribution of the notice.

We believe 15,727 LTC facilities must comply with these requirements. We estimate that proposed § 483.10 will impose a one-time 2 hour burden for the development of a standard written notice containing the name, address, and telephone number of the QIO. The total burden associated with this task is 31,454 hours. Similarly, we estimate that each LTC facility will distribute approximately 89 notices per year for a total of 1,399,703 annual notices. We estimate that it will take a total of 5 minutes to notify the beneficiary, the beneficiary's representative or surrogate and to document the distribution of the notice. The estimated annual burden for this requirement is 116,642 hours. The total estimated annual burden associated with all of the requirements in proposed § 483.10 is 148,096 hours. The total cost associated with this requirement is $5,623,716.

E. ICRs Regarding Condition of Participation: Patient Rights—Home Health Agencies (§ 484.10)

Proposed § 484.10(c)(1) would require that at the time of initiation of treatment, an HHA must inform all Medicare beneficiaries by written notice of their right to file a written complaint with the QIO in the State where services are being or were provided about the quality of care they are receiving or have received. Proposed § 484.10(c)(3) would require the HHA to document that the written notice was presented to the beneficiary, beneficiary's representative or surrogate. The burden associated with these requirements is the time and effort associated with developing and distributing a standard written notice and to document the distribution of the notice.

We believe 9,787 HHAs must comply with these requirements. We estimate that proposed § 484.10 will impose a one-time 2 hour burden for the development of a standard written notice containing the name, address, and telephone number of the QIO. The total burden associated with this task is 19,574 hours. Similarly, we estimate that each HHA will distribute approximately 625 notices per year for a total of 6,116,875 annual notices. We estimate that it will take a total of 5 minutes to notify the beneficiary, beneficiary's representative or surrogate and to document the distribution of the notice. The estimated annual burden for this requirement is 509,739 hours. The total estimated annual burden associated with all of the requirements in proposed § 484.10 is 529,313 hours. The total cost associated with this requirement is $18,799,991.

F. ICRs Regarding Condition of Participation: Governing Body and Administration—Comprehensive Outpatient Rehabilitation Facilities (§ 485.56)

Proposed § 485.56(e)(11) would require that the CORF provide patients with the address and telephone number of the State survey agency to report complaints. Proposed § 485.56(g)(1) would require that at the time of initiation of treatment, a CORF must inform all Medicare beneficiaries by written notice of their right to file a written complaint to the QIO in the State where services are being or were provided about the quality of care they are receiving or have received. Proposed § 485.56(g)(3) would require the CORF to document that the written notice was presented to the beneficiary, beneficiary's representative or surrogate. The burden associated with these requirements is the time and effort associated with developing and distributing a standard written notice and documenting the distribution of the notice.

We believe 476 CORFs must comply with these requirements. We estimate that proposed § 485.56 will impose a one-time 2 hour burden for the development of a standard written notice containing the address and telephone number of the State survey agency and the name, address, and telephone number of the QIO. The total burden associated with this task is 952 hours. Similarly, we estimate that each CORF will distribute approximately 13 notices per year for a total of 6,118 annual notices. We estimate that it will take a total of 5 minutes to notify the beneficiary, the beneficiary's representative or surrogate and to document distribution of the notice. The estimated annual burden for this requirement is 516 hours. The total estimated annual burden associated with all of the requirements in proposed § 485.56 is 1,468 hours. The total cost associated with this requirement is $64,708.

G. ICRs Regarding Condition of Participation: Organizational Structure—Critical Access Hospitals (§ 485.627)

Proposed § 485.627(c) would require that the CAHs provide all patients with the address and telephone number of the State survey agency to report complaints. Proposed § 485.627(d)(1) would require that at the time of service, the CAH must inform all outpatient Medicare beneficiary patients by written notice of their right to file a written complaint to the QIO in the State where services are being or were provided about the quality of care they are receiving or have received. Proposed § 485.627(d)(3) would require the CAH to document that the written notice was presented to the beneficiary, beneficiary's representative or surrogate. The burden associated with these requirements is the time and effort associated with developing and distributing a standard written notice and documenting the distribution of the notice.

We believe a total of 1310 CAHs must comply with these requirements. We estimate that proposed § 485.627 will impose a one-time 2 hour burden for the development of a standard written notice containing the address and telephone number of the State survey agency and the name, address, and telephone number of the QIO. The total burden associated with this task is 2620 hours. Similarly, we estimate that each CAH will distribute approximately 1000 notices per year for a total of 1,310,000 annual notices. We estimate that it will take a total of 5 minutes to notify the beneficiary, the beneficiary's representative or surrogate and to document distribution of the notice for a total annual burden of 109,167. The estimated annual burden associated with all of the requirements in proposed § 485.627 is 111,787 hours. The total cost associated with this requirement is $3,949,225.

H. ICRs Regarding Condition of Participation: Administrative Management—Clinic and Rehabilitation Agencies (§ 485.709)

Proposed § 485.709(e) would require that the clinic or rehabilitation agency provide patients with the address and telephone number of the State survey agency to report complaints. Proposed § 485.709(f)(1) would require that at the time of initiation of treatment, the clinic or rehabilitation agency must inform all Medicare beneficiaries by written notice of their right to file a written complaint with the QIO in the State where services are being or were provided about the quality of care they are receiving or have received. Proposed § 485.709(f)(3) would require the clinic, or rehabilitation agency to document that the written notice was presented to the beneficiary, beneficiary's representative or surrogate. The burden associated with these requirements is the time and effort associated with developing and distributing a standard written notice and documenting the distribution of the notice.

We believe a total of 2,781 clinics and rehabilitation agencies must comply with these requirements. We estimate that proposed § 485.709 will impose a one-time 2 hour burden for the development of a standard written notice containing the address and telephone number of the State survey agency and the name, address, and telephone number of the QIO. The total burden associated with this task is 5,562 hours. Similarly, we estimate that each clinic or rehabilitation agency will distribute approximately 1,084 notices per year for a total of 3,014,604 annual notices. We estimate that it will take a total of 5 minutes to notify the beneficiary, the beneficiary's representative or surrogate and to document distribution of the notice. The estimated annual burden for this requirement is 251,217 hours at a cost of $8,792,595. The total estimated annual burden associated with all of the requirements in proposed § 485.709 is 256,779 hours. The total cost associated with this requirement is $9,065,133.

I. ICRs Regarding Condition for Coverage: Referral for service and preservation of records—Portable X-ray Services (§ 486.106)

Proposed § 486.106(d) would require that the supplier of portable x-ray services provide patients with the address and telephone number of the State survey agency to report complaints. Proposed § 486.106(e)(1) would require that at the time that services are provided, a supplier of portable x-ray services must inform all Medicare beneficiaries by written notice of their right to file a written complaint about the quality of care they are receiving or have received to the QIO in the State where services are being or were provided. Proposed § 486.106(e)(3) would require the supplier of portable x-ray services to document that the written notice was presented to the beneficiary, beneficiary's representative or surrogate. The burden associated with these requirements is the time and effort associated with developing and distributing a standard written notice and documenting the distribution of the notice.

We believe 547 suppliers of portable x-ray services must comply with these requirements. We estimate that proposed § 486.106 will impose a one-time 2 hour burden for the development of a standard written notice containing the address and telephone number of the State survey agency and the name, address, and telephone number of the QIO. The total burden associated with this task is 1,094 hours at a cost of $53,606. Similarly, we estimate that each supplier of portable x-ray services will distribute approximately 2,437 notices per year for a total of 1,333,039 annual notices. We estimate that it will take a total of 5 minutes to notify the beneficiary, the beneficiary's representative or surrogate and to document distribution of the notice. The estimated annual burden for this requirement is 111,086 hours at a cost of $3,888,010. The total estimated annual burden associated with all of the requirements in proposed § 486.106 is 112,180 hours. The total cost associated with this requirement is $3,941,616.

J. ICRs Regarding Provision of Services—Rural Health Clinics or Federally Qualified Health Centers (§ 491.9)

Proposed § 491.9(e) would require that the RHC or FQHC provide patients with the address and telephone number of the State survey agency to report complaints. Proposed § 491.9(f)(1) would require that at the time of service, an RHC or FQHC must inform all Medicare beneficiaries by written notice of their right to file a written complaint with the QIO in the State where services are being or were provided about the quality of care they are receiving or have received. Proposed § 491.9(f)(3) would require the RHC or FQHC to document that the written notice was presented to the beneficiary, beneficiary's representative or surrogate. The burden associated with these requirements is the time and effort associated with developing and distributing a standard written notice and documenting the distribution of the notice.

We believe a total of 8,142 RHCs or FQHCs must comply with these requirements. We estimate that proposed § 491.9 will impose a one-time 2 hour burden for the development of a standard written notice containing the address and telephone number of the State survey agency to report complaints and the name, address, and telephone number of the QIO. The total burden associated with this task is 16,284 hours at a cost of $797,916. Similarly, we estimate that each RHC or FQHC will distribute approximately 8 notices per year for a total of 65,136 annual notices. We estimate that it will take a total of 5 minutes to notify the beneficiary, the beneficiary's representative or surrogate and to document distribution of the notice. The estimated annual burden for this requirement is 5,428 hours at a cost of $189,980. The total estimated annual burden associated with all of the requirements in proposed § 491.9 is 21,712 hours. The total cost associated with this requirement is $987,896.

TABLE 1—ESTIMATED ANNUAL BURDEN FOR RECORDKEEPING AND REPORTING REQUIREMENTS

Regulation section	OMB Control No.	Respondents	Responses	Burden per response (hours)	Total annual burden (hours)	Hourly labor cost of reporting ($)	Total labor cost of reporting ($)	Total capital/maintenance costs ($)	Total costs ($)
§ 416.50(c)(1)	0938–New	5,174	5,174	2	10,348	49	507,052	0	507,052
§ 416.50(c)(3)	0938–New	5,174	6,332,976	.0833	527,748	35	18,471,180	0	18,471,180
§ 418.52(c)(9) & (d)(1).	0938–New	3,346	3,346	2	6,692	49	327,908	0	327,908
§ 418.52(d)(3)	0938–New	3,346	1,050,644	.0833	87,554	35	3,064,390	0	3,064,390
§ 482.13(a)(i)	0938–New	4,859	4,859	1	4,859	49	238,091	0	238,091
§§ 482.13(a)(1)(ii)	0938–New	4,859	4,859	2	9,718	49	476,182	0	476,182
§ 482.13(a)(1)(ii)	0938–New	4,859	1,107,852	.0833	92,321	35	3,231,235	0	3,231,235
§ 483.10(c)(1)	0938–New	15,727	15,727	2	31,454	49	1,541,246	0	1,541,246
§ 483.10(c)(3)	0938–New	15,727	1,399,703	.0833	116,642	35	4,082,470	0	4,082,470
§ 484.10(c)(1)	0938–New	9,787	9,787	2	19,574	49	959,126	0	959,126
§ 484.10(c)(3)	0938–New	9,787	6,116,875	.0833	509,739	35	17,840,865	0	17,840,865
§ 485.56(e)(11) & (g)(1).	0938–New	476	476	2	952	49	46,648	0	46,648
§ 485.56(g)(3)	0938–New	476	6,188	.0833	516	35	18,060	0	18,060
§ 485.627(c) & (d)(1).	0938–New	1,310	1,310	2	2,620	49	128,380	0	128,380
§ 485.627(d)(3)	0938–New	1,310	1,310,000	.0833	109,167	35	3,820,845	0	3,820,845
§ 485.709(e) & (f)(1).	0938–New	2,781	2,781	2	5,562	49	272,538	0	272,538
§ 485.709(f)(3)	0938–New	2,781	3,014,604	.0833	251,217	35	8,792,595	0	8,792,595
§ 486.106(d) & (e)(1).	0938–New	547	547	2	1,094	49	53,606	0	53,606
§ 486.106(e)(3)	0938–New	547	1,333,039	.0833	111,086	35	3,888,010	0	3,888,010
§ 491.9(e) & (f)(1)	0938–New	8,142	8,142	2	16,284	49	797,916	0	797,916
§ 491.9(f)(3)	0938–New	8,142	65,136	.0833	5,428	35	189,980	0	189,980
Total		52,149	21,794,025		1,920,575				68,748,323

We have submitted a copy of this proposed rule to OMB for its review of the information collection requirements contained within this document. These requirements are not effective until they are approved by OMB.

If you comment on these information collection and recordkeeping requirements, please do either of the following:

1. Submit your comments electronically as specified in the **ADDRESSES** section of this proposed rule; or

2. Submit your comments to the Office of Information and Regulatory Affairs, Office of Management and Budget, Attention: CMS Desk Officer, CMS–3225–P; Fax: (202) 395–6974; or E-mail: *OIRA_submission@omb.eop.gov.*

V. Response to Comments

Because of the large number of public comments we normally receive on **Federal Register** documents, we are not able to acknowledge or respond to them individually. We will consider all comments we receive by the date and time specified in the **DATES** section of this preamble, and, when we proceed with a subsequent document, we will respond to the comments in the preamble to that document.

VI. Regulatory Impact Statement (or Analysis)

A. Overall Impact

We have examined the impact of this rule as required by Executive Order 12866 (September 1993, Regulatory Planning and Review), the Regulatory Flexibility Act (RFA) (September 19, 1980, Pub. L. 96–354), section 1102(b) of the Social Security Act, the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4), and Executive Order 13132.

Executive Order 12866 (as amended by Executive Order 13258, which merely reassigns responsibility of duties) directs agencies to assess all costs and benefits or available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). A regulatory impact analysis (RIA) must be prepared for major rules with economically significant effects ($100 million or more in any 1 year). We have examined the impact of this proposed rule, and we have determined that this rule is neither expected to meet the criteria to be considered economically significant, nor do we believe it will meet the criteria for a major rule.

This proposed rule would set forth new requirements for certain Medicare certified providers and suppliers that do not provide hospital in-patient care. This rule will implement regulations that are intended to increase awareness by Medicare beneficiaries of their right to contact the QIO in their State about the quality of care they are currently receiving or have received. In addition, the Medicare certified providers and suppliers would be required to provide their Medicare beneficiaries with written notice of the QIOs contact information, and document that the written notice was presented to the beneficiary, beneficiary's representative or surrogate. The RFA requires agencies to analyze options for regulatory relief of small entities. For purposes of the RFA, small entities include small businesses, nonprofit organizations, and small government jurisdictions. Individuals and States are not included in the definition of small entity. Most Medicare certified providers and suppliers are small entities, either by nonprofit status or by having revenues of $6 million to $29 million in any 1 year. For purposes of the RFA, most entities affected by this proposed rule are considered small businesses according to the Small Business Administration's size standards, with total revenues of $29 million or less in any 1 year (for details, see 65 FR 96432). We are not preparing analyses for either the RFA or section 1102(b) of the Act because we have determined, and we certify, that this rule will not have a significant economic impact on a substantial number of small entities or a significant impact on the operations of a substantial number of small rural facilities.

Section 202 of the unfunded Mandates Reform Act of 1995 also requires that agencies assess anticipated costs and benefits before issuing any rule that may result in expenditures in any year by state, local or tribal governments, in the aggregate, or by the private sector, of $120 million. This rule has no impact on the expenditures of State, local, or tribal governments, and the impact on the private sector is estimated to be less than $120 million.

Executive Order 13132 establishes certain requirements that an agency must meet when it promulgates a proposed rule (and subsequent final rule) that imposes substantial direct requirement costs on State and local governments, preempts State law, or otherwise has Federalism implications. This rule will not have any effect on State and local governments and does not have any Federalism implications.

B. Anticipated Effects

As described in the preamble, the proposed regulation will require ten different Medicare certified providers and suppliers to notify their Medicare beneficiaries by written notice of their right to contact the QIO in the State where services are being or were provided about the quality of care they are receiving or have received. Six of the eleven Medicare certified providers and suppliers that would be affected by this proposed rule already have a current patient rights condition that would be amended by this proposed rule. We believe that those Medicare certified providers and suppliers will be able to incorporate the proposed requirements into their normal business practices, and that the requirements will not present a significant additional workflow burden.

All Medicare certified providers and suppliers covered by this proposed rule would have to meet the notification of QIO rights standard by informing Medicare beneficiaries by written notice at the start of care (or for some providers or suppliers, at the time of inpatient admission or at an initial assessment visit in advance of furnishing care) of their right to file a written complaint to the QIO in the State where services are being or were provided regarding the quality of care they are receiving or have received. The written notice must contain the name of the QIO, its mailing address, electronic address and telephone number.

We recognize that in describing the effect of this rule on the different Medicare certified providers and suppliers, suggested burden estimates may not accurately reflect the experience of all of them. Facilities vary in the complexity of operations and processes, and therefore, associated costs may differ.

Table 2 contains data that is frequently used in this impact statement. The salary-related cost data is referenced from the *Salarywizard.com* Web site at *http://hrsalarycenter.salary.com.*

TABLE 2—ASSUMPTIONS AND ESTIMATES USED THROUGHOUT THE IMPACT ANALYSIS SECTION

Provider or supplier type	Number of providers or suppliers	Estimated annual Medicare beneficiary notifications
Clinics, Rehab agencies, Outpatient Physical Therapy	2,781	3,014,604
Comprehensive Outpatient Rehabilitation Facilities	476	6,188
Home Health Agencies	9,787	6,116,875
Hospices	3,346	1,050,644
Long Term Care Facilities	15,727	1,399,703
Hospitals	4,859	1,107,852
Critical Access Hospitals	1,310	1,310,000
Ambulatory Surgical Centers	5,174	6,332,976
Portable X-ray Services	547	1,333,039
Rural Health Clinics and Federally Qualified Health Centers	8,142	65,136

Job description/title	Hourly rate
Administrator	$49
Registered Nurse	35

Note: All salary estimates include a benefits package worth 30% of the fringe base salary.

We estimate that an administrator, earning $49.00 per hour, would be largely responsible for developing the written notice and ensuring the accuracy of the information that will be given to Medicare beneficiaries. We believe that Medicare certified providers and suppliers will use the approved Federal IM notice as an example to develop their written notice in order to avoid time spent on re-creating a similar document. We estimate that the one-time cost for one provider or supplier to develop and implement Medicare beneficiary notification of QIO rights and State agency contact information will be approximately 2 hours at $49.00 per hour for a total cost of $98.00.

We estimate that it will take a registered nurse approximately five minutes to provide each Medicare beneficiary with the written notice and document that the written notice was presented to the beneficiary, beneficiary's representative or surrogate. At the average hourly rate for a registered nurse ($35.00), it will cost $3 per patient to fulfill the requirement. The total cost to implement the requirement of presenting and documenting the written QIO notice to the Medicare Beneficiary for all ten Medicare certified providers and suppliers would be $68,748,323. 2 hours × $49 an hour = $98. $35 hour/60 minutes = $0.58 minutes × 5 minutes = $3.

TABLE 3—MEDICARE BENEFICIARY NOTIFICATION OF QIO RIGHTS BURDEN ASSESSMENT

Provider or supplier type	Time per patient (min.)	Time for all patients (hours)	Cost per patient	Cost for all patients
Clinics, Rehab Agencies, Outpatient Physical Therapy	5	251,117	$3.00	$9,065,133
Critical Access Hospitals	5	109,167	3.00	3,949,225
Comprehensive Outpatient Rehabilitation Facilities	5	516	3.00	64,708
Home Health Agencies	5	509,739	3.00	18,799,991
Hospices	5	87,554	3.00	3,392,298
Hospitals	5	92,231	3.00	3,707,417
Long term Care Facilities	5	116,642	3.00	5,623,716
Ambulatory Surgical Centers	5	527,748	3.00	18,978,232
Portable X-ray Services	5	111,086	3.00	3,941,616
Rural Health Clinics & Federally Qualified Health Centers	5	5,428	3.00	987,896
Total Cost (including one-time development of the QIO written notice)	N/A	N/A	N/A	68,748,323

In accordance with the provisions of Executive Order 12866, this regulation was reviewed by the Office of Management and Budget.

List of Subjects

42 CFR Part 416

Health facilities, Health professions, Medicare, Reporting and recordkeeping requirements.

42 CFR Part 418

Health facilities, Hospice care, Medicare, Reporting and recordkeeping requirements.

42 CFR Part 482

Grant programs—health, Hospitals, Medicaid, Medicare, Reporting and recordkeeping requirements

42 CFR Part 483

Grant programs—health, Health facilities, Health professions, Health records, Medicaid, Medicare, Nursing homes, Nutrition, Reporting and recordkeeping requirements, Safety.

42 CFR Part 484

Health facilities, Health professions, Medicare, Reporting and recordkeeping requirements.

42 CFR Part 485

Grant programs—health, Health facilities, Medicaid, Medicare, Reporting and recordkeeping requirements.

Critical Access Hospitals?

42 CFR Part 486

Grant programs—health, Health facilities, Medicare, Reporting and recordkeeping requirements, X-rays.

42 CFR Part 491

Grant programs—health, Health facilities, Medicaid, Medicare, Reporting and recordkeeping requirements, Rural areas.

For the reasons set forth in the preamble, the Centers for Medicare & Medicaid Services propose to amend 42 CFR chapter IV as set forth below:

PART 416—AMBULATORY SURGICAL SERVICES

1. The authority citation for part 416 continues to read as follows:

Authority: Secs. 1102 and 1871 of the Social Security Act (42 U.S.C. 1302 and 1395hh).

Subpart C—Specific Conditions for Coverage

2. Section 416.50 is amended by redesignating paragraphs (c) and (d) as paragraphs (d) and (e), respectively, and adding a new paragraph (c) to read as follows:

§ 416.50 Condition for coverage—Patient rights.

* * * * *

(c) *Standard: Notification of the right to access a Quality Improvement Organization (QIO).* (1) At the time of admission, the ASC must inform all Medicare beneficiaries by written notice of their right to file a written complaint with the QIO in the State where services are being or were provided about the quality of care they are receiving or have received.

(2) The written notice must contain the name of the QIO, its mailing address, electronic mail address, and telephone number.

(3) The ASC must document in the beneficiary's record that the written notice was presented to the beneficiary or beneficiary's representative or surrogate.

* * * * *

PART 418—HOSPICE CARE

3. The authority citation for part 418 continues to read as follows:

Authority: Secs. 1102 and 1871 of the Social Security Act (42 U.S.C. 1302 and 1395hh).

Subpart C—Conditions of Participation: Patient Care

4. Section 418.52 is amended by adding paragraphs (c)(9) and (d) to read as follows:

§ 418.52 Condition of participation: Patient's rights.

* * * * *

(c) * * *

(9) Receive the mailing address, electronic mail address, and telephone number of the State survey agency to report complaints.

(d) *Standard: Notification of the right to access a Quality Improvement Organization (QIO).* (1) During the initial assessment visit in advance of furnishing care, the hospice must inform all Medicare beneficiaries by written notice of their right to file a written complaint with the QIO in the State where services are being or were provided about the quality of care they are receiving or have received to the QIO in the State where services are being or were provided.

(2) The written notice must contain the name of the QIO, its mailing address, electronic mail address, and telephone number.

(3) The hospice must document in the beneficiary's record that the written notice was presented to the beneficiary or beneficiary's representative or surrogate.

PART 482—CONDITIONS OF PARTICIPATION FOR HOSPITALS

5. The authority citation for part 482 continues to read as follows:

Authority: Secs. 1102, 1871 and 1881 of the Social Security Act (42 U.S.C. 1302, 1395hh, and 1395rr), unless otherwise noted.

Subpart B—Administration

6. Section 482.13 is amended by adding paragraphs (a)(1)(i) and (ii) to read as follows:

§ 482.13 Condition of participation: Patients rights.

(a) * * *

(1) * * *

(i) The hospital must provide all patients with the mailing address, electronic mail address and telephone number of the State survey agency to report complaints.

(ii) At the time of inpatient admission or outpatient service, the hospital must inform all Medicare beneficiaries by written notice of their right to file a written complaint with the QIO in the State where services are being or were provided about the quality of care they are receiving or have received.

(A) The written notice must contain the name of the QIO, its mailing address, electronic mail address, and telephone number.

(B) The hospital must document in the beneficiary's record that the written notice was presented to the beneficiary or beneficiary's representative or surrogate.

PART 483—REQUIREMENTS FOR STATES AND LONG TERM CARE FACILITIES

8. The authority citation for part 483 continues to read as follows:

Authority: Secs. 1102 and 1871 of the Social Security Act (42 U.S.C. 1302 and 1395hh).

Subpart B—Requirements for Long Term Care Facilities

9. Section 483.10 is amended by—

A. Redesignating paragraphs (c) through (o) as paragraphs (d) through paragraphs (p).

B. Adding a new paragraph (c).

The addition reads as follows:

§ 483.10 Resident rights.

* * * * *

(c) *Standard: Notification of the right to access a Quality Improvement Organization (QIO).* (1) At the time of admission, the LTC facility must inform all Medicare beneficiaries by written notice of their right to file a written complaint with the QIO in the State where services are being or were provided about the quality of care they are receiving or have received.

(2) The written notice must contain the name of the QIO, its mailing address, electronic mail address, and telephone number.

(3) The LTC facility must document in the beneficiary's record that the written notice was presented to the beneficiary or beneficiary's representative or surrogate.

* * * * *

PART 484—HOME HEALTH SERVICES

10. The authority citation for part 484 continues to read as follows:

Authority: Secs. 1102 and 1871 of the Social Security Act (42 U.S.C. 1302 and 1395(hh)) unless otherwise indicated.

Subpart B—Administration

11. Section 484.10 is amended by—

A. Redesignating paragraphs (c) through (f) as paragraphs (d) through (g).

B. Adding a new paragraph (c).

The addition reads as follows:

§ 484.10 Condition of participation: Patient rights.

* * * * *

(c) *Standard: Notification of the right to access a Quality Improvement Organization (QIO).* (1) At the time of initiation of treatment, the HHA must inform all Medicare beneficiaries by written notice of their right to file a written complaint with the QIO in the State where services are being or were provided about the quality of care they are receiving or have received.

(2) The written notice must contain the name of the QIO, its mailing address, electronic mail address, and telephone number.

(3) The HHA must document in the beneficiary's record that the written

notice was presented to the beneficiary or beneficiary's representative or surrogate.

* * * * *

PART 485—CONDITIONS OF PARTICIPATION: SPECIALIZED PROVIDERS

12. The authority citation for part 485 continues to read as follows:

Authority: Secs. 1102 and 1871 of the Social Security Act (42 U.S.C. 1302 and 1395(hh)).

Subpart B—Conditions of Participation: Comprehensive Outpatient Rehabilitation Facilities

13. Section 485.56 is amended by adding paragraphs (e)(11) and (g) to read as follows:

§ 485.56 Condition of participation: Governing body and administration.

* * * * *

(e) * * *

(11) A requirement that patients receive the mailing address, electronic mail address, and telephone number of the State survey agency to report complaints.

(g) *Standard: Notification of the right to access a Quality Improvement Organization (QIO).* (1) At the time of initiation of treatment, the CORF must inform all Medicare beneficiaries by written notice of their right to file a written complaint with the QIO in the State where services are being or were provided about the quality of care they are receiving or have received.

(2) The written notice must contain the name of the QIO, its mailing address, electronic mail address, and telephone number.

(3) The CORF must document in the beneficiary's record that the written notice was presented to the beneficiary or beneficiary's representative or surrogate.

Subpart F—Conditions of Participation: Critical Access Hospitals (CAHs)

14. Section 485.627 is amended by adding paragraphs (c) and (d) to read as follows:

§ 485.627 Condition of participation: Organizational structure.

* * * * *

(c) *Standard: Patient complaints.* The CAH must provide all hospital outpatients with the mailing address, electronic mail address and telephone number of the State survey agency to report complaints.

(d) *Standard: Notification of the right to access a Quality Improvement Organization (QIO).* (1) At the time of service, the CAH must inform all outpatient Medicare beneficiaries by written notice of their right to file a written complaint with the QIO in the State where services are being or were provided about the quality of care they are receiving or have received.

(2) The written notice must contain the name of the QIO, its mailing address, electronic mail address, and telephone number.

(3) The CAH must document in the beneficiary's record that the written notice was presented to the beneficiary or beneficiary's representative or surrogate.

Subpart H—Conditions of Participation for Clinics, Rehabilitation Agencies, and Public Health Agencies as Providers of Outpatient Physical Therapy and Speech-Language Pathology Services

15. Section 485.709 is amended by adding paragraphs (e) and (f) to read as follows:

§ 485.709 Condition of participation: Administrative management.

* * * * *

(e) *Standard: Patient complaints.* The clinic or rehabilitation agency must provide patients with the mailing address, electronic mail address, and telephone number of the State survey agency to report complaints.

(f) *Standard: Notification of the right to access a Quality Improvement Organization (QIO).* (1) At the time of initiation of treatment, the clinic or rehabilitation agency must inform all Medicare beneficiaries by written notice of their right to file a written complaint with the QIO in the State where services are being or were provided about the quality of care they are receiving or have received.

(2) The written notice must contain the name of the QIO, its mailing address, electronic mail address, and telephone number.

(3) The clinic or rehabilitation agency must document in the beneficiary's record that the written notice was presented to the beneficiary or beneficiary's representative or surrogate.

PART 486—CONDITIONS FOR COVERAGE OF SPECIALIZED SERVICES FURNISHED BY SUPPLIERS

17. The authority citation for part 486 continues to read as follows:

Authority: Secs. 1102, 1138, and 1871 of the Social Security Act (42 U.S.C. 1302, 1320b–8, and 1395hh) and section 371 of the Public Health Service Act (42 U.S.C. 273).

Subpart C—Conditions for Coverage: Portable X-Ray Services

18. Section 486.106 is amended by adding paragraphs (d) and (e) to read as follows:

§ 486.106 Condition for coverage: Referral for service and preservation of records.

* * * * *

(d) *Standard: Patient complaints.* The supplier of portable x-ray services must provide patients with the mailing address, electronic mail address, and telephone number of the State survey agency to report complaints.

(e) *Standard: Notification of the right to access a Quality Improvement Organization (QIO).* (1) At the time services are provided, the supplier of portable x-ray services must inform all Medicare beneficiaries by written notice of their right to file a written complaint with the QIO in the State where services are being or were provided about the quality of care they are receiving or have received.

(2) The written notice must contain the name of the QIO, its mailing address, electronic mail address, and telephone number.

(3) The supplier of portable x-ray services must document in the beneficiary's record that the written notice was presented to the beneficiary or beneficiary's representative or surrogate.

PART 491—CERTIFICATION OF CERTAIN HEALTH FACILITIES

19. The authority citation for part 491 continues to read as follows:

Authority: Sec. 1102 of the Social Security Act (42 U.S.C. 1302); and sec. 353 of the Public Health Service Act (42 U.S.C. 263a).

Subpart A—Rural Health Clinics: Conditions for Certification; and FQHCs Conditions for Coverage

20. Section 491.9 is amended by adding paragraphs (e) and (f) to read as follows:

§ 491.9 Provision of services.

* * * * *

(e) *Standard: Patient complaints.* The clinic or center must provide patients with the mailing address, electronic mail address, and telephone number of the State survey agency to report complaints.

(f) *Standard: Notification of the right to access a Quality Improvement Organization (QIO).* (1) At the time of service, the clinic or center must inform all Medicare beneficiaries by written notice of their right to file a written complaint with the QIO in the State where services are being or were

provided about the quality of care they are receiving or have received.

(2) The written notice must contain the name of the QIO, its mailing address, electronic mail address, and telephone number.

(3) The clinic or center must document in the beneficiary's record that the written notice was presented to the beneficiary or beneficiary's representative or surrogate.

(Catalog of Federal Domestic Assistance Program No. 93.773, Medicare—Hospital Insurance; and Program No. 93.774, Medicare—Supplementary Medical Insurance Program) (Catalog of Federal Domestic Assistance Program No. 93.778, Medical Assistance Program)

Dated: August 26, 2010.

Donald M. Berwick,

Administrator, Centers for Medicare & Medicaid Services.

Approved: January 27, 2011

Kathleen Sebelius,

Secretary.

[FR Doc. 2011–2275 Filed 2–1–11; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HOMELAND SECURITY

Federal Emergency Management Agency

44 CFR Part 67

[Docket ID FEMA–2011–0002; Internal Agency Docket No. FEMA–B–1174]

Proposed Flood Elevation Determinations

AGENCY: Federal Emergency Management Agency, DHS.

ACTION: Proposed rule.

SUMMARY: Comments are requested on the proposed Base (1% annual-chance) Flood Elevations (BFEs) and proposed BFE modifications for the communities listed in the table below. The purpose of this proposed rule is to seek general information and comment regarding the proposed regulatory flood elevations for the reach described by the downstream and upstream locations in the table below. The BFEs and modified BFEs are a part of the floodplain management measures that the community is required either to adopt or to show evidence of having in effect in order to qualify or remain qualified for participation in the National Flood Insurance Program (NFIP). In addition, these elevations, once finalized, will be used by insurance agents and others to calculate appropriate flood insurance premium rates for new buildings and the contents in those buildings.

DATES: Comments are to be submitted on or before May 3, 2011.

ADDRESSES: The corresponding preliminary Flood Insurance Rate Map (FIRM) for the proposed BFEs for each community is available for inspection at the community's map repository. The respective addresses are listed in the table below.

You may submit comments, identified by Docket No. FEMA–B–1170, to Luis Rodriguez, Chief, Engineering Management Branch, Federal Insurance and Mitigation Administration, Federal Emergency Management Agency, 500 C Street, SW., Washington, DC 20472, (202) 646–4064, or (e-mail) *luis.rodriguez1@dhs.gov.*

FOR FURTHER INFORMATION CONTACT: Luis Rodriguez, Chief, Engineering Management Branch, Federal Insurance and Mitigation Administration, Federal Emergency Management Agency, 500 C Street, SW., Washington, DC 20472, (202) 646–4064, or (e-mail) *luis.rodriguez1@dhs.gov.*

SUPPLEMENTARY INFORMATION: The Federal Emergency Management Agency (FEMA) proposes to make determinations of BFEs and modified BFEs for each community listed below, in accordance with section 110 of the Flood Disaster Protection Act of 1973, 42 U.S.C. 4104, and 44 CFR 67.4(a).

These proposed BFEs and modified BFEs, together with the floodplain management criteria required by 44 CFR 60.3, are the minimum that are required. They should not be construed to mean that the community must change any existing ordinances that are more stringent in their floodplain management requirements. The community may at any time enact stricter requirements of its own or pursuant to policies established by other Federal, State, or regional entities. These proposed elevations are used to meet the floodplain management requirements of the NFIP and also are used to calculate the appropriate flood insurance premium rates for new buildings built after these elevations are made final, and for the contents in those buildings.

Comments on any aspect of the Flood Insurance Study and FIRM, other than the proposed BFEs, will be considered. A letter acknowledging receipt of any comments will not be sent.

National Environmental Policy Act. This proposed 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.

Executive Order 12866, Regulatory Planning and Review. This proposed rule is not a significant regulatory action under the criteria of section 3(f) of Executive Order 12866, as amended.

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

Executive Order 12988, Civil Justice Reform. This proposed 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 proposed to be 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.

§ 67.4 [Amended]

2. The tables published under the authority of § 67.4 are proposed to be 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)		Communities affected
		Effective	Modified	
Benton County, Arkansas, and Incorporated Areas				
Blossom Way Creek	At the Osage/Turtle Creek confluence	+1205	+1204	City of Rogers.
	Approximately 0.4 mile upstream of 1st Street	+1347	+1346	
Brush Creek	Approximately 1,530 feet upstream of the Little Sugar Creek confluence.	None	+1095	City of Little Flock, City of Rogers, Unincorporated Areas of Benton County.
	Approximately 1,600 feet upstream of State Highway 94 North.	None	+1198	
Brush Creek Tributary	At the Brush Creek confluence	None	+1114	City of Little Flock.
	Approximately 0.37 mile upstream of the Brush Creek confluence.	None	+1131	
Cross Creek	Approximately 1,875 feet downstream of Willow Ridge Way.	None	+1249	City of Rogers.
	At the upstream side of Mills Lane	None	+1313	
Cross Creek Tributary 1	At the Cross Creek confluence	None	+1267	City of Rogers.
	Approximately 1,625 feet upstream of West Drive	None	+1307	
Cross Creek Tributary 2	At the Cross Creek Tributary 1 confluence	None	+1267	City of Rogers.
	Approximately 150 feet upstream of West Drive	None	+1310	
East Flint Creek	At the Flint Creek confluence	None	+1201	Town of Springtown, Unincorporated Areas of Benton County.
	Approximately 1,830 feet upstream of Aubrey Long Road.	None	+1211	
East Tributary of Blossom Way Creek.	At the Blossom Way Creek confluence	+1281	+1280	City of Rogers.
	Approximately 0.41 mile upstream of the Blossom Way Creek confluence.	None	+1303	
Flint Creek	Approximately 0.45 mile downstream of the North Flint Creek and East Flint Creek confluence.	None	+1193	Town of Springtown, Unincorporated Areas of Benton County.
	At the North Flint Creek and East Flint Creek confluence.	None	+1201	
Little Osage Creek (downstream reach).	Approximately 0.71 mile downstream of Southwest Regional Airport Boulevard.	None	+1163	City of Bentonville, Unincorporated Areas of Benton County.
	At the Little Osage Creek Tributary 2 confluence	None	+1182	
Little Osage Creek (upstream reach).	Approximately 390 feet downstream of Brookside Road.	None	+1219	City of Bentonville, City of Centerton.
	Approximately 600 feet upstream of the upstream crossing of West Fish Hatchery Road.	None	+1258	
Little Osage Creek Tributary 2.	Approximately 210 feet downstream of Southwest Opal Road.	None	+1182	City of Bentonville, Unincorporated Areas of Benton County.
	Approximately 0.5 mile downstream of Southwest I Street.	None	+1268	
Little Osage Creek Tributary 2.1.	At the Little Osage Creek Tributary 2 confluence	None	+1205	City of Bentonville, City of Centerton, Unincorporated Areas of Benton County.
	Approximately 1,510 feet upstream of Greenhouse Road.	None	+1244	
Little Osage Creek Tributary 2.1.1.	At the Little Osage Creek Tributary 2.1 confluence	None	+1228	City of Centerton.
	Approximately 0.68 mile upstream of the Little Osage Creek Tributary 2.1 confluence.	None	+1257	
Little Osage Creek Tributary 2.1.2.	At the Little Osage Creek Tributary 2.1 confluence	None	+1237	City of Centerton, Unincorporated Areas of Benton County.
	Approximately 0.52 mile upstream of the Little Osage Creek Tributary 2.1 confluence.	None	+1254	
North Flint Creek	At the Flint Creek confluence	None	+1201	Town of Springtown, Unincorporated Areas of Benton County.
	Approximately 0.55 mile upstream of the Flint Creek confluence.	None	+1212	
Osage Tributary 1	At the Osage/Turtle Creek confluence	+1196	+1194	City of Bentonville, City of Rogers.

Flooding source(s)	Location of referenced elevation**	* Elevation in feet (NGVD) + Elevation in feet (NAVD) # Depth in feet above ground ∧ Elevation in meters (MSL)		Communities affected
		Effective	Modified	
	At the downstream side of Riviera Road	+1256	+1257	
Osage Tributary 2	At the Osage Tributary 1 confluence	+1251	+1256	City of Bentonville, City of Rogers.
	Approximately 1,450 feet upstream of I–540	None	+1283	
Osage Tributary 3	At the Osage Tributary 1 confluence	+1268	+1269	City of Rogers.
	Approximately 1,550 feet upstream of I–540	None	+1284	
Osage Tributary 4	At the Osage/Turtle Creek confluence	+1190	+1189	City of Rogers, Unincorporated Areas of Benton County.
	Approximately 1,800 feet upstream of South Rainbow Road.	None	+1270	
Osage/Turtle Creek	Approximately 0.47 mile downstream of Southgate Road.	None	+1152	City of Cave Springs, City of Rogers, Unincorporated Areas of Benton County.
	Approximately 700 feet upstream of 5th Street	+1347	+1346	
Superior Tributary to Osage/Turtle Creek.	At the Osage/Turtle Creek confluence	+1284	+1288	City of Rogers.
	Approximately 50 feet downstream of Dixieland Road	+1310	+1309	
Tributary 1 to Blossom Way Creek.	At the Blossom Way Creek confluence	+1289	+1288	City of Rogers.
	At the downstream side of South 8th Street	None	+1331	
Tributary 2 to Blossom Way Creek.	At the Tributary 1 to Blossom Way Creek confluence	+1302	+1303	City of Rogers.
	Approximately 750 feet upstream of South 1st Street	None	+1333	
Turtle Creek Tributary	At the Osage/Turtle Creek confluence	+1277	+1276	City of Little Flock, City of Rogers.
	Approximately 1,580 feet upstream of 2nd Street	None	+1352	
Turtle Creek Tributary 1A	At the Turtle Creek Tributary confluence	None	+1324	City of Rogers.
	Approximately 1,050 feet upstream of West Easy Street.	None	+1355	
Unnamed Tributary to Puppy Creek.	Approximately 370 feet upstream of West Monroe Avenue.	None	+1273	City of Lowell.
	Approximately 300 feet upstream of Links Drive	None	+1285	
West Tributary to Blossom Way Creek.	At the Blossom Way Creek confluence	+1277	+1276	City of Rogers.
	Approximately 0.49 mile upstream of the Blossom Way Creek confluence.	None	+1303	

* National Geodetic Vertical Datum.
+ North American Vertical Datum.
# Depth in feet above ground.
∧ Mean Sea Level, rounded to the nearest 0.1 meter.
** BFEs to be changed include the listed downstream and upstream BFEs, and include BFEs located on the stream reach between the referenced locations above. Please refer to the revised Flood Insurance Rate Map located at the community map repository (see below) for exact locations of all BFEs to be changed.

Send comments to Luis Rodriguez, Chief, Engineering Management Branch, Federal Insurance and Mitigation Administration, Federal Emergency Management Agency, 500 C Street, SW., Washington, DC 20472.

ADDRESSES

City of Bentonville
Maps are available for inspection at City Hall, 117 West Central Avenue, Bentonville, AR 72712.

City of Cave Springs
Maps are available for inspection at City Hall, 134 North Main Street, Cave Springs, AR 72718.

City of Centerton
Maps are available for inspection at City Hall, 290 Main Street, Centerton, AR 72719.

City of Little Flock
Maps are available for inspection at City Hall, 1500 Little Flock Drive, Rogers, AR 72756.

City of Lowell
Maps are available for inspection at City Hall, 216 North Lincoln Street, Lowell, AR 72745.

City of Rogers
Maps are available for inspection at City Hall, 301 West Chestnut Street, Rogers, AR 72756.

Town of Springtown
Maps are available for inspection at the Town Hall, 12055 Wasson Road, Springtown, AR 72734.

Unincorporated Areas of Benton County
Maps are available for inspection at the Benton County Administration Building, 215 East Central Avenue, Bentonville, AR 72712.

Flooding source(s)	Location of referenced elevation**	* Elevation in feet (NGVD) + Elevation in feet (NAVD) # Depth in feet above ground ∧ Elevation in meters (MSL)		Communities affected
		Effective	Modified	
White County, Illinois, and Incorporated Areas				
Griffith Lake	Entire shoreline within community	None	+391	City of Carmi.
Little Wabash River	Approximately 0.7 mile upstream of County Highway 23.	+376	+377	City of Carmi, Unincorporated Areas of White County.
	At County Road 1200 East (Lowe Road)	+379	+381	
Old Channel Wabash River	Approximately 0.82 mile downstream of Mulberry Street extended.	None	+386	City of Grayville.
	Approximately 250 feet downstream of North Street extended.	None	+386	
Unnamed Ponding Area	Entire area of ponding north of the abandoned railroad.	None	+398	City of Carmi, Unincorporated Areas of White County.
Unnamed Tributary to Little Wabash River.	At the upstream side of College Boulevard	+377	+379	City of Carmi, Unincorporated Areas of White County.
	At the downstream side of the abandoned railroad (approximately 1.94 miles upstream of the Little Wabash River confluence).	None	+394	
Unnamed Tributary to Little Wabash River, West Branch.	At the Unnamed Tributary to Little Wabash River confluence.	None	+380	City of Carmi, Unincorporated Areas of White County.
	At the downstream side of Fairground Road	None	+383	
Wabash River	Approximately 0.51 mile downstream of County Road 1100 North (Emma Street) extended.	None	+374	Village of Maunie.
	Approximately 480 feet upstream of County Road 1100 North (Emma Street) extended.	None	+375	

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ADDRESSES

City of Carmi

Maps are available for inspection at City Hall, 225 East Main Street, Carmi, IL 62821.

City of Grayville

Maps are available for inspection at City Hall, 122 South Court Street, Grayville, IL 62844.

Unincorporated Areas of White County

Maps are available for inspection at the White County Courthouse, 301 East Main Street, Carmi, IL 62821.

Village of Maunie

Maps are available for inspection at the Village Hall, 328 Sheridan Street, Maunie, IL 62861

Missouri River	At the Atchison County boundary	None	+797	City of Elwood, City of Wathena, City of White Cloud, Iowa Tribe of Kansas And Nebraska, Unincorporated Areas of Doniphan County.
	Approximately 1.7 miles upstream of Main Street	None	+858	
Peters Creek	At the Missouri River confluence	+811	+813	Unincorporated Areas of Doniphan County, City of Wathena.
	At the upstream side of Chicago Rock Island and Pacific Railroad.	+812	+813	

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		Effective	Modified	

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ADDRESSES

City of Elwood

Maps are available for inspection at City Hall, 207 North 6th Street, Elwood, KS 66024.

City of Wathena

Maps are available for inspection at City Hall, 206 Saint Joseph Street, Wathena, KS 66090.

City of White Cloud

Maps are available for inspection at City Hall, 2017 Main Street, White Cloud, KS 66094.

Iowa Tribe of Kansas and Nebraska

Maps are available for inspection at 3345 B Thrasher Road, White Cloud, KS 66094.

Unincorporated Areas of Doniphan County

Maps are available for inspection at 120 East Chesnut Street, Doniphan County Courthouse, Troy, KS 66087.

Blair County, Pennsylvania (All Jurisdictions)

Bells Gap Run	At the downstream side of Becker Road	None	+1044	Borough of Bellwood.
	At the upstream side of Becker Road	None	+1067	
Blair Gap Run	Approximately 0.59 mile upstream of Mill Road	None	+1136	Township of Allegheny.
	Approximately 0.69 mile upstream of Mill Road	None	+1141	
Blair Gap Run	Approximately 975 feet upstream of the railroad	None	+1019	Township of Allegheny.
	Approximately 890 feet downstream of 2nd Avenue	None	+1022	
Brush Run	At the upstream side of 17th Street	None	+1096	Township of Logan.
	Approximately 149 feet upstream of 17th Street	None	+1098	
Burgoon Run	Approximately 405 feet upstream of Oak Avenue	None	+1132	Township of Logan.
	Approximately 585 feet upstream of Oak Avenue	None	+1135	
Cabbage Creek	Approximately 745 feet upstream of Main Street	+1223	+1222	Township of Taylor.
	Approximately 975 feet upstream of Main Street	+1224	+1223	
Clover Creek	Approximately 130 feet upstream of Private Drive	+1075	+1072	Township of Huston, Township of Woodbury.
	Approximately 700 feet upstream of Private Drive	+1075	+1074	
Frankstown Branch Juniata River.	Approximately 1,855 feet downstream of State Route 36 (Woodbury Pike).	+998	+995	Township of Freedom.
	Approximately 1,050 feet downstream of State Route 36 (Woodbury Pike).	+999	+998	
Halter Creek	Approximately 709 feet downstream of Mountain Street.	+1143	+1144	Borough of Roaring Spring.
	Approximately 479 feet downstream of Mountain Street.	+1144	+1146	
Laurel Run	Approximately 1,025 feet upstream of Clite's Road	None	+1016	Township of Snyder.
	Approximately 1,045 feet upstream of Clite's Road	None	+1017	
Little Juniata River	Approximately 1,415 feet downstream of the Homer Gap Run confluence.	None	+1081	Township of Logan.
	Approximately 1,205 feet downstream of the Homer Gap Run confluence.	None	+1081	
Mill Run	At the downstream side of 58th Street	+1051	+1052	City of Altoona.
Poplar Run	Approximately 550 feet upstream of Poplar Run Road	None	+1234	Township of Freedom.
	Approximately 780 feet upstream of Poplar Run Road	None	+1239	

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Send comments to Luis Rodriguez, Chief, Engineering Management Branch, Federal Insurance and Mitigation Administration, Federal Emergency Management Agency, 500 C Street, SW., Washington, DC 20472.

ADDRESSES

Borough of Bellwood

Maps are available for inspection at the Borough Hall, 400 North 1st Street, Bellwood, PA 16617.

Borough of Roaring Spring

Maps are available for inspection at the Borough Building, 616 Spang Street, Roaring Spring, PA 16673.

Flooding source(s)	Location of referenced elevation**	* Elevation in feet (NGVD) + Elevation in feet (NAVD) # Depth in feet above ground ∧ Elevation in meters (MSL)		Communities affected
		Effective	Modified	

City of Altoona
Maps are available for inspection at City Hall, 1301 12th Street, Suite 300, Altoona, PA 16601.

Township of Allegheny
Maps are available for inspection at the Allegheny Township Building, 3131 Colonial Drive, Duncansville, PA 16635.

Township of Freedom
Maps are available for inspection at the Freedom Township Building, 131 Municipal Street, East Freedom, PA 16637.

Township of Huston
Maps are available for inspection at the Huston Township Office, 1538 Sportsman Road, Martinsburg, PA 16662.

Township of Logan
Maps are available for inspection at the Logan Township Building, 100 Chief Logan Circle, Altoona, PA 16602.

Township of Snyder
Maps are available for inspection at the Snyder Township Building, 108 Baughman Hollow Road, Tyrone, PA 16686.

Township of Taylor
Maps are available for inspection at the Taylor Township Municipal Building, 1002 Route 36, Roaring Spring, PA 16673.

Township of Woodbury
Maps are available for inspection at the Woodbury Township Building, 6385 Clover Creek Road, Williamsburg, PA 16693.

(Catalog of Federal Domestic Assistance No. 97.022, "Flood Insurance.")

Dated: January 24, 2011.

Sandra K. Knight,

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

[FR Doc. 2011–2281 Filed 2–1–11; 8:45 am]

BILLING CODE 9110–12–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

45 CFR Part 170

[OCIIO–9983–NC; Docket No. THE SECRETARY–OS–2010–0034]

RIN 0950–AA19

Planning and Establishment of Consumer Operated and Oriented Plan Program; Request for Comments Regarding Provisions of Consumer Operated and Oriented Plan Program

AGENCY: Office of Consumer Information and Insurance Oversight, Department of Health and Human Services.

ACTION: Request for comments.

SUMMARY: This document is a request for comments regarding the provisions of section 1322 of the Patient Protection and Affordable Care Act (the Affordable Care Act), enacted on March 23, 2010, which requires the Secretary to establish the Consumer Operated and Oriented Plan program. The Secretary of Health and Human Services invites public comments in advance of future rulemaking and grant and loan solicitations.

DATES: To be assured consideration, comments must be received at one of the addresses provided below, no later than 5 p.m. on March 4, 2011.

ADDRESSES: All comments will be made available to the public. WARNING: Do not include any confidential business information that you do not want publicly disclosed. All comments are posted on the Internet exactly as received, and can be retrieved by most Internet search engines. No deletions, modifications, or redactions will be made to the comments received, as they are public records.

In commenting, please refer to file code OCIIO–9983–NC. Because of staff and resource limitations, we cannot accept comments by facsimile (FAX) transmission. You may submit comments using any of the following methods (please choose only one of the ways listed):

- *Electronically.* You may submit electronic comments to *http://www.regulations.gov.* Follow the instructions under the "More Search Options" tab.
- *Mail.* You may mail written comments to the following address ONLY: Office of Consumer Information and Insurance Oversight, Department of Health and Human Services, Attention: OCIIO–9983–NC, Room 445–G, Hubert H. Humphrey Building, 200 Independence Avenue, SW., Washington, DC 20201. Please allow sufficient time for mailed comments to be received before the close of the comment period.
- *Hand or Courier.* If you prefer, you may deliver (by hand or courier) your written comments before the close of the comment period to the following address: Office of Consumer Information and Insurance Oversight, Department of Health and Human Services, Attention: OCIIO–9983–NC, Room 445–G, Hubert H. Humphrey Building, 200 Independence Avenue, SW., Washington, DC 20201.

Because access to the interior of the Hubert H. Humphrey Building is not readily available to persons without Federal government identification, commenters are encouraged to leave their comments in the OCIIO drop slots located in the main lobby of the building. A stamp-in clock is available for persons wishing to retain a proof of filing by stamping in and retaining an extra copy of the comments being filed.

Comments mailed to the address indicated as appropriate for hand or courier delivery may be delayed and received after the close of the comment period.

FOR FURTHER INFORMATION CONTACT: Catherine Halverson, Office of Consumer Information and Insurance Oversight, Department of Health and Human Services, at (301) 492–4391. *Customer Service Information:* Individuals interested in obtaining information about the Patient Protection and Affordable Care Act may visit the Secretary of Health and Human Services' Web site (*http://www.HealthCare.gov*).

SUPPLEMENTARY INFORMATION:

I. Background

Section 1322 of Patient Protection and Affordable Care Act (the Affordable Care Act) requires the Secretary to establish the Consumer Operated and Oriented Plan program (CO–OP program) to foster the creation of "qualified nonprofit health insurance issuers" (qualified nonprofit issuers) that will offer qualified health plans in the individual and small group markets. Such qualified nonprofit issuers must, as directed by the new law, operate with a strong consumer focus and use any profits to lower premiums, improve benefits, or improve the quality of health care delivered to plan members. For purposes of this document, "a CO–OP" refers to a qualified health plan offered by a qualified nonprofit issuer.

Under the CO–OP program, the Secretary will make loans to assist in funding start-up costs for qualified nonprofit issuers and will award grants (repayable in 15 years) to assist such issuers in meeting State solvency requirements. The Secretary must award the loans and grants and begin funding distribution no later than July 1, 2013. Loans must be repaid within 5 years and grants must be repaid within 15 years, taking into account State reserve requirements and solvency regulations.

The Affordable Care Act requires the Secretary to convene a Federal advisory board. This advisory board will offer recommendations to the Secretary on the awarding of loans and grants to emerging co-ops under Section 1322.

II. Solicitation of Comments

We are inviting public comment to aid in the development of regulations regarding this loan and grant program. To assist interested parties in responding, this request for comment describes various topics about which the Secretary is particularly interested in receiving public comments. Commenters should use the questions below to provide the Secretary with relevant information for the development of regulations regarding the CO–OP program. However, it is not necessary for commenters to address every question below, and commenters may also address additional issues related to the provisions for the CO–OP program in the Affordable Care Act. Individuals, groups, and organizations interested in providing comments may do so by following the instructions in the **ADDRESSES** section above.

Below, we summarize relevant statutory provisions and solicit public comment on the topics about which the Secretary is particularly interested.

A. Section 1322(a) of the Affordable Care Act

Section 1322(a) of the Affordable Care Act directs the Secretary to establish a program to foster, through grants and loans, the establishment of qualified nonprofit health insurance issuers. Substantially all of the activities of the qualified nonprofit issuers must be in the individual and small group markets. The issuers must be licensed in the State(s) in which they operate. The CO–OP program shall provide for the awarding of loans and grants to provide assistance for the establishment of qualified nonprofit issuers.

Section 1322(c) of the Affordable Care Act defines a "qualified nonprofit health insurance issuer" as one: (1) That is organized under State law as a nonprofit member corporation, (2) substantially all of the activities of which consist of the issuance of qualified health plans in the individual and small group markets, and (3) that meets other requirements of section 1322(c). To qualify for a loan or grant, the qualified nonprofit issuer (or a related entity or predecessor) must not have been a health insurance issuer on July 16, 2009 and must not be sponsored by a State or local government, any political subdivision thereof, or any instrumentality of such government or political subdivision. Section 1322(c)(4) provides that an organization cannot be a qualified nonprofit health insurance issuer unless any profits made by the organization are required to be used to lower premiums, to improve benefits, and for other programs intended to improve the quality of health care delivered to its members. Section 1322(e) provides that no representative of any Federal, State, or local government (or any political subdivision or instrumentality thereof), and no representative of a health insurance issuer or a related entity, may serve on the board of directors.

1. What is your assessment of the types of groups or organizations that would meet the criteria outlined above, and be successful in establishing durable qualified plans in the individual and small group markets? Do any organizations currently exist that would satisfy these statutory eligibility criteria for receiving a loan or grant under the CO–OP program? To what extent, and in what way, do funding needs of qualified nonprofit issuers that have already been established differ from the needs of those that have not been? How might funding needs differ for other groups or organizations that do not currently exist, but would be successful in establishing durable qualified plans in the individual and small group markets? How would such differences be considered in determining appropriate financing terms for Federal loans or grants?

2. What skills, background, and expertise should be required of the loan or grant applicant? What skills, background and expertise should be required of the management team of the qualified nonprofit issuer once the entity is operational (*e.g.*, experience in providing coverage)? What factors are most likely to lead to the successful operation and sustainability of a CO–OP?

3. What relationship with CO–OP enrollees would promote initial and continued enrollment, *e.g.,* service to a geographic community, a strong provider network, its health care mission, etc.?

4. What issues might a qualified nonprofit issuer face in developing provider networks in rural or other medical shortage areas?

5. How much time would a new qualified non-profit issuer need to establish a plan, become operational, begin to accept enrollment and provide health insurance coverage? What factors may affect the timeline necessary to become operational, and how?

6. What specific details should be required in feasibility studies, business plans, and marketing plans provided by prospective applicants before any loan or grant award is made? What should be included in the scope and content of these studies and plans? What level of detail should be required at the time of application?

7. What level of investment would be required by a qualified nonprofit issuer to develop sufficient administrative and claims processing information technology (IT) systems? Is there a minimum level of investment that would be required regardless of the size of enrollment? Does it vary according to enrollment size, geographic location, or other factors, and by how much? Are funding needs for this purpose different for any qualified nonprofit issuers that may already be in existence, and if so, in what way?

8. What level of investment would be required by a qualified nonprofit issuer to develop sufficient health information technology systems necessary to operate a health plan in the health insurance Exchange market, including the use of electronic health records? Is there a minimum level of investment that would be required regardless of the size of enrollment? Does it vary according to enrollment size, enrollee characteristics, or other factors, and by how much? Are funding needs for this purpose different for any qualified nonprofit issuers that

may already be in existence, and if so, in what way?

9. What is the range of funding necessary to capitalize and fund the establishment of a new qualified nonprofit issuer? How much of that amount can be raised privately, or funded through non-Federal government support? What factors should be considered in determining the appropriate amount of Federal loans and/or grants that would be needed to support the establishment of a new nonprofit health insurance issuer? To what extent do the funds needed to capitalize a qualified nonprofit issuer, and the degree of Federal support necessary likely to vary across issuers?

10. What level of investment is needed to maintain appropriate fiduciary management and oversight, including setting actuarially sound premiums?

11. Are you aware of any State laws that could create opportunities for or barriers to the formation of qualified nonprofit issuers? Do you think States are likely to create or amend licensure laws to accommodate the formation of qualified nonprofit issuers? Under what circumstances could regional qualified nonprofit issuers serving multiple states be formed? Is there a role for a federation of qualified nonprofit issuers to serve more than one state or region, with risk shared among the issuers? Would this approach be desirable for specific types of communities (for example, agricultural/rural communities)? How would such a federation be organized? How would it be capitalized? What are the advantages and disadvantages of a regional qualified nonprofit issuer or a regional federation of issuers? What barriers would need to be overcome? What would be the advantages of, and barriers to, serving a metropolitan area that crosses State lines?

12. While "substantially all" of a qualified nonprofit issuer's activities must be in the individual and small group markets, in what other markets or product lines, if any, would it be desirable for qualified nonprofit issuers to participate? For instance, could they participate in Medicaid or the Children's Health Insurance Program (CHIP) and still satisfy the statutory criteria for being a qualified nonprofit issuer? How difficult would it be for a new qualified nonprofit issuer to successfully participate in the small group market? How difficult would it be for a new qualified nonprofit issuer to successfully participate in the individual market? To what extent would participation in other markets affect the viability of new qualified nonprofit issuers or their ability to satisfy the statutory criteria for being a qualified nonprofit issuer? What type of start-up costs are necessary and reasonable for establishing a qualifying CO–OP? What startup costs might be associated with establishing a private purchasing council?

13. Are there other considerations that should inform what costs would be eligible for a CO–OP loan? Should there be limited time periods for which Federal loans for start-up costs may be available? Are there any start-up costs that would be incurred after the qualified nonprofit issuer begins to provide coverage under one or more plans?

14. What market factors would most likely affect a qualified nonprofit issuer's durability in the market? What factors should be considered in determining which issuers are likely to be viable in the long-term?

15. In evaluating applications for loans and grants, what actuarial and minimum plan enrollment criteria should be considered? What is the effect, if any, if providers are anticipated to bear risk? How would such criteria affect the financial soundness of the qualified issuer?

16. What types of technical assistance, if any, should the Secretary provide to grantees? How should such technical assistance be structured?

17. In what geographic areas are qualified nonprofit issuers most likely to be successful (*e.g.,* rural or metropolitan areas or certain regions of the country)?

18. How can qualified nonprofit issuers build provider networks? What strategies have proven effective?

19. What is the extent of interest in forming qualified nonprofit issuers under Section 1322 of the Affordable Care Act? In what State(s) or geographic region are these entities likely to be established?

B. Section 1322(b) of the Affordable Care Act

Section 1322(b) of the Affordable Care Act requires that the Secretary shall give priority to applicants that will offer qualified health plans on a statewide basis, utilize integrated care models, and have significant private support.

1. How should the term "integrated care model" be defined in the context of section 1322? How should the degree of integration and the degree to which integrated care is used be measured? Should qualified nonprofit issuers formed by primary care networks, even if they contract with secondary and tertiary providers, also be given priority for the award of a grant or loan? To what degree should priority be based on whether providers share risk?

2. How should "significant private support" be defined in this context?

3. What options for private support should qualified nonprofit issuers be able to pursue while maintaining nonprofit status? How can such support be structured to avoid inurnment to the benefit of non-members and protect the independence of consumer governance?

4. What types of organizations are most likely to be successful in meeting any or all of the statutory priority criteria?

C. Section 1322(b)(2)(a)(iii) of the Affordable Care Act

Section 1322(b)(2)(A)(iii) of the Affordable Care Act requires the Secretary to ensure that there is sufficient funding to establish at least one qualified nonprofit issuer in each State, except that nothing shall prevent the establishment of multiple issuers in a State if the funding is sufficient. Section 1322(b)(2)(B) provides that if no issuer applies to be a qualified nonprofit health insurance issuer in a State, the Secretary may use the amounts for the awarding of grants to encourage the establishment of an issuer or the expansion of another qualified nonprofit health insurance issuer from another State into the State where no issuer applied.

1. How can the Secretary best ensure sufficient funding to establish at least one qualified nonprofit issuer in each State?

2. How might the Secretary encourage the establishment of a CO–OP in a state without a qualified nonprofit issuer?

D. Section 1322(b)(C)(ii) of the Affordable Care Act

Section 1322(b)(C)(ii) of the Affordable Care Act restricts the use of loan and grant funds for (i) carrying out propaganda, or otherwise attempting to influence legislation, or (ii) for marketing.

1. How should the restriction on the use of federal funds for marketing be applied?

2. What other sources of financing for marketing would be available to qualified nonprofit issuers?

3. What accounting standards and metrics should be used to determine the sources of funding for marketing activities? If qualified nonprofit issuers did engage in these activities using non-federal funding, what rules should be in place to ensure federal funds are not used?

E. Section 1322(b)(2)(D) of the Affordable Care Act

Section 1322(b)(2)(D) of the Affordable Care Act requires the Secretary to award and begin the distribution of loans and grants not later than July 1, 2013.

1. To what extent is it necessary for new qualified nonprofit issuers to be operational by 2014 in order to be successful? How soon should grants or loans be distributed to establish qualified nonprofit issuers that can be operational in 2014?

2. How might funds be best allocated and, to what extent should distribution of loan funds be front-loaded to meet the statute's goal of establishing a CO–OP in each state?

3. Given the limited funding for this program, how long should draw down on grants and loans be permitted after the award date if loans and grants are not being utilized?

F. Section 1322(b)(3) of the Affordable Care Act

Section 1322(b)(3) of the Affordable Care Act requires that regulations regarding the repayment of loans and grants be "consistent with State solvency regulations and other similar State laws that may apply." Loans shall be repaid within 5 years and grants shall be repaid within 15 years, taking into consideration any appropriate State reserve requirements, solvency regulations, and requisite surplus note arrangements that must be constructed to provide for repayment prior to awarding loans/grants.

1. When developing a repayment schedule, how should HHS take into consideration state reserve requirements?

2. What factors will determine the ability of qualified nonprofit issuers to generate sufficient revenues to repay the loans and grants? How and when will such issuers likely develop sufficient revenues to start the repayment of grants provided to fund reserves?

3. What interim benchmarks after initial funding should the Secretary use to determine an issuer's ongoing likelihood of success and whether corrective actions, or other protective measures might be necessary with respect to loan and grant funds?

4. What data are available about the potential success and failure rate of nonprofit health plans who may apply for grants and loans? If data are not available, what proxy data would be useful to inform benchmarks, or other performance standards?

G. Section 1322(c)(2) of the Affordable Care Act

Section 1322(c)(2) of the Affordable Care Act provides that an organization shall not be treated as a qualified nonprofit issuer (and therefore shall not be qualified to apply for loans and grants under the CO–OP program) if the organization or a related entity (or a predecessor of either) was a health insurance issuer on July 16, 2009. Section 1322(c)(2) of the Affordable Care Act also provides that an organization shall not be treated as a qualified nonprofit issuer if it is sponsored by a State or local government, political subdivision thereof, or an instrumentality of such government or political subdivision.

1. What should and should not constitute a "related entity" or "predecessor" of a health insurance issuer for purposes of Section 1322 of the Affordable Care Act?

H. Section 1322(c)(3) of the Affordable Care Act

Section 1322(c)(3) of the Affordable Care Act requires that a qualified nonprofit issuer must be a nonprofit, member corporation and meet a number of governance requirements including the following:

- The governance of the organization must be subject to a majority vote of its members;
- Its governing documents must incorporate ethics and conflict of interest standards against insurance industry involvement and interference; and
- The organization is required to operate with a strong consumer focus, including timeliness, responsiveness, and accountability to members.

1. How can prospective applicants demonstrate a commitment to operating with a strong consumer focus, including responsiveness and accountability to members? How can prospective applicants demonstrate a commitment to responsiveness and accountability to members from diverse populations?

2. What type(s) of governance structure(s) should be required? What criteria should be used in determining who is eligible to be members of the organization and of the governing body? What type of characteristics should the governing body have to ensure consumer representation and involvement? What are the options for consumer governance, beyond electing the board of directors, that would most promote ongoing consumer engagement and responsiveness of the qualified nonprofit issuer to consumer needs?

I. Section 1322(c)(4) of the Affordable Care Act

Section 1322(c)(4) of the Affordable Care Act provides that an organization cannot be a qualified nonprofit health insurance issuer unless any profits made by the organization are required to be used to lower premiums, to improve benefits, and for other programs intended to improve the quality of health care delivered to its members.

1. How could the governance structure and type of organization help ensure that excess revenues are used for the benefit of members? What accounting standards and metrics should be used to determine how such funds are applied? Should such funds in one year be used to lower premiums in a subsequent year? What types of benefits might be considered? Should excess funds be used to prepay loans or grants, to allow for greater revenues/benefits to the members over time? Is this preferable to giving refunds to members for the year in which the profit was earned?

2. How should programs intended to improve the quality of care be defined and measured in this context?

J. Section 1322(c)(5) of the Affordable Care Act

Section 1322(c)(5) of the Affordable Care Act requires qualified nonprofit issuers to meet all the requirements that other issuers of qualified health plans are required to meet, including solvency and licensure requirements, rules on payments to providers, network adequacy rules, rate and form filing rules, any applicable State premium assessments and any other State laws described in section 1324(b).

1. Do any States permit newly-formed issuers (or plans) to meet these requirements incrementally over a period of time after enrollment and provision of health insurance coverage?

K. What other considerations should be addressed relating to the CO–OP program?

Please include in your comment letter any additional questions or comments you have about the CO–OP program.

Dated: January 26, 2011.

Marilyn Tavevnner,

Principal Deputy Administrator and Chief Operating Officer.

[FR Doc. 2011–2254 Filed 1–28–11; 4:15 pm]

BILLING CODE 4150–03–P

Notices

Federal Register

Vol. 76, No. 22

Wednesday, February 2, 2011

This section of the FEDERAL REGISTER contains documents other than rules or proposed rules that are applicable to the public. Notices of hearings and investigations, committee meetings, agency decisions and rulings, delegations of authority, filing of petitions and applications and agency statements of organization and functions are examples of documents appearing in this section.

DEPARTMENT OF AGRICULTURE

Submission for OMB Review; Comment Request

January 28, 2011.

The Department of Agriculture has submitted the following information collection requirement(s) to OMB for review and clearance under the Paperwork Reduction Act of 1995, Public Law 104–13. Comments regarding (a) Whether the collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility; (b) the accuracy of the agency's estimate of burden including the validity of the methodology and assumptions used; (c) ways to enhance the quality, utility and clarity of the information to be collected; (d) ways to minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology should be addressed to: Desk Officer for Agriculture, Office of Information and Regulatory Affairs, Office of Management and Budget (OMB), *OIRA_Submission@OMB.EOP.GOV* or fax (202) 395–5806 and to Departmental Clearance Office, USDA, OCIO, Mail Stop 7602, Washington, DC 20250–7602. Comments regarding these information collections are best assured of having their full effect if received within 30 days of this notification. Copies of the submission(s) may be obtained by calling (202) 720–8681.

An agency may not conduct or sponsor a collection of information unless the collection of information displays a currently valid OMB control number and the agency informs potential persons who are to respond to the collection of information that such persons are not required to respond to the collection of information unless it displays a currently valid OMB control number.

Agricultural Marketing Service

Title: Organic Handler Market Promotion Assessment Exemption.

OMB Control Number: 0581–0216.

Summary of Collection: Industries enter into a marketing order program under the Agricultural Marketing Agreement Act (AMAA) of 1937, as amended by U.S.C. 601–674. Marketing Order programs provide an opportunity for producers of fresh fruit, vegetables, and specialty crops, in specified production areas, to work together to solve marketing problems that cannot be solved individually. In 2002, section 501 of the FAIR Act was amended (7 U.S.C. 7401) to exempt any person that produces and markets solely 100 percent organic products, and that does not produce any conventional or non-organic products, from paying assessments under a commodity promotion law with respect to any agricultural commodity that is produced on a certified organic farm as defined in section 2103 of the Organic Foods Production Act of 1990.

Need and Use of the Information: The information collected on form FV–649, is necessary to assist the applicants in making their certifications and the committees or boards to determine an applicant's eligibility, to properly administer the assessment exemption and to verify compliance.

Description of Respondents: Business or other for-profit; Farms.

Number of Respondents: 65.

Frequency of Responses: Recordkeeping; Reporting: On occasion; Annually.

Total Burden Hours: 33.

Agricultural Marketing Service

Title: Farmers Market Promotion Program (FMPP).

OMB Control Number: 0581–0235.

Summary of Collection: The purposes of the Farmers Market Promotion Program (FMPP) are to increase domestic consumption of agricultural commodities by improving and expanding, assisting in the improvement and expansion, and to develop or aid in the development of new domestic farmers' markets, roadside stands, community-supported agriculture programs, and other direct producer-to-consumer infrastructure. The Farmer-to-Consumer Marketing Act of 1976 (Act) directs USDA to encourage the direct marketing of agricultural commodities from farmers to consumers, and to promote the development and expansion of direct marketing of agricultural commodities from farmers to consumers. The recently authorized Farmer's Market Promotion Program (FMPP) (7 U.S.C. 3005), Section 6 of 7 U.S.C. 3004 directs the Secretary of Agriculture to "carry out a program to make grants to eligible entities for projects to establish, expand, and promote farmers' markets."

Need and Use of the Information: The Agricultural Marketing Service will review grant application information to determine eligibility of applicants for participation in FMPP, evaluate goals, objectives, work-plans, expected results and budget for the project.

Description of Respondents: Business or other for-profit; Not-for-profit institutions; State, Local or Tribal Government.

Number of Respondents: 1,500.

Frequency of Responses: Recordkeeping; Reporting: One time.

Total Burden Hours: 20,988.

Charlene Parker,

Departmental Information Collection Clearance Officer.

[FR Doc. 2011–2272 Filed 2–1–11; 8:45 am]

BILLING CODE 3410–02–P

DEPARTMENT OF AGRICULTURE

Public Availability of the Department of Agriculture FY 2010 Service Contract Inventory

AGENCY: Office of Procurement and Property Management, USDA.

ACTION: Notice of public availability of FY 2010 Service Contract inventories.

SUMMARY: In accordance with Section 743 of Division C of the Consolidated Appropriations Act of 2010 (Pub. L. 111–117), Department of Agriculture is publishing this notice to advise the public of the availability of the FY 2010 Service Contract inventory. This inventory provides information on service contract actions over $25,000 that were made in FY 2010. The information is organized by function to show how contracted resources are distributed throughout the agency. The inventory has been developed in accordance with guidance issued on

November 5, 2010 by the Office of Management and Budget's Office of Federal Procurement Policy (OFPP). OFPP's guidance is available at *http://www.whitehouse.gov/sites/default/files/omb/procurement/memo/service-contract-inventories-guidance-11052010.pdf.* Department of Agriculture has posted its inventory and a summary of the inventory on the Office of Procurement and Property Management homepage at the following link: *http://www.dm.usda.gov/procurement/.*

FOR FURTHER INFORMATION CONTACT: Questions regarding the service contract inventory should be directed to Mrs. Dorothy Lilly in the Procurement Policy Division, of OPPM at 202–690–2064 or *Dorothy.Lay@dm.usda.gov.*

Dated: January 25, 2011.

Dorothy Lilly,

Division Chief for Procurement Policy, Departmental, Office of Procurement and Property Management.

[FR Doc. 2011–2137 Filed 2–1–11; 8:45 am]

BILLING CODE 3410–96–P

DEPARTMENT OF AGRICULTURE

Agricultural Marketing Service

[Doc. No. AMS–FV–10–0096]

Fruit and Vegetable Industry Advisory Committee

AGENCY: Agricultural Marketing Service, USDA.

ACTION: Notice of public meeting.

SUMMARY: The purpose of this notice is to notify all interested parties that the Agricultural Marketing Service (AMS) will hold a Fruit and Vegetable Industry Advisory Committee (Committee) meeting that is open to the public. The U.S. Department of Agriculture (USDA) established the Committee to examine the full spectrum of issues faced by the fruit and vegetable industry and to provide suggestions and ideas to the Secretary of Agriculture on how USDA can tailor its programs to meet the fruit and vegetable industry's needs. This notice sets forth the schedule and location for the meeting.

DATES: Monday, February 28, 2011, from 8 a.m. to 5 p.m., and Tuesday, March 1, 2011, from 8 a.m. to 3 p.m.

ADDRESSES: The Committee meeting will be held at the Hyatt Hotel Crystal City, 2799 Jefferson Davis Highway, Arlington, Virginia 22202.

FOR FURTHER INFORMATION CONTACT: Pamela Stanziani, Designated Federal Official, USDA, AMS, Fruit and Vegetable Programs. Telephone: (202) 690–0182. Facsimile: (202) 720–0016. E-mail: *Pamela.stanziani@ams.usda.gov.*

SUPPLEMENTARY INFORMATION: Pursuant to the Federal Advisory Committee Act (FACA) (5 U.S.C. App. II), the Secretary of Agriculture established the Committee in August 2001 to examine the full spectrum of issues faced by the fruit and vegetable industry and to provide suggestions and ideas to the Secretary on how USDA can tailor its programs to meet the fruit and vegetable industry's needs. The Committee was re-chartered March 31, 2009 with new members appointed December 2009 by USDA from industry nominations.

AMS Deputy Administrator for Fruit and Vegetable Programs, Robert C. Keeney, serves as the Committee's Executive Secretary. Representatives from USDA mission areas and other government agencies affecting the fruit and vegetable industry are called upon to participate in the Committee's meetings as determined by the Committee Chairperson. AMS is giving notice of the Committee meeting to the public so that they may attend and present their recommendations. The meeting is open to the public. Reference the date and address section of this announcement for the time and place of the meeting.

Topics of discussion at the advisory committee meeting will include the following: GAP harmonization, traceability and audit requirements, food safety updates, local farmer/education initiatives, commodity purchasing programs, and working group reports and recommendations to the full committee.

Those parties that would like to speak at the meeting should contact USDA on or before February 11, 2011. To register as a speaker, please e-mail your name, affiliation, business address, e-mail address, and phone number to Ms. Pamela Stanziani at: *Pamela.stanziani@ams.usda.gov* or facsimile to (202) 720–0016. Speakers who have registered in advance will be given priority. Groups and individuals may submit comments for the Committee's consideration to the same e-mail address, or mail to: 1400 Independence Avenue, SW., Room 2085-South, Washington, DC 20250. The meeting will be recorded, and information about obtaining a transcript will be provided at the meeting. All presentations must be provided and displayed electronically, and submitted upon designated due date.

If you require special accommodations, such as a sign language interpreter, please use either contact name listed above.

Dated: January 26, 2011.

David R. Shipman,

Associate Administrator, Agricultural Marketing Service.

[FR Doc. 2011–2233 Filed 2–1–11; 8:45 am]

BILLING CODE 3410–02–P

DEPARTMENT OF AGRICULTURE

Animal and Plant Health Inspection Service

[Docket No. APHIS–2010–0112]

Notice of Availability of a Pest Risk Analysis for the Importation of Fresh Litchi From the Republic of South Africa Into the Continental United States

AGENCY: Animal and Plant Health Inspection Service, USDA.

ACTION: Notice.

SUMMARY: We are advising the public that we have prepared a pest risk analysis that evaluates the risks associated with the importation of fresh litchi from the Republic of South Africa into the continental United States. Based on that analysis, we have concluded that the application of one or more designated phytosanitary measures will be sufficient to mitigate the risks of introducing or disseminating plant pests or noxious weeds via the importation of litchi from the Republic of South Africa. We are making the pest risk analysis available to the public for review and comment.

DATES: We will consider all comments that we receive on or before April 4, 2011.

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

- *Federal eRulemaking Portal:* Go to *http://www.regulations.gov/fdmspublic/component/main?main=DocketDetail&d=APHIS-2010-0112* to submit or view comments and to view supporting and related materials available electronically.
- *Postal Mail/Commercial Delivery:* Please send one copy of your comment to Docket No. APHIS–2010–0112, Regulatory Analysis and Development, PPD, APHIS, Station 3A–03.8, 4700 River Road Unit 118, Riverdale, MD 20737–1238. Please state that your comment refers to Docket No. APHIS–2010–0112.

Reading Room: You may read any comments that we receive on this docket in our reading room. The reading room is located in room 1141 of the USDA South Building, 14th Street and Independence Avenue, SW., Washington, DC. Normal reading room

hours are 8 a.m. to 4:30 p.m., Monday through Friday, except holidays. To be sure someone is there to help you, please call (202) 690–2817 before coming.

Other Information: Additional information about APHIS and its programs is available on the Internet at *http://www.aphis.usda.gov*.

FOR FURTHER INFORMATION CONTACT: Mr. Marc Phillips, Import Specialist, Regulatory Coordination and Compliance, PPQ, APHIS, 4700 River Road Unit 133, Riverdale, MD 20737; (301) 734–4394.

SUPPLEMENTARY INFORMATION:

Background

Under the regulations in "Subpart—Fruits and Vegetables" (7 CFR 319.56–1 through 319.56–50, referred to below as the regulations), the Animal and Plant Health Inspection Service (APHIS) of the U.S. Department of Agriculture prohibits or restricts the importation of fruits and vegetables into the United States from certain parts of the world to prevent plant pests from being introduced into and spread within the United States.

Section 319.56–4 contains a performance-based process for approving the importation of commodities that, based on the findings of a pest risk analysis, can be safely imported subject to one or more of the designated phytosanitary measures listed in paragraph (b) of that section. These measures are:

- The fruits or vegetables are subject to inspection upon arrival in the United States and comply with all applicable provisions of § 319.56–3;
- The fruits or vegetables are imported from a pest-free area in the country of origin that meets the requirements of § 319.56–5 for freedom from that pest and are accompanied by a phytosanitary certificate stating that the fruits or vegetables originated in a pest-free area in the country of origin;
- The fruits or vegetables are treated in accordance with 7 CFR part 305;
- The fruits or vegetables are inspected in the country of origin by an inspector or an official of the national plant protection organization of the exporting country, and have been found free of one or more specific quarantine pests identified by the risk analysis as likely to follow the import pathway; and/or
- The fruits or vegetables are imported as a commercial consignment.

APHIS received a request from the Government of the Republic of South Africa to allow the importation of fresh litchi fruits, *Litchi chinensis,* into the continental United States. Currently, fresh litchi fruits are not authorized for entry from the Republic of South Africa. We completed a pest risk assessment to identify pests of quarantine significance that could follow the pathway of importation if such imports were to be allowed and, based on the pest risk assessment, have prepared a risk management document to identify phytosanitary measures that could be applied to the commodity to mitigate the pest risks. We have concluded that fresh litchi fruits can safely be imported into the continental United States from the Republic of South Africa using one or more of the five designated phytosanitary measures listed in § 319.56–4(b). Therefore, in accordance with § 319.56–4(c)(2), we are announcing the availability of our pest risk analysis for public review and comment. The analysis may be viewed on the Regulations.gov Web site or in our reading room (*see* **ADDRESSES** above for instructions for accessing Regulations.gov and information on the location and hours of the reading room). You may request paper copies of the analysis by calling or writing to the person listed under **FOR FURTHER INFORMATION CONTACT**. Please refer to the subject of the analysis that you wish to review when requesting copies.

After reviewing any comments we receive, we will announce our decision regarding the import status of fresh litchi fruits from the Republic of South Africa in a subsequent notice. If the overall conclusions of the analysis and the Administrator's determination of risk remain unchanged following our consideration of the comments, then we will begin issuing permits for the importation of fresh litchi fruits from the Republic of South Africa into the continental United States subject to the requirements specified in the risk management document.

Authority: 7 U.S.C. 450, 7701–7772, and 7781–7786; 21 U.S.C. 136 and 136a; 7 CFR 2.22, 2.80, and 371.3.

Done in Washington, DC, this 27th day of January 2011.

Kevin Shea,

Acting Administrator, Animal and Plant Health Inspection Service.

[FR Doc. 2011–2235 Filed 2–1–11; 8:45 am]

BILLING CODE 3410–34–P

DEPARTMENT OF AGRICULTURE

Animal and Plant Health Inspection Service

[Docket No. APHIS–2007–0044]

Determination of Regulated Status of Alfalfa Genetically Engineered for Tolerance to the Herbicide Glyphosate; Record of Decision

AGENCY: Animal and Plant Health Inspection Service, USDA.

ACTION: Notice.

SUMMARY: This notice advises the public of the Animal and Plant Health Inspection Service's (APHIS) record of decision and determination on the petition regarding the regulated status of alfalfa genetically engineered for tolerance to the herbicide glyphosate based on APHIS' final environmental impact statement.

FOR FURTHER INFORMATION CONTACT: Dr. Rebecca L. Stankiewicz Gabel, Senior Environmental Protection Specialist, Environmental Risk Analysis Programs, BRS, APHIS, 4700 River Road Unit 147, Riverdale, MD 20737–1238; (301) 734–5603. To obtain copies of the record of decision or the final environmental impact statement on which the record of decision is based, contact Ms. Cindy Eck at (301) 734–0667, e-mail: *cynthia.a.eck@aphis.usda.gov.*

SUPPLEMENTARY INFORMATION: This notice advises the public that the Animal and Plant Health Inspection Service (APHIS) has prepared a record of decision and determination on the petition regarding the regulated status of alfalfa genetically engineered for tolerance to the herbicide glyphosate based on an environmental impact statement (EIS) prepared in connection with its determination.

The regulations in 7 CFR part 340, "Introduction of Organisms and Products Altered or Produced Through Genetic Engineering Which Are Plant Pests or Which There Is Reason to Believe Are Plant Pests," regulate, among other things, the introduction (importation, interstate movement, or release into the environment) of organisms and products altered or produced through genetic engineering that are plant pests or that there is reason to believe are plant pests. Such genetically engineered (GE) organisms and products are considered "regulated articles."

The regulations in § 340.6(a) provide that any person may submit a petition to APHIS seeking a determination that an article should not be regulated under 7 CFR part 340. Paragraphs (b) and (c)

of § 340.6 describe the form that a petition for a determination of nonregulated status must take and the information that must be included in the petition.

In a notice published in the **Federal Register** on June 27, 2005 (70 FR 36917–36919, Docket No. 04–085–3), APHIS advised the public of its determination, effective June 14, 2005, that the Monsanto and Forage Genetics International GE glyphosate-tolerant alfalfa lines designated as events J101 and J163 were no longer considered regulated articles under the regulations governing the introduction of certain GE organisms. That determination was subsequently challenged in the United States District Court for the Northern District of California by the Center for Food Safety, other associations, and several organic alfalfa growers. The lawsuit alleged that APHIS' decision to deregulate the GE alfalfa events J101 and J163 violated the National Environmental Policy Act (NEPA), the Endangered Species Act, and the Plant Protection Act.

On February 13, 2007, the court in that case issued its memorandum and order in which it determined that APHIS had violated NEPA by not preparing an EIS in connection with its deregulation determination. The court ruled that the environmental assessment prepared by APHIS for its deregulation determination failed to adequately consider certain environmental impacts in violation of NEPA. The deregulation determination was vacated and APHIS was directed by the court to prepare an EIS in connection with making a new determination on the regulated status of the GE alfalfa.

On December 18, 2009, the Environmental Protection Agency published a notice in the **Federal Register** (74 FR 67206–67207, Docket No. ER–FRL–8986–6) announcing the availability of a draft EIS in connection with making a determination on the regulated status of the GE alfalfa. Comments on the draft EIS were to have been received on or before February 16, 2010. APHIS subsequently published a notice [1] in the **Federal Register** on February 24, 2010 (75 FR 8299–8300, Docket No. APHIS–2007–0044), extending the comment period through March 3, 2010.

In December 2010, APHIS published and distributed the final EIS, which included discussion of the public comments received on the draft EIS. On December 23, 2010, the Environmental Protection Agency published a notice in the **Federal Register** (75 FR 80807–80808, Docket No. ER–FRL–8994–3) announcing the availability of the final EIS. The NEPA implementing regulations in 40 CFR 1506.10 require a 30-day review period between the time a final EIS is published and the time an agency makes a decision on an action covered by the EIS. APHIS received more than 16,000 comments on the final EIS by the time this review period ended on January 24, 2011.

APHIS has reviewed the final EIS and has concluded that it has fully analyzed the issues covered by the draft EIS and those comments and suggestions submitted by commenters. APHIS has now prepared a record of decision based on the final EIS and is making that record available to the public. The record of decision and the final EIS on which the record of decision is based may be viewed on the Internet at *http://www.regulations.gov/fdmspublic/component/main?main=DocketDetail&d=APHIS-2007-0044.* Copies of those documents may also be obtained from the person listed under **FOR FURTHER INFORMATION CONTACT**.

The record of decision has been prepared in accordance with: (1) NEPA, (2) regulations of the Council on Environmental Quality for implementing the procedural provisions of NEPA (40 CFR parts 1500–1508), (3) USDA regulations implementing NEPA (7 CFR part 1b), and (4) APHIS' NEPA Implementing Procedures (7 CFR part 372).

Done in Washington, DC, this January 27, 2011.

Kevin Shea,

Acting Administrator, Animal and Plant Health Inspection Service.

[FR Doc. 2011–2268 Filed 2–1–11; 8:45 am]

BILLING CODE 3410–34–P

[1] This and the subsequent notices mentioned in this notice, as well as comments received, supporting and related materials, and other documents can be viewed at *http://www.regulations.gov/fdmspublic/component/main?main=DocketDetail&d=APHIS–2007–0044.*

DEPARTMENT OF AGRICULTURE

Forest Service

Uinta-Wasatch-Cache National Forest Resource Advisory Committee

AGENCY: Forest Service, USDA.

ACTION: Notice of meeting.

SUMMARY: The Uinta-Wasatch-Cache National Forest Resource Advisory Committee will conduct a meeting in Salt Lake City, Utah. The committee is meeting as authorized under the Secure Rural Schools and Community Self-Determination Act (Pub. L. 110–343) and in compliance with the Federal Advisory Committee Act. The purpose is to continue the review of project submittals.

DATES: The meeting will be held on February 17, 2011, from 3 p.m. to 5:30 p.m.

ADDRESSES: The meeting will be held at the Salt Lake County Government Center, Room S1002, 2001 South State Street, Salt Lake City, Utah. Written comments should be sent to Loyal Clark, Uinta-Wasatch-Cache National Forest, 88 West 100 North, Provo, Utah 84601. Comments may also be sent via e-mail to *lfclark@fs.fed.us,* via facsimile to 801–342–5144.

All comments, including names and addresses when provided, are placed in the record and are available for inspection and copying. The public may inspect comments received at the Uinta-Wasatch-Cache National Forest, 88 West 100 North, Provo, Utah 84601.

FOR FURTHER INFORMATION CONTACT: Loyal Clark, RAC Coordinator, USDA, Uinta-Wasatch-Cache National Forest, 88 West 100 North, Provo, Utah 84601; 801–342–5117; *lfclark@fs.fed.us.*

SUPPLEMENTARY INFORMATION: The meeting is open to the public. The following business will be conducted: (1) review Forest Service project approval letter, and (2) review new proposals. Persons who wish to bring related matters to the attention of the Committee may file written statements with the Committee staff before or after the meeting.

Dated: January 21, 2011.

Cheryl Probert,

Deputy Forest Supervisor.

[FR Doc. 2011–2163 Filed 2–1–11; 8:45 am]

BILLING CODE P

COMMISSION ON CIVIL RIGHTS

Agenda and Notice of Public Meeting of the Texas 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 Texas Advisory Committee to the Commission will convene by conference call at 10 a.m. and adjourn at approximately 12 noon on Wednesday, February 23, 2011 at 2300 E. University Drive, Denton, TX, 76206. The purpose of this meeting is to discuss the Committee's civil rights project on human trafficking.

Members of the public are entitled to submit written comments; the

comments must be received in the regional office by March 23, 2011. The address is 300 N. Los Angeles St., Suite 2010, Los Angeles, California 90012. Persons wishing to e-mail their comments or who desire additional information should contact Angelica Trevino, Administrative Assistant, at (213) 894–3437 or (800) 877–8339 for individuals who are deaf, hearing impaired, and/or have speech disabilities or by e-mail to: *atrevino@usccr.gov.*

Hearing-impaired persons who wish to submit written comments 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 Western 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 Western 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, January 27, 2011.

Peter Minarik,

Acting Chief, Regional Programs Coordination Unit.

[FR Doc. 2011–2213 Filed 2–1–11; 8:45 am]

BILLING CODE 6335–01–P

DEPARTMENT OF COMMERCE

Submission for OMB Review; Comment Request

The Department of Commerce will submit to the Office of Management and Budget (OMB) for clearance the following proposal for collection of information under the provisions of the Paperwork Reduction Act (44 U.S.C. Chapter 35).

Agency: National Oceanic and Atmospheric Administration (NOAA).

Title: Tag Recapture Card.

OMB Control Number: 0648–0259.

Form Number(s): NA.

Type of Request: Regular submission.

Number of Respondents: 240.

Average Hours per Response: 2 minutes.

Burden Hours: 8.

Needs and Uses: This request is for the renewal of a currently approved information collection.

The Cooperative Game Fish Tagging Program (CGFTP) was initiated in 1954 by Woods Hole Oceanographic Institution (WHOI). In 1973 the CGFTP became a cooperative effort between WHOI and the National Marine Fisheries (NMFS) as part of a comprehensive research program resulting from passage of the Migratory Game Fish Study Act of 1959 (Pub. L. 86–359) and other legislative acts under which the NMFS operates. In 1980 sole control of the CGFTP was handed over to the NMFS. The CGFTP was later renamed the Cooperative Tagging Center (CTC). The CTC attempts to determine the migratory patterns and other biological information of billfish, tunas, and swordfish by having fishermen tag and release their catch, so that fish can be subsequently recaptured.

The primary objectives of a tagging program are to obtain scientific information on fish growth and movements necessary to assist in stock assessment and management. This is accomplished by the random recapture of tagged fish by fishermen and the subsequent voluntary submission of the appropriate data.

Affected Public: Individuals or households.

Frequency: On occasion.

Respondent's Obligation: Voluntary.

OMB Desk Officer: *OIRA_Submission@omb.eop.gov.*

Copies of the above information collection proposal can be obtained by calling or writing Diana Hynek, Departmental Paperwork Clearance Officer, (202) 482–0266, Department of Commerce, Room 6616, 14th and Constitution Avenue, NW., Washington, DC 20230 (or via the Internet at *dHynek@doc.gov*).

Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to *OIRA_Submission@omb.eop.gov.*

Dated: January 28, 2011.

Gwellnar Banks,

Management Analyst, Office of the Chief Information Officer.

[FR Doc. 2011–2232 Filed 2–1–11; 8:45 am]

BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE

International Trade Administration

[A–122–853]

Citric Acid and Certain Citrate Salts From Canada: Preliminary Results of Antidumping Duty Administrative Review

AGENCY: Import Administration, International Trade Administration, Department of Commerce.

SUMMARY: In response to a timely request by one manufacturer/exporter, Jungbunzlauer Canada Inc. (JBL Canada), the Department of Commerce (the Department) is conducting the first administrative review of the antidumping duty order on citric acid and certain citrate salts (citric acid) from Canada with respect to JBL Canada. The review covers the period November 20, 2008, through May 19, 2009, and May 29, 2009, through April 30, 2010. We preliminarily determine that JBL Canada made sales below normal value (NV).

If the preliminary results are adopted in our final results of the administrative review, we will instruct U.S. Customs and Border Protection (CBP) to assess antidumping duties on all appropriate entries. Interested parties are invited to comment on the preliminary results.

FOR FURTHER INFORMATION CONTACT: Rebecca Trainor or Kate Johnson, 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) 482–4007 or (202) 482–4929, respectively.

SUPPLEMENTARY INFORMATION:

Background

In response to a timely request by JBL Canada, on June 30, 2010, the Department published in the **Federal Register** a notice of initiation of an administrative review of the antidumping duty order on citric acid from Canada with respect to JBL Canada covering the period November 20, 2008, through May 19, 2009, and May 29, 2009, through April 30, 2010. *See Initiation of Antidumping and Countervailing Duty Administrative Reviews and Requests for Revocation in Part,* 75 FR 37759 (June 30, 2010).

Also on June 30, 2010, we issued the antidumping duty questionnaire to JBL Canada. In August 2010, we received responses to sections A (*i.e.,* the section covering general information about the company), B (*i.e.,* the section covering comparison-market sales), C (*i.e.,* the section covering U.S. sales), and D (the

section covering cost of production (COP) and constructed value (CV)) of the antidumping duty questionnaire from JBL Canada.

During the period October through December 2010, we issued to JBL Canada supplemental questionnaires regarding sections A, B, C, and D of the original questionnaire. We received responses to these questionnaires during the period October 2010 through January 2011.

Scope of the Order

The scope of this order includes all grades and granulation sizes of citric acid, sodium citrate, and potassium citrate in their unblended forms, whether dry or in solution, and regardless of packaging type. The scope also includes blends of citric acid, sodium citrate, and potassium citrate; as well as blends with other ingredients, such as sugar, where the unblended form(s) of citric acid, sodium citrate, and potassium citrate constitute 40 percent or more, by weight, of the blend. The scope of this order also includes all forms of crude calcium citrate, including dicalcium citrate monohydrate, and tricalcium citrate tetrahydrate, which are intermediate products in the production of citric acid, sodium citrate, and potassium citrate. The scope of this order does not include calcium citrate that satisfies the standards set forth in the United States Pharmacopeia and has been mixed with a functional excipient, such as dextrose or starch, where the excipient constitutes at least 2 percent, by weight, of the product. The scope of this order includes the hydrous and anhydrous forms of citric acid, the dihydrate and anhydrous forms of sodium citrate, otherwise known as citric acid sodium salt, and the monohydrate and monopotassium forms of potassium citrate. Sodium citrate also includes both trisodium citrate and monosodium citrate, which are also known as citric acid trisodium salt and citric acid monosodium salt, respectively. Citric acid and sodium citrate are classifiable under 2918.14.0000 and 2918.15.1000 of the Harmonized Tariff Schedule of the United States (HTSUS), respectively. Potassium citrate and crude calcium citrate are classifiable under 2918.15.5000 and 3824.90.9290 of the HTSUS, respectively. Blends that include citric acid, sodium citrate, and potassium citrate are classifiable under 3824.90.9290 of the HTSUS. Although the HTSUS subheadings are provided for convenience and customs purposes, the written description of the merchandise is dispositive.

Period of Review

The period of review (POR) is November 20, 2008, through May 19, 2009, and May 29, 2009, through April 30, 2010. In accordance with section 733(d) of the Tariff Act of 1930, as amended (the Act), and subsequent to the imposition of the antidumping duty order, we instructed CBP to terminate the suspension of liquidation and to liquidate, without regard to antidumping duties, entries of subject merchandise for the period May 20, 2009, through May 28, 2009. Accordingly, this administrative review does not include the period May 20, 2009, through May 28, 2009.

Facts Available

Section 776(a) of the Act provides that the Department will apply "facts otherwise available" if necessary information is not available on the record or an interested party: (1) Withholds information that has been requested by the Department; (2) fails to provide such information within the deadlines established, or in the form or manner requested by the Department, subject to subsections (c)(1) and (e) of section 782 of the Act; (3) significantly impedes a proceeding; or (4) provides such information, but the information cannot be verified.

The Department's original and first supplemental antidumping questionnaires instructed JBL Canada to report its prices and expenses in the currencies in which they were incurred, in accordance with section 773A of the Act, and 19 CFR 351.415(a).[1] Despite our instructions, JBL Canada reported its home market price and expense data in Canadian dollars (CAD) and its U.S. market price and expense data in U.S. dollars (USD), regardless of the currencies in which they were incurred. JBL Canada explained that its data processing system automatically converts all foreign currency transactions into the currency of the respective JBL Group entity at the moment of posting. Although the system maintains a record of the original currency in which the price or expense was incurred and the exchange rate used to make currency conversions, JBL Canada failed to report certain prices and expenses in their original currencies, maintaining that retrieving the original currency values from the system would be "an extremely laborious and time-consuming undertaking." *See* JBL Canada's October 29, 2010, supplemental questionnaire response at pages 7–8. Therefore, pursuant to section 776(a)(2)(B) of the Act, we find that JBL Canada failed to provide information in the form and manner requested by the Department and that it is appropriate to resort to facts otherwise available to account for the unreported information.

In selecting from among the facts otherwise available, section 776(b) of the Act authorizes the Department to use an adverse inference if the Department finds that an interested party failed to cooperate by not acting to the best of its ability to comply with a request for information. The legislative history of the Act also provides guidance by explaining that adverse inferences are appropriate "to ensure that the party does not obtain a more favorable result by failing to cooperate than if it had cooperated fully." *See* Statement of Administrative Action (SAA) accompanying the Uruguay Round Agreements Act, H.R. Doc. No. 103–465 at 870 (1995). Information used to make an adverse inference may include such sources as the petition, other information placed on the record, or determinations in a prior proceeding regarding the subject merchandise. *Id.* and 19 CFR 351.308(c). Furthermore, "affirmative evidence of bad faith on the part of a respondent is not required before the Department may make an adverse inference." *See Antidumping Duties; Countervailing Duties,* 62 FR 27296, 27340 (May 19, 1997); *see also Nippon Steel Corp.* v. *United States,* 337 F.3d 1373, 1383 (Fed. Cir. 2003) (*Nippon*).

Based on JBL Canada's questionnaire response description of how exchange rate information is currently stored in its data processing system, we find that it was possible for JBL Canada to report all of its sales data in the currencies in which they were incurred. This is consistent with our determination in *Citric Acid LTFV* with respect to the same issue.[2] Because JBL Canada could have reported the information at issue in the form and manner requested by the Department, but failed to do so, we find that JBL Canada has failed to cooperate to the best of its ability with our requests for information in the original and supplemental questionnaires. Specifically, we find that an adverse inference is appropriate because: (1) JBL Canada had the necessary information within its control

[1] We also referred JBL Canada to the Department's adverse facts available (AFA) determination on this same issue in the less-than-fair-value (LTFV) investigation. *See* Comment 4 of the Issues and Decision Memorandum (LTFV I&D Memo) accompanying the *Notice of Final Determination of Sales at Less Than Fair Value: Citric Acid and Certain Citrate Salts from Canada,* 74 FR 16843 (April 13, 2009) (*Citric Acid LTFV*).

[2] *See* Comment 4 of the LTFV I&D Memo.

and it did not report this information; and 2) it failed to put forth its maximum effort to provide the requested information. *See, e.g., Nippon,* 337 F.3d at 1883; and *Notice of Final Results of Antidumping Duty Administrative Review, Rescission of Administrative Review in Part, and Final Determination to Not Revoke Order in Part: Canned Pineapple Fruit from Thailand,* 68 FR 65247 (November 19, 2003), and accompanying Issues and Decision Memorandum at Comment 20b. Thus, for these preliminary results, pursuant to section 776(b) of the Act, we find that it is appropriate to apply AFA to the following home market variables which JBL Canada converted to CAD from the original currency: Gross unit price, billing adjustments, inland insurance, and indirect selling expenses. Likewise, we applied AFA to the following U.S. market variables which JBL Canada converted to USD from the original currency: Foreign inland freight (warehouse to port), foreign inland insurance, U.S. inland freight (port to warehouse and warehouse to customer), indirect selling expenses, inventory carrying costs, and packing. Specifically, as AFA, we increased JBL Canada's reported home market sales prices as well as the above-specified U.S. and home market expenses by the highest difference between the Department's weighted-average monthly exchange rates (used to convert comparison-market values to USD in the margin program), and JBL Canada's monthly exchange rates (used by JBL Canada's data processing system for currency conversion purposes). For further explanation, *see* Memorandum to the File entitled "2008–2010 Administrative Review of Citric Acid and Certain Citrate Salts from Canada," dated concurrently with this notice.

Comparisons to Normal Value

To determine whether JBL Canada's sales of citric acid from Canada to the United States were made at less than NV, we compared the constructed export price (CEP) to the NV, as described in the "Constructed Export Price" and "Normal Value" sections of this notice.

Pursuant to section 777A(d)(2) of the Act, for JBL Canada we compared the CEPs of individual U.S. transactions to the weighted-average NV of the foreign like product where there were sales made in the ordinary course of trade. *See* discussion below.

Product Comparisons

In accordance with section 771(16) of the Act, we considered all products produced by JBL Canada covered by the description in the "Scope of the Order" section, above, to be foreign like products for purposes of determining appropriate product comparisons to U.S. sales. Pursuant to 19 CFR 351.414(e)(2), we compared JBL Canada's U.S. sales of citric acid to its sales of citric acid made in the home market. Where there were no contemporaneous sales within the definition of 19 CFR 351.414(e)(2)(i), pursuant to 19 CFR 351.414(e)(2)(ii) and (iii), we compared sales within the contemporaneous window period, which extends from three months prior to the month of the U.S. sale until two months after the sale.

In making the product comparisons, we matched foreign like products based on the physical characteristics reported by JBL Canada in the following order: type, form, grade, and particle size.

Constructed Export Price

For all U.S. sales made by JBL Canada, we calculated CEP in accordance with section 772(b) of the Act because the subject merchandise was first sold (or agreed to be sold) in the United States before or after the date of importation by or for the account of the producer or exporter, or by a seller affiliated with the producer or exporter, to a purchaser not affiliated with the producer or exporter.

We based CEP on packed, ex-factory or delivered prices to unaffiliated purchasers in the United States. Where appropriate, we adjusted the starting prices for billing adjustments, rebates and interest revenue, in accordance with 19 CFR 351.401(c). We made deductions for movement expenses, where appropriate, in accordance with section 772(c)(2)(A) of the Act; these included, where appropriate, foreign inland freight expenses, foreign inland insurance expenses, U.S. brokerage and handling expenses, U.S. inland freight expenses, U.S. warehousing expenses, and U.S. inland insurance expenses. In accordance with section 772(d)(1) of the Act and 19 CFR 351.402(b), we deducted those selling expenses associated with economic activities occurring in the United States, including direct selling expenses (*e.g.,* imputed credit expenses), and indirect selling expenses (including inventory carrying costs).

Pursuant to section 772(d)(3) of the Act, we further reduced the starting price by an amount for profit to arrive at CEP. In accordance with section 772(f) of the Act, we calculated the CEP profit rate using the expenses incurred by JBL Canada on its sales of the subject merchandise in the United States and the profit associated with those sales.

Normal Value

A. Home Market Viability and Selection of Comparison Market

To determine whether there was a sufficient volume of sales in the home market to serve as a viable basis for calculating NV, we compared the volume of home market sales of the foreign like product to the volume of U.S. sales of the subject merchandise, in accordance with section 773(a)(1)(C) of the Act. Based on this comparison, we determined that, pursuant to 19 CFR 351.404(b) JBL Canada had a viable home market during the POR. Consequently, pursuant to section 773(a)(1)(B)(i) of the Act and 19 CFR 351.404(c)(i), we based NV on home market sales.

B. Level of Trade

Section 773(a)(1)(B)(i) of the Act states that, to the extent practicable, the Department will calculate NV based on sales of foreign like products at the same level of trade (LOT) as the export price or CEP. Sales are made at different LOTs if they are made at different marketing stages (or their equivalent). *See* 19 CFR 351.412(c)(2). Substantial differences in selling activities are a necessary, but not sufficient, condition for determining that there is a difference in the stages of marketing. *See Id.; see also Notice of Final Determination of Sales at Less Than Fair Value: Certain Cut-to-Length Carbon Steel Plate From South Africa,* 62 FR 61731, 61732 (November 19, 1997) (*Plate from South Africa*). In order to determine whether the comparison-market sales were at different stages in the marketing process than the U.S. sales, we reviewed the distribution system in each market (*i.e.,* the chain of distribution), including selling functions, class of customer (customer category), and the level of selling expenses for each type of sale.

Pursuant to section 773(a)(1)(B)(i) of the Act, in identifying LOTs for EP and comparison-market sales (*i.e.,* where NV is based on either home market or third country prices),[3] we consider the starting prices before any adjustments. For CEP sales, we consider only the selling activities reflected in the price after the deduction of expenses and profit under section 772(d) of the Act. *See Micron Technology, Inc.* v. *United States,* 243 F. 3d 1301, 1314 (Fed. Cir. 2001). When the Department is unable to match U.S. sales of the foreign like product in the comparison market at the same LOT as the EP or CEP, the

[3] Where NV is based on CV, we determine the NV LOT based on the LOT of the sales from which we derive selling expenses, general and administrative (G&A) expenses, and profit for CV, where possible.

Department may compare the U.S. sales to sales at a different LOT in the comparison market. In comparing EP or CEP sales at a different LOT in the comparison market, where available data make it practicable, we make an LOT adjustment under section 773(a)(7)(A) of the Act. Finally, for CEP sales only, if the NV LOT is at a more advanced stage of distribution than the LOT of the CEP and there is no basis for determining whether the difference in LOTs between NV and CEP affects price comparability (*i.e.,* no LOT adjustment was practicable), the Department shall grant a CEP offset, as provided in section 773(a)(7)(B) of the Act. *See Plate from South Africa,* 62 FR at 61732–33.

In this administrative review, we obtained information from JBL Canada regarding the marketing stages involved in making its reported home market and U.S. sales, including a description of the selling activities performed by the respondent and its affiliates for each channel of distribution.

During the POR, JBL Canada reported that it sold citric acid to end-users and distributors through two channels of distribution in both the U.S. and home markets. JBL Canada stated that its selling process was essentially the same for all channels of distribution. Because the details of JBL Canada's reported selling functions for each channel of distribution are business proprietary, our analysis of these selling functions for purposes of determining whether different LOTs exist is contained in a separate memorandum to James Maeder, Director, AD/CVD Operations Office 2, from the Team entitled "Preliminary Level-of-Trade Analysis," dated contemporaneously with this notice.

Based on our analysis, we find that the selling functions JBL Canada performed for each of its channels of distribution in the U.S. market were essentially the same, with the exception of one selling function which we determined was not sufficient to warrant an LOT distinction between these channels. Therefore, we determined preliminarily that there is only one LOT (for CEP sales) in the U.S. market. Similarly, we found that the selling functions that JBL Canada (and its affiliates) performed for each of the channels of distribution in the home market were essentially the same, with the exception of certain selling activities which we determined were not sufficient to warrant an LOT distinction between these channels. Therefore, we preliminarily determine that there is only one LOT in the home market.

In comparing the home market LOT to the CEP LOT, we found that the selling activities performed by JBL Canada (and its affiliates) for its CEP sales were significantly fewer than the selling activities that it performed for its home market sales, and that the home-market LOT was more remote from the factory than the CEP LOT. Accordingly, we considered the CEP LOT to be different from the home-market LOT and to be at a less advanced stage of distribution than the home-market LOT.

Therefore, we could not match CEP sales to sales at the same LOT in the home market, nor could we determine an LOT adjustment based on JBL Canada's home market sales because there is only one LOT in the home market, and it is not possible to determine if there is a pattern of consistent price differences between the sales on which NV is based and home market sales at the LOT of the export transaction. *See* section 773(a)(7)(A) of the Act. Furthermore, we have no other information that provides an appropriate basis for determining an LOT adjustment. Consequently, because the available data do not form an appropriate basis for making an LOT adjustment but the home market LOT is at a more advanced stage of distribution than the CEP LOT, we find it is appropriate to make a CEP offset to NV in accordance with section 773(a)(7)(B) of the Act. The CEP offset is calculated as the lesser of: (1) The indirect selling expenses incurred on the home market sales, or (2) the indirect selling expenses deducted from the starting price in calculating CEP.

C. Cost of Production Analysis

Whenever the Department has reasonable grounds to believe or suspect that sales of the foreign like product under consideration for the determination of NV have been made at prices which represent less than the COP, the Department shall determine whether, in fact, such sales were made at less than COP. *See* section 773(b)(1) of the Act. We found that JBL Canada made home market sales below the COP in the LTFV investigation and such sales were disregarded. *See Citric Acid and Certain Citrate Salts from Canada: Notice of Preliminary Determination of Sales at Less Than Fair Value and Postponement of Final Determination,* 73 FR 70324 (November 20, 2008); unchanged in *Citric Acid LTFV.* Thus, in accordance with section 773(b)(2)(A)(ii) of the Act, we find that there are reasonable grounds to believe or suspect that JBL Canada made sales in its home market at prices below the cost of producing the merchandise in the current review period.

1. Calculation of Cost of Production

In accordance with section 773(b)(3) of the Act, we calculated COP based on the sum of the cost of materials and conversion for the foreign like product, plus an amount for G&A expenses and interest expenses (*see* "Test of Comparison-Market Sales Prices" section below for treatment of comparison-market selling expenses and packing costs).

The Department relied on the COP data submitted by JBL Canada in the November 8, 2010, supplemental response to section D of the questionnaire for the COP calculations. We made an adjustment to the reported depreciation expenses associated with an affiliated party transaction. For adjustment details, see the Memorandum to Neal M. Halper, Director, Office of Accounting, "Cost of Production and Constructed Value Calculation Adjustments for the Preliminary Results—Jungbunzlauer Canada, Inc," dated concurrently with this notice.

Based on the review of record evidence, JBL Canada did not appear to experience significant changes in cost of manufacturing during the POR. Therefore, we followed our normal methodology of calculating a POR-wide weighted-average cost.

2. Test of Comparison-Market Sales Prices

On a product-specific basis, we compared the weighted-average COP to the prices of home market sales of the foreign like product, as required under section 773(b) of the Act, in order to determine whether the sale prices were below the COP. For purposes of this comparison, we used COP exclusive of selling and packing expenses. The prices, adjusted for any applicable billing adjustments, rebates, and interest revenue, were also exclusive of any applicable movement charges, direct and indirect selling expenses,[4] and packing expenses.

3. Results of the COP Test

After concluding that we had reasonable grounds to believe or suspect that JBL Canada's sales of foreign like product were made at prices less than COP, to determine whether to disregard such sales, we examined, in accordance with sections 773(b)(1)(A) and (B) of the Act: (1) Whether, within an extended period of time, such sales were made in substantial quantities; and (2) whether

[4] We recalculated home market credit expenses in order to account for the application of AFA to home market prices used in the credit expense calculation.

such sales were made at prices which permitted the recovery of all costs within a reasonable period of time in the normal course of trade. Where less than 20 percent of a respondent's comparison-market sales of a given product are at prices less than the COP, we do not disregard any below-cost sales of that product because we determine that, in such instances, the below-cost sales were not made within an extended period of time in "substantial quantities." Where 20 percent or more of a respondent's sales of a given product are at prices less than the COP, we disregard the below-cost sales because: (1) They were made within an extended period of time in "substantial quantities," in accordance with sections 773(b)(2)(B) and (C) of the Act, and (2) based on our comparison of prices to the weighted-average COPs for the POR, they were at prices which would not permit the recovery of all costs within a reasonable period of time, in accordance with section 773(b)(2)(D) of the Act.

Based on this test, we did not disregard any of JBL Canada's home market sales of citric acid because for all products, we found that less than 20 percent of these sales were at prices less than the COP.

D. Calculation of Normal Value Based on Comparison-Market Prices

We based NV for JBL Canada on packed, ex-factory or delivered prices to unaffiliated customers in the home market. Where appropriate, we adjusted the starting prices for billing adjustments, rebates and interest revenue, in accordance with 19 CFR 351.401(c). We made deductions, where appropriate, from the starting price for movement expenses, including inland freight and inland insurance, under section 773(a)(6)(B)(ii) of the Act.

We made adjustments under section 773(a)(6)(C) of the Act for differences in circumstances-of-sale for imputed credit expenses, where appropriate.

We also deducted home market packing costs and added U.S. packing costs, in accordance with section 773(a)(6)(A) and (B) of the Act.

Finally, as discussed in the "Level of Trade" section above, we made a CEP offset pursuant to section 773(a)(7)(B) of the Act and 19 CFR 351.412(f). We calculated the CEP offset as the lesser of the indirect selling expenses incurred on the home-market sales or the indirect selling expenses deducted from the starting price in calculating CEP.

Currency Conversion

It is our normal practice to make currency conversions into U.S. dollars, in accordance with section 773A(a) of the Act, based on exchange rates in effect on the dates of the U.S. sales, as certified by the Federal Reserve Bank. *See* "Facts Available" section, above, for further discussion of currency conversion in this administrative review.

Preliminary Results of the Review

We preliminarily determine that a weighted-average dumping margin exists for JBL Canada for the period November 20, 2008, through May 19, 2009, and May 29, 2009, through April 30, 2010, as follows:

Manufacturer/exporter	Percent margin
Jungbunzlauer Canada Inc	1.51

Disclosure and Public Hearing

The Department will disclose to parties the calculations performed in connection with these preliminary results within five days of the date of publication of this notice. *See* 19 CFR 351.224(b). Pursuant to 19 CFR 351.309, interested parties may submit case briefs not later than 30 days after the date of publication of this notice. Rebuttal briefs, limited to issues raised in the case briefs, may be filed not later than five days after the date for filing case briefs. Parties who submit case briefs or rebuttal briefs in this proceeding are encouraged to submit with each argument: (1) A statement of the issue; (2) a brief summary of the argument; and (3) a table of authorities.

Interested parties who wish to request a hearing or to participate if one is requested must submit a written request to the Assistant Secretary for Import Administration, Room 1870, within 30 days of the date of publication of this notice. Requests should contain: (1) The party's name, address and telephone number; (2) the number of participants; and (3) a list of issues to be discussed. *See* 19 CFR 351.310(c). Issues raised in the hearing will be limited to those raised in the respective case briefs.

The Department will issue the final results of this administrative review, including the results of its analysis of issues raised in any written briefs, not later than 120 days after the date of publication of this notice, pursuant to section 751(a)(3)(A) of the Act.

Assessment Rates

Upon completion of the administrative review, the Department shall determine, and CBP shall assess, antidumping duties on all appropriate entries, in accordance with 19 CFR 351.212. The Department intends to issue appropriate appraisement instructions for the companies subject to this review directly to CBP 15 days after the date of publication of the final results of this review.

Because the respondent did not report entered value for all sales to each importer or customer, we will calculate importer- or customer-specific per-unit duty assessment rates by aggregating the total amount of antidumping duties calculated for the examined sales and dividing this amount by the total quantity of those sales. To determine whether the duty assessment rates are *de minimis,* in accordance with the requirement set forth in 19 CFR 351.106(c)(2), we will calculate importer-specific *ad valorem* ratios based on the estimated entered value.

We will instruct CBP to assess antidumping duties on all appropriate entries covered by this review if any importer-specific assessment rate calculated in the final results of this review is above *de minimis* (*i.e.,* at or above 0.50 percent). Pursuant to 19 CFR 351.106(c)(2), we will instruct CBP to liquidate without regard to antidumping duties any entries for which the assessment rate is *de minimis* (*i.e.,* less than 0.50 percent). The final results of this review shall be the basis for the assessment of antidumping duties on entries of merchandise covered by the final results of this review and for future deposits of estimated duties, where applicable.

The Department clarified its "automatic assessment" regulation on May 6, 2003. *See Antidumping and Countervailing Duty Proceedings: Assessment of Antidumping Duties,* 68 FR 23954 (May 6, 2003) (*Assessment Policy Notice*). This clarification will apply to entries of subject merchandise during the POR produced by companies included in these final results of review for which the reviewed companies did not know that the merchandise they sold to the intermediary (*e.g.,* a reseller, trading company, or exporter) was destined for the United States. In such instances, we will instruct CBP to liquidate unreviewed entries at the all-others rate effective during the POR if there is no rate for the intermediary involved in the transaction. *See Assessment Policy Notice* for a full discussion of this clarification.

Cash Deposit Requirements

The following cash deposit requirements will be effective for all shipments of the subject merchandise entered, or withdrawn from warehouse, for consumption on or after the publication date of the final results of this administrative review, as provided

by section 751(a)(2)(C) of the Act: (1) The cash deposit rate for the company listed above will be that established in the final results of this review, except if the rate is less than 0.50 percent and, therefore, *de minimis* within the meaning of 19 CFR 351.106(c)(1), in which case the cash deposit rate will be zero; (2) for previously reviewed or investigated companies not participating in this review, the cash deposit rate will continue to be the company-specific rate published for the most recent period; (3) if the exporter is not a firm covered in this review, a previous review, or the original LTFV investigation, but the manufacturer is, the cash deposit rate will be the rate established for the most recent period for the manufacturer of the merchandise; and (4) the cash deposit rate for all other manufacturers or exporters will continue to be 23.21 percent, the all-others rate made effective by the LTFV investigation. *See Citric Acid and Certain Citrate Salts from Canada and the People's Republic of China: Antidumping Duty Orders,* 74 FR 25703 (May 29, 2009). These requirements, when imposed, shall remain in effect until further notice.

Notification to Importers

This notice also serves as a preliminary reminder to importers of their responsibility under 19 CFR 351.402(f) to file a certificate regarding the reimbursement of antidumping duties prior to liquidation of the relevant entries during this review period. Failure to comply with this requirement could result in the Secretary's presumption that reimbursement of antidumping duties occurred and the subsequent assessment of double antidumping duties.

This administrative review and notice are published in accordance with sections 751(a)(1) and 777(i)(1) of the Act and 19 CFR 351.221.

Dated: January 26, 2011.

Ronald K. Lorentzen,

Deputy Assistant Secretary for Import Administration.

[FR Doc. 2011–2276 Filed 2–1–11; 8:45 am]

BILLING CODE 3510–DS–P

DEPARTMENT OF EDUCATION

Notice of Submission for OMB Review

AGENCY: Department of Education.

ACTION: Comment request.

SUMMARY: The Director, Information Collection Clearance Division, Regulatory Information Management Services, Office of Management invites comments on the submission for OMB review as required by the Paperwork Reduction Act of 1995 (Pub. L. 104–13).

DATES: Interested persons are invited to submit comments on or before March 4, 2011.

ADDRESSES: Written comments should be addressed to the Office of Information and Regulatory Affairs, Attention: Education Desk Officer, Office of Management and Budget, 725 17th Street, NW., Room 10222, New Executive Office Building, Washington, DC 20503, be faxed to (202) 395–5806 or e-mailed to *oira_submission@omb.eop.gov* with a cc: to *ICDocketMgr@ed.gov.* Please note that written comments received in response to this notice will be considered public records.

SUPPLEMENTARY INFORMATION: Section 3506 of the Paperwork Reduction Act of 1995 (44 U.S.C. chapter 35) requires that the Office of Management and Budget (OMB) provide interested Federal agencies and the public an early opportunity to comment on information collection requests. 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.

Dated: January 27, 2011.

Darrin A. King,

Director, Information Collection Clearance Division, Regulatory Information Management Services, Office of Management.

Federal Student Aid

Type of Review: Extension.

Title of Collection: Consolidation Loan Rebate Fee Report.

OMB Control Number: 1845–0046.

Agency Form Number(s): ED Form 4–619.

Frequency of Responses: Monthly.

Affected Public: Businesses or other for-profit.

Total Estimated Number of Annual Responses: 11,400.

Total Estimated Annual Burden Hours: 12,350.

Abstract: The Consolidation Loan Rebate Fee Report for Payment by check or Electronic Funds Transfer will be used by approximately 950 lenders participating in the Title IV, Part B loan programs. The information collected is used to transmit interest payment rebate fees to the Secretary of Education.

Requests for copies of the information collection submission for OMB review may be accessed from the RegInfo.gov Web site at *http://www.reginfo.gov/public/do/PRAMain* or from the Department's Web site at *http://edicsweb.ed.gov,* by selecting the "Browse Pending Collections" link and by clicking on link number 4417. When you access the information collection, click on "Download Attachments " to view. Written requests for information should be addressed to U.S. Department of Education, 400 Maryland Avenue, SW., LBJ, Washington, DC 20202–4537. Requests may also be electronically mailed to the Internet address *ICDocketMgr@ed.gov* or faxed to 202–401–0920. Please specify the complete title of the information collection and OMB Control Number when making your request.

Individuals who use a telecommunications device for the deaf (TDD) may call the Federal Information Relay Service (FIRS) at 1–800–877–8339.

[FR Doc. 2011–2274 Filed 2–1–11; 8:45 am]

BILLING CODE 4000–01–P

DEPARTMENT OF EDUCATION

[CFDA Nos. 84.038, 84.033, and 84.007]

Federal Perkins Loan, Federal Work-Study, and Federal Supplemental Educational Opportunity Grant Programs

ACTION: Notice of the 2011–2012 award year deadline dates for the campus-based programs.

SUMMARY: The Secretary announces the 2011–2012 award year deadline dates for the submission of requests and documents from postsecondary institutions for the campus-based programs.

SUPPLEMENTARY INFORMATION: The Federal Perkins Loan, Federal Work-Study (FWS), and Federal Supplemental Educational Opportunity Grant (FSEOG) programs are collectively known as the campus-based programs.

The Federal Perkins Loan Program encourages institutions to make low-interest, long-term loans to needy undergraduate and graduate students to help pay for their education.

The FWS Program encourages the part-time employment of needy undergraduate and graduate students to help pay for their education and to involve the students in community service activities.

The FSEOG Program encourages institutions to provide grants to exceptionally needy undergraduate students to help pay for their cost of education.

The Federal Perkins Loan, FWS, and FSEOG programs are authorized by parts E and C, and part A, subpart 3, respectively, of title IV of the Higher Education Act of 1965, as amended.

Throughout the year, in its "Electronic Announcements," the Department will continue to provide additional information for the individual deadline dates listed in the table under the DEADLINE DATES section of this notice, via the Information for Financial Aid Professionals (IFAP) Web site at: *http://www.ifap.ed.gov.*

Deadline Dates: The following table provides the 2011–2012 award year deadline dates for the submission of applications, reports, waiver requests, and other documents for the campus-based programs. Institutions must meet the established deadline dates to ensure consideration for funding or a waiver, as appropriate.

2011–2012 AWARD YEAR DEADLINE DATES

What does an institution submit?	How is it submitted?	What is the deadline for submission?
1. The Campus-Based Reallocation Form designated for the return of 2010–2011 funds and the request of supplemental FWS funds for the 2011–2012 award year.	The Reallocation Form must be submitted electronically via the Internet and is located in the "Setup" section of the FISAP on the Web at: *http://www.cbfisap.ed.gov*.	August 19, 2011.
2. The 2010–2011 Fiscal Operations Report and 2012–2013 Application to Participate (FISAP).	The FISAP is located on the Internet at the following Web site: *http://www.cbfisap.ed.gov*. The FISAP must be submitted electronically via the Internet, and the FISAP's signature page must be mailed to: FISAP Administrator, 2020 Company, LLC, 3110 Fairview Park Drive, Suite 950, Falls Church, VA 22042.	September 30, 2011.
3. The Work Colleges Program Report of 2010–2011 award year expenditures.	The Work Colleges Program Report can be found in the "Setup" section of the FISAP on the Web at: *http://www.cbfisap.ed.gov.* The report must be submitted electronically via the Internet, and a printed copy with an original signature must be submitted by one of the following methods: Hand deliver to: United States Department of Education, Federal Student Aid, Grants & Campus-Based Division, 830 First Street, NE., Room 62E3, ATTN: Work Colleges Coordinator, Washington, DC 20002, or Mail to: The address listed above for hand delivery. However, please use ZIP Code 20202–5453.	September 30, 2011.
4. The 2010–2011 FISAP Edit Corrections and Perkins Cash on Hand Update.	The FISAP is located on the Internet at the following Web site: *http://www.cbfisap.ed.gov*. The FISAP Edit Corrections and Perkins Cash on Hand Update must be submitted electronically via the Internet.	December 15, 2011.
5. A request for a waiver of the 2012–2013 award year penalty for the underuse of 2010–2011 award year funds.	The request for a waiver can be found in Part II, Section C of the FISAP on the Web at: *http://www.cbfisap.ed.gov.* The request and justification must be submitted electronically via the Internet.	February 10, 2012.
6. The Institutional Application and Agreement for Participation in the Work Colleges Program for the 2012–2013 award year.	The Institutional Application and Agreement for Participation in the Work Colleges Program can be found in the "Setup" section of the FISAP on the Web at: *http://www.cbfisap.ed.gov.* The application and agreement must be submitted electronically via the Internet, and a printed copy with original signature must be submitted by one of the following methods:. Hand deliver to: United States Department of Education, Federal Student Aid, Grants & Campus-Based Division, 830 First Street, NE., Room 62E3, ATTN: Work Colleges Coordinator, Washington, DC 20002, or. Mail to: The address listed above for hand delivery. However, please use ZIP Code 20202–5453.	March 9, 2012.

2011–2012 AWARD YEAR DEADLINE DATES—Continued

What does an institution submit?	How is it submitted?	What is the deadline for submission?
7. A request for a waiver of the FWS Community Service Expenditure Requirement for the 2012–2013 award year.	The FWS Community Service waiver request can be found in the "Setup" section of the FISAP on the Web at: *http://www.cbfisap.ed.gov.* The request and justification must be submitted electronically via the Internet.	April 20, 2012.

Note:
- The deadline for electronic submissions is 11:59: p.m. (Washington, DC time) on the applicable deadline date. Transmissions must be completed and accepted by 12:00: midnight to meet the deadline.
- Paper documents that are sent through the U.S. Postal Service must be postmarked by the applicable deadline date.
- Paper documents that are hand delivered by a commercial courier must be received no later than 4:30: p.m. (Washington, DC time) on the applicable deadline date.
- The Secretary may consider on a case-by-case basis the effect that a major disaster, as defined in section 102(2) of the Robert T. Stafford Disaster Relief and Emergency Assistance Act (42 U.S.C. 5122(2)), or another unusual circumstance has on an institution in meeting the deadlines.

Proof of Mailing or Hand Delivery of Paper Documents

If you submit paper documents when permitted by mail or by hand delivery (or from a commercial courier), we accept as proof one of the following:

(1) A legible mail receipt with the date of mailing stamped by the U.S. Postal Service.

(2) A legibly dated U.S. Postal Service postmark.

(3) A legibly dated shipping label, invoice, or receipt from a commercial courier.

(4) Other proof of mailing or delivery acceptable to the Secretary.

If the paper documents are sent through the U.S. Postal Service, we do not accept either of the following as proof of mailing: (1) A private metered postmark, or (2) a mail receipt that is not dated by the U.S. Postal Service. An institution should note that the U.S. Postal Service does not uniformly provide a dated postmark. Before relying on this method, an institution should check with its local post office. All institutions are encouraged to use certified or at least first-class mail.

The Department accepts hand deliveries from you or a commercial courier between 8:00 a.m. and 4:30 p.m., Washington, DC time, Monday through Friday except Federal holidays.

Sources for Detailed Information on These Requests

A more detailed discussion of each request for funds or waiver is provided in specific "Electronic Announcements," which are posted on the Department's IFAP Web site (*http://www.ifap.ed.gov*) at least 30 days before the established deadline date for the specific request. Information on these items is also found in the Federal Student Aid Handbook.

Applicable Regulations: The following regulations apply to these programs:

(1) Student Assistance General Provisions, 34 CFR part 668.

(2) General Provisions for the Federal Perkins Loan Program, Federal Work-Study Program, and Federal Supplemental Educational Opportunity Grant Program, 34 CFR part 673.

(3) Federal Perkins Loan Program, 34 CFR part 674.

(4) Federal Work-Study Programs, 34 CFR part 675.

(5) Federal Supplemental Educational Opportunity Grant Program, 34 CFR part 676.

(6) Institutional Eligibility under the Higher Education Act of 1965, as amended, 34 CFR part 600.

(7) New Restrictions on Lobbying, 34 CFR part 82.

(8) Governmentwide Requirements for Drug-Free Workplace (Financial Assistance), 34 CFR part 84.

(9) Governmentwide Debarment and Suspension (Nonprocurement), 34 CFR part 85.

(10) Drug and Alcohol Abuse Prevention, 34 CFR part 86.

FOR FURTHER INFORMATION CONTACT: Kathleen Wicks, Director of Grants & Campus-Based Division, U.S. Department of Education, Federal Student Aid, 830 First Street, NE., Union Center Plaza, room 62E3, Washington, DC 20202–5453. Telephone: (202) 377–3110 or via the Internet: *kathleen.wicks@ed.gov.*

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 program contact person listed under **FOR FURTHER INFORMATION CONTACT.**

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.*

Program Authority: 20 U.S.C. 1087aa *et seq.;* 42 U.S.C. 2751 *et seq.;* and 20 U.S.C. 1070b *et seq.*

Dated: January 28, 2011.

William J. Taggart,

Chief Operating Officer, Federal Student Aid.

[FR Doc. 2011–2307 Filed 2–1–11; 8:45 am]

BILLING CODE 4000–01–P

DEPARTMENT OF EDUCATION

Teaching American History Grant Program; Office of Innovation and Improvement; Overview Information; Teaching American History Grant Program; Notice Inviting Applications for New Awards for Fiscal Year (FY) 2011

Catalog of Federal Domestic Assistance (CFDA) Number: 84.215X.

Dates:

Applications Available: February 2, 2011.

Deadline for Notice of Intent to Apply: March 4, 2011.

Dates of Pre-Application Meetings: Pre-application meetings for prospective applicants will be held on March 11, 2011.

Deadline for Transmittal of Applications: April 4, 2011.

Deadline for Intergovernmental Review: June 2, 2011.

Full Text of Announcement

I. Funding Opportunity Description

Purpose of Program: The Teaching American History (TAH) grant program supports projects that aim to raise student achievement by improving teachers' knowledge, understanding, and appreciation of traditional American history as a separate subject within the core elementary and secondary school curriculum. Grant awards assist local educational agencies (LEAs), in partnership with entities that have extensive content expertise, in developing, implementing, documenting, evaluating, and disseminating innovative, cohesive models of professional development.

Priorities: This competition includes one absolute priority and four competitive preference priorities that are described in the following paragraphs.

Absolute Priority: In accordance with 34 CFR 75.105(b)(2)(iv), this priority is from section 2351 of the Elementary and Secondary Education Act of 1965, as amended (ESEA) (20 U.S.C. 6721(b)). For FY 2011 and any subsequent year in which we make awards from the list of unfunded applicants from this competition, this priority is an absolute priority. Under 34 CFR 75.105(c)(3) we consider only applications that meet this priority.

This priority is:

Partnerships With Other Agencies or Institutions

Each applicant LEA must propose to work in partnership with one or more of the following:

- An institution of higher education.
- A non-profit history or humanities organization.
- A library or museum.

Competitive Preference Priorities: These priorities are from the notice of final supplemental priorities and definitions for discretionary grant programs published in the **Federal Register** on December 15, 2010 (75 FR 78486). For FY 2011 and any subsequent year in which we make awards from the list of unfunded applicants from this competition, these priorities are competitive preference priorities. Applicants may choose to address one or more of these competitive preference priorities. Consistent with 34 CFR 75.105(c)(2)(i), we may award up to an additional twelve points to an application, depending on how well the application meets these priorities. These points are in addition to any points the application earns under the selection criteria.

These priorities are:

Priority 1—Improving the Effectiveness and Distribution of Effective Teachers or Principals (up to three additional points).

Projects that are designed to address the following priority area:

Increasing the number or percentage of teachers or principals who are effective or reducing the number or percentage of teachers or principals who are ineffective, particularly in high-poverty schools (as defined in this notice) including through such activities as improving the preparation, recruitment, development, and evaluation of teachers and principals; implementing performance-based certification and retention systems; and reforming compensation and advancement systems.

For the purposes of this priority, teacher and principal effectiveness should be measured using:

(1) Teacher or principal evaluation data, in States or local educational agencies that have in place a high-quality teacher evaluation system that takes into account student growth (as defined in this notice) in significant part and uses multiple measures that, in the case of teachers, may include observations for determining teacher effectiveness (such as systems that meet the criteria for evaluation systems under the Race to the Top program as described in criterion (D)(2)(ii) of the Race to the Top notice inviting applications (74 FR 59803)); or

(2) Data that include, in significant part, student achievement (as defined in this notice) or student growth (as defined in this notice) data and may include multiple measures in States or local educational agencies that do not have the teacher or principal evaluation systems described in paragraph (1).

Note: The Teaching American History program is a professional development program for elementary and secondary school teachers. Consequently, in responding to this priority, applicants must focus their efforts on improving the effectiveness and distribution of effective elementary and secondary school teachers.

Priority 2—Improving Achievement and High School Graduation Rates (up to three additional points)

Projects that are designed to address one or both of the following priority areas:

(a) Accelerating learning and helping to improve high school graduation rates (as defined in this notice) and college enrollment rates for high-need students (as defined in this notice).

(b) Accelerating learning and helping to improve high school graduation rates (as defined in this notice) and college enrollment rates in high-poverty schools (as defined in this notice).

Note: For Priority 2, applicants may earn a maximum of up to three points by responding to priority areas (a) and (b). If the applicant chooses to respond to only priority area (a) or priority area (b), the maximum points earned will still be up to three points.

Priority 3—Enabling More Data-Based Decision-Making (up to three additional points).

Projects that are designed to collect (or obtain), analyze, and use high-quality and timely data, including data on program participant outcomes, in accordance with privacy requirements (as defined in this notice), in one or both of the following priority areas:

(a) Improving instructional practices, policies, and student outcomes in elementary and secondary schools.

(b) Providing reliable and comprehensive information on the implementation of Department of Education programs, and participant outcomes in these programs by using data from State longitudinal data systems or by obtaining data from reliable third-party sources.

Note: For Priority 3, applicants may earn a maximum of up to three points by responding to priority areas (a) and (b). If the applicant chooses to respond to only priority area (a) or priority area (b), the maximum points earned will still be up to three points.

Priority 4—Technology (up to three additional points).

Projects that are designed to improve student achievement or teacher effectiveness through the use of high-quality digital tools or materials, which may include preparing teachers to use the technology to improve instruction, as well as developing, implementing, or evaluating digital tools or materials.

DEFINITIONS: For the purposes of Competitive Preference Priorities 1 through 4, the following definitions apply. These definitions are from the notice of final supplemental priorities and definitions for discretionary grant programs published in the **Federal Register** on December 15, 2010 (75 FR 78486).

Graduation rate means a four-year adjusted cohort graduation rate consistent with 34 CFR 200.19(b)(1) and may also include an extended-year adjusted cohort graduation rate consistent with 34 CFR 200.19(b)(1)(v) if the State in which the proposed project is implemented has been approved by the Secretary to use such a rate under Title I of the ESEA.

High-need children and high-need students means children and students at risk of educational failure, such as children and students who are living in

poverty, who are English learners, who are far below grade level or who are not on track to becoming college- or career-ready by graduation, who have left school or college before receiving, respectively, a regular high school diploma or a college degree or certificate, who are at risk of not graduating with a diploma on time, who are homeless, who are in foster care, who are pregnant or parenting teenagers, who have been incarcerated, who are new immigrants, who are migrant, or who have disabilities.

High-poverty school means a school in which at least 50 percent of students are eligible for free or reduced-price lunches under the Richard B. Russell National School Lunch Act or in which at least 50 percent of students are from low-income families as determined using one of the criteria specified under section 1113(a)(5) of the Elementary and Secondary Education Act of 1965, as amended. For middle and high schools, eligibility may be calculated on the basis of comparable data from feeder schools. Eligibility as a high-poverty school under this definition is determined on the basis of the most currently available data.

Privacy requirements means the requirements of the Family Educational Rights and Privacy Act (FERPA), 20 U.S.C. 1232g, and its implementing regulations in 34 CFR part 99, the Privacy Act, 5 U.S.C. 552a, as well as all applicable Federal, State and local requirements regarding privacy.

Student achievement means (a) For tested grades and subjects: (1) A student's score on the State's assessments under the ESEA; and, as appropriate, (2) other measures of student learning, such as those described in paragraph (b) of this definition, provided they are rigorous and comparable across schools. (b) For non-tested grades and subjects: Alternative measures of student learning and performance, such as student scores on pre-tests and end-of-course tests; student performance on English language proficiency assessments; and other measures of student achievement that are rigorous and comparable across schools.

Student growth means the change in student achievement (as defined in this notice) for an individual student between two or more points in time. A State may also include other measures that are rigorous and comparable across classrooms.

Program Authority: 20 U.S.C. 6721.

Applicable Regulations: (a) The Education Department General Administrative Regulations (EDGAR) in 34 CFR parts 74, 75, 77, 79, 80, 81, 82, 84, 85, 86, 97, 98, and 99. (b) The notice of final selection criteria and other application requirements published in the **Federal Register** on April 15, 2005 (70 FR 19939). (c) The notice of final revisions to selection criteria, published in the **Federal Register** on December 23, 2008 (73 FR 78761). (d) The notice of final supplemental priorities and definitions for discretionary grant programs published in the **Federal Register** on December 15, 2010 (75 FR 78486).

Note: The regulations in 34 CFR part 79 apply to all applicants except federally recognized Indian tribes.

Note: The regulations in 34 CFR part 86 apply to institutions of higher education only.

II. Award Information

Type of Award: Discretionary grants.

Estimated Available Funds:

The Administration's budget request for FY 2011 does not include funds for this program. In place of this and several other, sometimes narrowly targeted, programs focused on student achievement in specific subject areas, the Administration has proposed to create, through the reauthorization of the Elementary and Secondary Education Act of 1965, a broader program, Effective Teaching and Learning for a Well-Rounded Education, that would support activities to improve student achievement and teacher effectiveness in American history among other subject areas. However, we are inviting applications for the TAH program to allow enough time to complete the grant process before the end of the current fiscal year, if Congress appropriates funds for this program.

Contingent upon the availability of funds and the quality of applications, we may make additional awards in FY 2012 from the list of unfunded applicants from this competition.

Estimated Range of Awards: $250,000–$2,000,000.

Estimated Average Size of Awards: $910,000.

Maximum Award: The following maximum award amounts are from the notice of final selection criteria and other application requirements for this program, published in the **Federal Register** on April 15, 2005 (70 FR 19939).

(1) Total funding for a three-year project period is a maximum of $500,000 for LEAs with enrollments of less than 20,000 students; $1,000,000 for LEAs with enrollments of 20,000–300,000 students; and $2,000,000 for LEAs with enrollments above 300,000 students. LEAs may form consortia and combine their enrollments in order to receive a grant reflective of their combined enrollment. For districts applying jointly as a consortium, the maximum award is based on the combined enrollment of the individual districts in the consortium. If more than one LEA wishes to form a consortium, they must follow the procedures for group applications described in 34 CFR 75.127 through 34 CFR 75.129 of the Education Department Administrative Regulations.

(2) A maximum of one grant will be awarded per applicant per competition.

Estimated Number of Awards: 75–80.

Note: The Department is not bound by any estimates in this notice.

Project Period: Up to 36 months. The Department anticipates funding the entire project period of each grant with fiscal year 2011 funds. There will be no continuation grant awards for projects funded under this competition.

III. Eligibility Information

1. *Eligible Applicants:* LEAs, including charter schools that are considered LEAs under State law and regulations, which must work in partnership with one or more of the following entities:

- An institution of higher education.
- A non-profit history or humanities organization.
- A library or museum.

An LEA may form a consortium with one or more other LEAs and submit a joint application for funds. The consortium must follow the procedures for joint applications described in 34 CFR 75.127 through 75.129.

2. *Cost Sharing or Matching:* This program does not require cost sharing or matching.

IV. Application and Submission Information

1. *Address to Request Application Package:* You can obtain an application package via the Internet, from the Education Publications Center (ED Pubs), or from the program office.

To obtain a copy via the Internet, use the following address: *http://www.ed.gov/fund/grant/apply/grantapps/index.html.*

To obtain a copy from ED Pubs, write, fax, or call the following: ED Pubs, U.S. Department of Education, P.O. Box 22207, Alexandria, VA 22304. Telephone, toll free: 1–877–433–7827. FAX: (703) 605–6794. If you use a telecommunications device for the deaf (TDD), call, toll free: 1–877–576–7734.

You can contact ED Pubs at its Web site, also: *http://www.EDPubs.gov* or at its e-mail address: *edpubs@inet.ed.gov.*

If you request an application package from ED Pubs, be sure to identify this program as follows: CFDA number 84.215X.

To obtain a copy from the program office, contact: Mia Howerton, Margarita Melendez, or Adam Bookman, U.S. Department of Education, 400 Maryland Avenue, SW., room 4C123, Washington, DC 20202–5960. Telephone: (202) 205–0147 or by e-mail: *teachingamericanhistory@ed.gov.* If you use a TDD, call the Federal Relay Service (FRS), toll free, at 1–800–877–8339.

Individuals with disabilities can obtain a copy of the application package in an accessible format (*e.g.,* braille, large print, audiotape, or computer diskette) by contacting one of the three individuals listed under *For Further Information Contact* in section VII of this notice.

2. *Content and Form of Application Submission:* Requirements concerning the content of an application, together with the forms you must submit, are in the application package for this program. Additional information about this competition and the application requirements also can be found at *http://www.ed.gov/programs/teachinghistory/index.html.*

Notice of Intent to Apply: The Department will be able to develop a more efficient process for reviewing grant applications if it has a better understanding of the number of entities that intend to apply for funding under this competition. Therefore, the Secretary strongly encourages each potential applicant to notify the Department by sending a short e-mail message indicating the applicant's intent to submit an application for funding. The e-mail need not include information regarding the content of the proposed application, only the applicant's intent to submit it. The Secretary requests that this e-mail notification be sent to Mia Howerton at: *teachingamericanhistory@ed.gov.*

Applicants that do not provide this e-mail notification may still apply for funding.

Page Limit: The application narrative (Part III of the application) is where you, the applicant, address the selection criteria that reviewers use to evaluate your application. Applicants are strongly encouraged to limit the application narrative and the appendix to a total of no more than 50 pages, using the following standards:

- A "page" is 8.5″ x 11″, on one side only, with 1″ margins at the top, bottom, and both sides.
- Double space (no more than three lines per vertical inch) all text in the application narrative, including titles, headings, footnotes, quotations, references, and captions. However, you may single space all text in charts, tables, figures, and graphs.
- Use a font that is either 12 point or larger or no smaller than 10 pitch (characters per inch).
- Use one of the following fonts: Times New Roman, Courier, Courier New, or Arial.

The page limit does not apply to Part I, the cover sheet; Part II, the budget section, including the narrative budget justification; Part IV, the assurances and certifications; or the one-page abstract. However, the page limit does apply to all of the application narrative section (Part III). It also applies to the resumes, the bibliography, and letters of support which should be included in the appendix.

3. *Submission Dates and Times:*

Applications Available: February 2, 2011.

Deadline for Intent to Apply: March 4, 2011.

Dates of Pre-Application Meetings: There will be two pre-application meetings for prospective applicants: (1) March 11, 2011 from 10 a.m. to 12 p.m. in the LBJ Auditorium at the U.S. Department of Education Headquarters, 400 Maryland Avenue, SW., Washington, DC 20202; (2) March 11, 2011 from 2 p.m. to 4 p.m. in the LBJ Auditorium at the U.S. Department of Education Headquarters, 400 Maryland Avenue, SW., Washington, DC 20202. The Department is accessible by Metro on the Blue, Orange, Green, and Yellow lines at the 7th Street and Maryland Avenue Exit of the L'Enfant Plaza Metro Station. Please continue to check the Teaching American History Web site at *http://www.ed.gov/programs/teachinghistory/* for further details on how to register for these pre-application meetings. Please contact the U.S. Department of Education contact persons listed under **FOR FURTHER INFORMATION CONTACT** if you have any questions about the details of the pre-application meetings.

Assistance to Individuals With Disabilities at the Pre-Application Meetings.

The meeting site is accessible to individuals with disabilities. If you will need an auxiliary aid or service to participate in the meeting (*e.g.,* interpreting service, assistive listening device, or materials in an alternate format), notify the contact person listed in this notice at least two weeks before the scheduled meeting date. Although we will attempt to meet a request we receive after that date, we may not be able to make available the requested auxiliary aid or service because of insufficient time to arrange it.

Deadline for Transmittal of Applications: April 4, 2011.

Applications for grants under this program must be submitted electronically using the Grants.gov Apply site (Grants.gov). For information (including dates and times) about how to submit your application electronically, please refer to section IV. 6. *Other Submission Requirements* of this notice.

We do not consider an application that does not comply with the deadline requirements.

Individuals with disabilities who need an accommodation or auxiliary aid in connection with the application process should contact one of the three individuals listed under **FOR FURTHER INFORMATION CONTACT** in section VII of this notice. If the Department provides an accommodation or auxiliary aid to an individual with a disability in connection with the application process, the individual's application remains subject to all other requirements and limitations in this notice.

Deadline for Intergovernmental Review: June 2, 2011.

4. *Intergovernmental Review:* This program is subject to Executive Order 12372 and the regulations in 34 CFR part 79. Information about Intergovernmental Review of Federal Programs under Executive Order 12372 is in the application package for this program.

5. *Funding Restrictions:* We reference regulations outlining funding restrictions in the *Applicable Regulations* section of this notice.

6. *Data Universal Numbering System Number, Taxpayer Identification Number, and Central Contractor Registry:* To do business with the Department of Education, you must—

a. Have a Data Universal Numbering System (DUNS) number and a Taxpayer Identification Number (TIN);

b. Register both your DUNS number and TIN with the Central Contractor Registry (CCR), the Government's primary registrant database;

c. Provide your DUNS number and TIN on your application; and

d. Maintain an active CCR registration with current information while your application is under review by the Department and, if you are awarded a grant, during the project period.

You can obtain a DUNS number from Dun and Bradstreet. A DUNS number can be created within one business day.

If you are a corporate entity, agency, institution, or organization, you can obtain a TIN from the Internal Revenue

Service. If you are an individual, you can obtain a TIN from the Internal Revenue Service or the Social Security Administration. If you need a new TIN, please allow 2–5 weeks for your TIN to become active.

The CCR registration process may take five or more business days to complete. If you are currently registered with the CCR, you may not need to make any changes. However, please make certain that the TIN associated with your DUNS number is correct. Also note that you will need to update your CCR registration on an annual basis. This may take three or more business days to complete.

In addition, if you are submitting your application via Grants.gov, you must (1) be designated by your organization as an Authorized Organization Representative (AOR); and (2) register yourself with Grants.gov as an AOR. Details on these steps are outlined in the Grants.gov 3-Step Registration Guide (*see http://www.grants.gov/section910/Grants.govRegistrationBrochure.pdf*).

7. *Other Submission Requirements:* Applications for grants under this program must be submitted electronically unless you qualify for an exception to this requirement in accordance with the instructions in this section.

a. *Electronic Submission of Applications.*

Applications for grants under the Teaching American History program, CFDA number 84.215X, must be submitted electronically using the Government-wide Grants.gov Apply site at *www.Grants.gov.* Through this site, you will be able to download a copy of the application package, complete it offline, and then upload and submit your application. You may not e-mail an electronic copy of a grant application to us.

We will reject your application if you submit it in paper format unless, as described elsewhere in this section, you qualify for one of the exceptions to the electronic submission requirement and submit, no later than two weeks before the application deadline date, a written statement to the Department that you qualify for one of these exceptions. Further information regarding calculation of the date that is two weeks before the application deadline date is provided later in this section under *Exception to Electronic Submission Requirement.*

You may access the electronic grant application for the Teaching American History program at www.Grants.gov. You must search for the downloadable application package for this program by the CFDA number. Do not include the CFDA number's alpha suffix in your search (*e.g.,* search for 84.215, not 84.215X).

Please note the following:

- When you enter the Grants.gov site, you will find information about submitting an application electronically through the site, as well as the hours of operation.
- Applications received by Grants.gov are date and time stamped. Your application must be fully uploaded and submitted and must be date and time stamped by the Grants.gov system no later than 4:30:00 p.m., Washington, DC time, on the application deadline date. Except as otherwise noted in this section, we will not accept your application if it is received—that is, date and time stamped by the Grants.gov system—after 4:30:00 p.m., Washington, DC time, on the application deadline date. We do not consider an application that does not comply with the deadline requirements. When we retrieve your application from Grants.gov, we will notify you if we are rejecting your application because it was date and time stamped by the Grants.gov system after 4:30:00 p.m., Washington, DC time, on the application deadline date.
- The amount of time it can take to upload an application will vary depending on a variety of factors, including the size of the application and the speed of your Internet connection. Therefore, we strongly recommend that you do not wait until the application deadline date to begin the submission process through Grants.gov.
- You should review and follow the Education Submission Procedures for submitting an application through Grants.gov that are included in the application package for this program to ensure that you submit your application in a timely manner to the Grants.gov system. You can also find the Education Submission Procedures pertaining to Grants.gov under News and Events on the Department's G5 system home page at *http://www.G5.gov.*
- You will not receive additional point value because you submit your application in electronic format, nor will we penalize you if you qualify for an exception to the electronic submission requirement, as described elsewhere in this section, and submit your application in paper format.
- You must submit all documents electronically, including all information you typically provide on the following forms: The Application for Federal Assistance (SF 424), the Department of Education Supplemental Information for SF 424, Budget Information—Non-Construction Programs (ED 524), and all necessary assurances and certifications.
- You must attach any narrative sections of your application as files in a .PDF (Portable Document) format only. If you upload a file type other than a .PDF or submit a password-protected file, we will not review that material.
- Your electronic application must comply with any page-limit requirements described in this notice.
- After you electronically submit your application, you will receive from Grants.gov an automatic notification of receipt that contains a Grants.gov tracking number. (This notification indicates receipt by Grants.gov only, not receipt by the Department.) The Department then will retrieve your application from Grants.gov and send a second notification to you by e-mail. This second notification indicates that the Department has received your application and has assigned your application a PR/Award number (an ED-specified identifying number unique to your application).
- We may request that you provide us original signatures on forms at a later date.

Application Deadline Date Extension in Case of Technical Issues With the Grants.gov System: If you are experiencing problems submitting your application through Grants.gov, please contact the Grants.gov Support Desk, toll free, at 1–800–518–4726. You must obtain a Grants.gov Support Desk Case Number and must keep a record of it.

If you are prevented from electronically submitting your application on the application deadline date because of technical problems with the Grants.gov system, we will grant you an extension until 4:30:00 p.m., Washington, DC time, the following business day to enable you to transmit your application electronically or by hand delivery. You also may mail your application by following the mailing instructions described elsewhere in this notice.

If you submit an application after 4:30:00 p.m., Washington, DC time, on the application deadline date, please contact one of the individuals listed under *For Further Information Contact* in section VII of this notice and provide an explanation of the technical problem you experienced with Grants.gov, along with the Grants.gov Support Desk Case Number. We will accept your application if we can confirm that a technical problem occurred with the Grants.gov system and that that problem affected your ability to submit your application by 4:30:00 p.m., Washington, DC time, on the application deadline date. The Department will contact you after a

determination is made on whether your application will be accepted.

Note: The extensions to which we refer in this section apply only to the unavailability of, or technical problems with, the Grants.gov system. We will not grant you an extension if you failed to fully register to submit your application to Grants.gov before the application deadline date and time or if the technical problem you experienced is unrelated to the Grants.gov system.

Exception to Electronic Submission Requirement: You qualify for an exception to the electronic submission requirement, and may submit your application in paper format, if you are unable to submit an application through the Grants.gov system because—

- You do not have access to the Internet; or
- You do not have the capacity to upload large documents to the Grants.gov system; and
- No later than two weeks before the application deadline date (14 calendar days or, if the fourteenth calendar day before the application deadline date falls on a Federal holiday, the next business day following the Federal holiday), you mail or fax a written statement to the Department, explaining which of the two grounds for an exception prevent you from using the Internet to submit your application.

If you mail your written statement to the Department, it must be postmarked no later than two weeks before the application deadline date. If you fax your written statement to the Department, we must receive the faxed statement no later than two weeks before the application deadline date.

Address and mail or fax your statement to: Mia Howerton, U.S. Department of Education, 400 Maryland Avenue, SW., room 4C123, Washington, DC, 20202–5960. FAX: (202)401–8466.

Your paper application must be submitted in accordance with the mail or hand delivery instructions described in this notice.

b. *Submission of Paper Applications by Mail.*

If you qualify for an exception to the electronic submission requirement, you may mail (through the U.S. Postal Service or a commercial carrier) your application to the Department. You must mail the original and two copies of your application, on or before the application deadline date, to the Department at the following address: U.S. Department of Education, Application Control Center, Attention: (CFDA Number 84.215X), LBJ Basement Level 1, 400 Maryland Avenue, SW., Washington, DC 20202–4260.

You must show proof of mailing consisting of one of the following:

(1) A legibly dated U.S. Postal Service postmark.

(2) A legible mail receipt with the date of mailing stamped by the U.S. Postal Service.

(3) A dated shipping label, invoice, or receipt from a commercial carrier.

(4) Any other proof of mailing acceptable to the Secretary of the U.S. Department of Education.

If you mail your application through the U.S. Postal Service, we do not accept either of the following as proof of mailing:

(1) A private metered postmark.

(2) A mail receipt that is not dated by the U.S. Postal Service.

If your application is postmarked after the application deadline date, we will not consider your application.

Note: The U.S. Postal Service does not uniformly provide a dated postmark. Before relying on this method, you should check with your local post office.

c. *Submission of Paper Applications by Hand Delivery.*

If you qualify for an exception to the electronic submission requirement, you (or a courier service) may deliver your paper application to the Department by hand. You must deliver the original and two copies of your application by hand, on or before the application deadline date, to the Department at the following address: U.S. Department of Education, Application Control Center, Attention: (CFDA Number 84.215X), 550 12th Street, SW., Room 7041, Potomac Center Plaza, Washington, DC 20202–4260. The Application Control Center accepts hand deliveries daily between 8:00 a.m. and 4:30:00 p.m., Washington, DC time, except Saturdays, Sundays, and Federal holidays.

Note for Mail or Hand Delivery of Paper Applications: If you mail or hand deliver your application to the Department—

(1) You must indicate on the envelope and—if not provided by the Department—in Item 11 of the SF 424 the CFDA number, including suffix letter, if any, of the competition under which you are submitting your application; and

(2) The Application Control Center will mail to you a notification of receipt of your grant application. If you do not receive this notification within 15 business days from the application deadline date, you should call the U.S. Department of Education Application Control Center at (202) 245–6288.

V. Application Review Information

1. *Selection Criteria:* The selection criteria for this program are from the notice of final selection criteria and other application requirements published in the **Federal Register** on April 15, 2005 (70 FR 19939) and from 34 CFR 75.210, as permitted under the notice of final revisions to selection criteria, published in the **Federal Register** on December 23, 2008 (73 FR 78761). The Notes following the selection criteria are guidance to help applicants in preparing their applications and are not required by statute or regulations. We encourage applicants to consider those Notes.

The selection criteria are as follows:

(1) *Project quality* (35 points). The Secretary considers the quality of the proposed project by considering:

(a) The likelihood that the proposed project will develop, implement, and strengthen programs to teach traditional American history as a separate academic subject (not as a component of social studies) within elementary school and secondary school curricula.

(b) How specific traditional American history content (including the significant issues, episodes, and turning points in the history of the United States; how the words and deeds of individual Americans have determined the course of our Nation; and how the principles of freedom and democracy articulated in the founding documents of this Nation have shaped America's struggles and achievements and its social, political, and legal institutions and relations) will be covered by the grant; the format in which the project will deliver the history content; and the quality of the staff and consultants responsible for delivering these content-based professional development activities, emphasizing, where relevant, their postsecondary teaching experience and scholarship in subject areas relevant to the teaching of traditional American history. The applicant may also attach curriculum vitae for individuals who will provide the content training to the teachers.

(c) How well the applicant describes a plan that meets the statutory requirement to carry out activities under the grant in partnership with one or more of the following:

(i) An institution of higher education.

(ii) A non-profit history or humanities organization.

(iii) A library or museum.

(d) The applicant's rationale for selecting the partner(s) and its description of specific activities that the partner(s) will contribute to the grant during each year of the project. The applicant should include a memorandum of understanding or detailed letters of commitment from the partner(s) in an appendix to the application narrative.

Note: The Secretary encourages applicants to describe, in particular, how the proposed

history content addresses traditional American history as discussed in paragraph (b) of the *Project quality* criterion. Applicants are also encouraged to submit a detailed course of study for project participants, including a rationale for selecting the course of study, and a schedule of activities to be carried out. Finally, applicants are encouraged to discuss the role and commitment of each partner and document that each partner has been apprised of the partner's responsibilities for the project.

(2) *Quality of the project design* (35 points). The Secretary considers the quality of the design of the proposed project. In determining the quality of the design of the proposed project, the Secretary considers:

(a) The extent to which there is a conceptual framework underlying the proposed research or demonstration activities and the quality of that framework.

(b) The extent to which the proposed activities constitute a coherent, sustained program of training in the field.

(c) The extent to which the proposed project is part of a comprehensive effort to improve teaching and learning and support rigorous academic standards for students.

(d) The extent to which the proposed project is designed to build capacity and yield results that will extend beyond the period of Federal financial assistance.

(3) *Need for project* (20 points). The Secretary considers the need for the proposed project. In determining the need for the proposed project, the Secretary considers:

(a) The magnitude or severity of the problem to be addressed by the proposed project.

(b) The magnitude of the need for the services to be provided or the activities to be carried out by the proposed project.

(c) The extent to which specific gaps or weaknesses in services, infrastructure, or opportunities have been identified and will be addressed by the proposed project, including the nature and magnitude of those gaps or weaknesses.

Note: The Secretary encourages applicants to provide information on the district's American history program, including on the number of teachers, the teachers' qualifications and certifications, the American history professional development currently being offered in the district, and student performance in American history class. The applicant is also encouraged to address how its proposed professional development strategy will significantly improve both teachers' ability to teach traditional American history content and student performance with regard to traditional American history. Applicants' responses to the *Need for project* criterion should address the American history content needs of the teachers, not the socioeconomic needs of the teachers or the students they serve.

(4) *Quality of the management plan* (10 points). The Secretary considers the quality of the management plan for the proposed project. In determining the quality of the management plan for the proposed project, the Secretary considers:

(a) The adequacy of the management plan to achieve the objectives of the proposed project on time and within budget, including clearly defined responsibilities, timelines, and milestones for accomplishing project tasks.

(b) The extent to which the time commitments of the project director and other key project personnel are appropriate and adequate to meet the objectives of the proposed project.

(c) The adequacy of procedures for ensuring feedback and continuous improvement in the operation of the proposed project.

Note: Section 75.112 of EDGAR requires that an applicant (a) propose a project period for the project and (b) include a narrative that describes how and when, in each budget period of the project, the applicant plans to meet each project objective. The Secretary encourages each applicant to address this criterion by including in this narrative a clear implementation plan that includes annual timelines, key project milestones, and a schedule of activities, as well as a description of the personnel who would be responsible for each activity and the level of effort each activity entails.

(5) *Quality of the project evaluation* (25 points). The Secretary considers the quality of the evaluation to be conducted of the proposed project. In determining the quality of the evaluation, the Secretary considers:

(a) The extent to which the methods of evaluation include the use of objective performance measures that are clearly related to the intended outcomes of the project and will produce quantitative and qualitative data to the extent possible.

(b) How well the evaluation plans are aligned with the project design explained under the *Project quality* criterion.

(c) Whether the evaluation includes benchmarks to monitor progress toward specific project objectives, and outcome measures to assess the impact on teaching and learning or other important outcomes for project participants.

(d) Whether the applicant identifies the individual and/or organization that has agreed to serve as evaluator for the project and includes a description of the qualifications of that evaluator.

(e) The extent to which the applicant indicates the following:

(i) What types of data will be collected.

(ii) When various types of data will be collected.

(iii) What methods will be used to collect data.

(iv) What data collection instruments will be developed.

(v) How the data will be analyzed.

(vi) When reports of results and outcomes will be available.

(vii) How the applicant will use the information collected through the evaluation to monitor the progress of the funded project and to provide accountability information about both success at the initial site and effective strategies for replication in other settings.

(viii) How the applicant will devote an appropriate level of resources to project evaluation.

Note: The Secretary encourages each applicant to specify how the project's evaluation plan will address the TAH performance measures established by the Department under the Government Performance and Results Act of 1993 (GPRA). (The specific performance measures established for the TAH Program are discussed under Performance Measures in section VI of this notice.) Further, each applicant is encouraged to describe how the applicant's evaluation plan will be designed to collect both output data (*e.g.,* number of teachers participating in a project, number of workshops held) and outcome data (*e.g.,* improvements in teacher classroom practice, increases in student history achievement). Finally, each applicant is encouraged to select an independent, objective evaluator who has experience in evaluating educational programs and who will play an active role in the design and development of the project. For resources on what to consider in designing and conducting project evaluations, go to *http://www.whatworkshelpdesk.ed.gov/.*

2. *Review and Selection Process:* The Department intends to conduct a two-tier review process for this competition. All eligible applications will be reviewed and scored on the first four criteria. Only applications that score highly on the first four criteria will then be reviewed and scored on the fifth criterion, *Quality of the Project Evaluation.*

We remind potential applicants that in reviewing applications in any discretionary grant competition, the Secretary may consider, under 34 CFR 75.217(d)(3), the past performance of the applicant in carrying out a previous award, such as the applicant's use of funds, achievement of project objectives, and compliance with grant conditions. The Secretary may also

consider whether the applicant failed to submit a timely performance report or submitted a report of unacceptable quality.

In addition, in making a competitive grant award, the Secretary also requires various assurances including those applicable to Federal civil rights laws that prohibit discrimination in programs or activities receiving Federal financial assistance from the Department of Education (34 CFR 100.4, 104.5, 106.4, 108.8, and 110.23).

3. *Special Conditions:* Under 34 CFR 74.14 and 80.12, the Secretary may impose special conditions on a grant if the applicant or grantee is not financially stable; has a history of unsatisfactory performance; has a financial or other management system that does not meet the standards in 34 CFR parts 74 or 80, as applicable; has not fulfilled the conditions of a prior grant; or is otherwise not responsible.

VI. Award Administration Information

1. *Award Notices:* If your application is successful, we notify your U.S. Representative and U.S. Senators and send you a Grant Award Notification (GAN). We may notify you informally, also.

If your application is not evaluated or not selected for funding, we notify you.

2. *Administrative and National Policy Requirements:* We identify administrative and national policy requirements in the application package and reference these and other requirements in the *Applicable Regulations* section of this notice.

We reference the regulations outlining the terms and conditions of an award in the *Applicable Regulations* section of this notice and include these and other specific conditions in the GAN. The GAN also incorporates your approved application as part of your binding commitments under the grant.

3. *Reporting:* (a) If you apply for a grant under this competition, you must ensure that you have in place the necessary processes and systems to comply with the reporting requirements in 2 CFR part 170 should you receive funding under the competition. This does not apply if you have an exception under 2 CFR 170.110(b).

(b) At the end of your project period, you must submit a final performance report, including financial information, as directed by the Secretary. If you receive a multi-year award, you must submit an annual performance report that provides the most current performance and financial expenditure information as directed by the Secretary under 34 CFR 75.118. The Secretary may also require more frequent performance reports under 34 CFR 75.720(c). For specific requirements on reporting, please go to *http://www.ed.gov/fund/grant/apply/appforms/appforms.html.*

4. *Performance Measures:* We have established two performance measures for the TAH Program. The measures are: (1) The average percentage change in the scores (on a pre-post assessment of American history) of participants who complete at least 75 percent of the professional development hours offered by the project. The assessment must be aligned with the content provided by the TAH project, and at least 50 percent of its questions must come from a validated test of American history, and (2) the percentage of TAH participants who complete 75 percent or more of the total hours of professional development offered. Grantees will be expected to provide data on the two measures.

VII. Agency Contacts

For Further Information Contact: Mia Howerton, Margarita Melendez, or Adam Bookman, U.S. Department of Education, 400 Maryland Avenue, SW., room 4C123, Washington, DC 20202–5960. Telephone: (202) 205–0147 or by e-mail: *teachingamericanhistory@ed.gov.* If you use a TDD, call the FRS, toll-free, at 1–800–877–8339.

VIII. Other Information

Accessible Format: Individuals with disabilities can obtain this document and a copy of the application package in an accessible format (*e.g.,* braille, large print, audiotape, or computer diskette) on request to one of the program contact persons listed under *For Further Information Contact* in section VII of this notice.

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. You can view this document in text or PDF at the following site, also: *http://www2.ed.gov/programs/teachinghistory/applicant.html.*

Note: The official version of this document is the document published in the **Federal Register**. Free Internet access to the official edition of the **Federal Register** and the Code of Federal Regulations is available on GPO Access at: *http://www.gpoaccess.gov/nara/index.html.*

Dated: January 26, 2011.

James H. Shelton III,

Assistant Deputy Secretary for Innovation and Improvement.

[FR Doc. 2011–2290 Filed 2–1–11; 8:45 am]

BILLING CODE 4000–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. CP11–60–000]

Gas Transmission Northwest Corporation; Notice of Application

January 26, 2011.

Take notice that on January 14, 2011, Gas Transmission Northwest Corporation (GTN), 717 Texas Street, Houston, Texas 77002–2761 filed with the Federal Energy Regulatory Commission (Commission) an application under section 7(b) of the Natural Gas Act for permission and approval to abandon certain system capacity and GTN's related obligation to provide transportation service related to maximum allowable operating pressure (MAOP) de-rates on its A-Line in Boundary, Bonner and Kootenai Counties, Idaho, and Spokane County, Washington.

Any questions concerning this application should be directed to Rene Staeb, Manager, Project Determinations & Regulatory Administration, Gas Transmission Northwest Corporation, 717 Texas Street, Houston, Texas 77002–2761, at (832) 320–5215 or fax (832) 320–6215 or *Rene_Staeb@transcanada.com.*

Pursuant to section 157.9 of the Commission's rules, 18 CFR 157.9, within 90 days of this Notice the Commission staff will either: Complete its environmental assessment (EA) and place it into the Commission's public record (eLibrary) for this proceeding; or issue a Notice of Schedule for Environmental Review. If a Notice of Schedule for Environmental Review is issued, it will indicate, among other milestones, the anticipated date for the Commission staff's issuance of the final environmental impact statement (FEIS) or EA for this proposal. The filing of the EA in the Commission's public record for this proceeding or the issuance of a Notice of Schedule for Environmental Review will serve to notify federal and state agencies of the timing for the completion of all necessary reviews, and the subsequent need to complete all federal authorizations within 90 days of the date of issuance of the Commission staff's FEIS or EA.

There are two ways to become involved in the Commission's review of this project. First, any person wishing to obtain legal status by becoming a party to the proceedings for this project should, on or before the comment date stated below, file with the Federal Energy Regulatory Commission, 888 First Street, NE., Washington, DC 20426, a motion to intervene in accordance with the requirements of the Commission's Rules of Practice and Procedure (18 CFR 385.214 or 385.211) and the Regulations under the NGA (18 CFR 157.10). A person obtaining party status will be placed on the service list maintained by the Secretary of the Commission and will receive copies of all documents filed by the applicant and by all other parties. A party must submit 7 copies of filings made with the Commission and must mail a copy to the applicant and to every other party in the proceeding. Only parties to the proceeding can ask for court review of Commission orders in the proceeding.

However, a person does not have to intervene in order to have comments considered. The second way to participate is by filing with the Secretary of the Commission, as soon as possible, an original and two copies of comments in support of or in opposition to this project. The Commission will consider these comments in determining the appropriate action to be taken, but the filing of a comment alone will not serve to make the filer a party to the proceeding. The Commission's rules require that persons filing comments in opposition to the project provide copies of their protests only to the party or parties directly involved in the protest.

Persons who wish to comment only on the environmental review of this project should submit an original and two copies of their comments to the Secretary of the Commission. Environmental commentors will be placed on the Commission's environmental mailing list, will receive copies of the environmental documents, and will be notified of meetings associated with the Commission's environmental review process. Environmental commentors will not be required to serve copies of filed documents on all other parties. However, the non-party commentors will not receive copies of all documents filed by other parties or issued by the Commission (except for the mailing of environmental documents issued by the Commission) and will not have the right to seek court review of the Commission's final order.

The Commission strongly encourages electronic filings of comments, protests and interventions in lieu of paper using the "eFiling" link at *http://www.ferc.gov.* Persons unable to file electronically should submit an original and 7 copies of the protest or intervention to the Federal Energy regulatory Commission, 888 First Street, NE., Washington, DC 20426.

This filing is accessible on-line at *http://www.ferc.gov*, using the "eLibrary" link and is available for review in the Commission's Public Reference Room in Washington, DC. There is an "eSubscription" link on the Web site that enables subscribers to receive e-mail notification when a document is added to a subscribed docket(s). For assistance with any FERC Online service, please e-mail *FERCOnlineSupport@ferc.gov*, or call (866) 208–3676 (toll free). For TTY, call (202) 502–8659.

Comment Date: February 16, 2011.

Kimberly D. Bose,

Secretary.

[FR Doc. 2011–2221 Filed 2–1–11; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. PR10–114–001; Docket No. PR10–129–001; Docket No. PR10–131–001; Docket No. PR10–68–002 Not Consolidated]

Notice of Baseline Filings

January 26, 2010.

The Narragansett Electric Company	Docket No. PR10–114–001.
Boston Gas Company	Docket No. PR10–129–001.
KeySpan Gas East Corporation	Docket No. PR10–131–001.
The Brooklyn Union Gas Company	Docket No. PR11–82–000.
Atmos Energy—Kentucky/Mid-States Division	Docket No. PR10–68–002. Not Consolidated.

Take notice that on January 20, 2011, January 21, 2011, and January 25, 2011, respectively the applicants listed above submitted a revised baseline filing of their Statement of Operating Conditions for services provided under section 311 of the Natural Gas Policy Act of 1978 ("NGPA").

Any person desiring to participate in this rate proceeding must file a motion to intervene or to protest this filing must file in accordance with Rules 211 and 214 of the Commission's Rules of Practice and Procedure (18 CFR 385.211 and 385.214). Protests will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make protestants parties to the proceeding. Any person wishing to become a party must file a notice of intervention or motion to intervene, as appropriate. Such notices, motions, or protests must be filed on or before the date as indicated below. Anyone filing an intervention or protest must serve a copy of that document on the Applicant. Anyone filing an intervention or protest on or before the intervention or protest date need not serve motions to intervene or protests on persons other than the Applicant.

The Commission encourages electronic submission of protests and interventions in lieu of paper using the "eFiling" link at *http://www.ferc.gov.* Persons unable to file electronically should submit an original and 7 copies of the protest or intervention to the Federal Energy Regulatory Commission, 888 First Street, NE., Washington, DC 20426.

This filing is accessible on-line at *http://www.ferc.gov,* using the "eLibrary" link and is available for review in the Commission's Public Reference Room in Washington, DC. There is an "eSubscription" link on the Web site that enables subscribers to receive e-mail notification when a document is added to a subscribed docket(s). For assistance with any FERC Online service, please e-mail *FERCOnlineSupport@ferc.gov,* or call (866) 208–3676 (toll free). For TTY, call (202) 502–8659.

Comment Date: 5 p.m. Eastern time on Friday, February 11, 2011.

Kimberly D. Bose,

Secretary.

[FR Doc. 2011–2218 Filed 2–1–11; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

Combined Notice of Filings

January 12, 2011.

Take notice that the Commission has received the following Natural Gas Pipeline Rate and Refund Report filings:

Docket Numbers: RP11–1693–000.
Applicants: Rockies Express Pipeline LLC.
Description: Rockies Express Pipeline LLC submits tariff filing per 154.204: Negotiated Rate 2011–01–07 Concord and Noble Americas to be effective 1/8/2011.
Filed Date: 01/07/2011.
Accession Number: 20110107–5265.
Comment Date: 5 p.m. Eastern Time on Wednesday, January 19, 2011.

Docket Numbers: RP11–1694–000.
Applicants: Texas Eastern Transmission, LP.
Description: Texas Eastern Transmission, LP submits tariff filing per 154.204: TETLP cleanup filing Jan2011 to be effective 2/10/2011.
Filed Date: 01/10/2011.
Accession Number: 20110110–5042.
Comment Date: 5 p.m. Eastern Time on Monday, January 24, 2011.

Docket Numbers: RP11–1695–000.
Applicants: Dominion Transmission, Inc.
Description: Dominion Transmission, Inc. submits tariff filing per 154.204: DTI—Gas Quality to be effective 3/1/2011.
Filed Date: 01/10/2011.
Accession Number: 20110110–5100.
Comment Date: 5 p.m. Eastern Time on Monday, January 24, 2011.

Docket Numbers: RP11–1696–000.
Applicants: Gulf South Pipeline Company, LP.
Description: Gulf South Pipeline Company, LP submits tariff filing per 154.204: HK Transportation 1–7–11 Amendment to be effective 1/7/2011.
Filed Date: 01/10/2011.
Accession Number: 20110110–5198.
Comment Date: 5 p.m. Eastern Time on Monday, January 24, 2011.

Docket Numbers: RP11–1697–000.
Applicants: Algonquin Gas Transmission, LLC.
Description: Algonquin Gas Transmission, LLC submits tariff filing per 154.204: Con Ed-Great Eastern-Sempra 2011–01–01 Release to be effective 1/1/2011.
Filed Date: 01/11/2011.
Accession Number: 20110111–5066.
Comment Date: 5 p.m. Eastern Time on Monday, January 24, 2011.

Docket Numbers: RP11–1698–000.
Applicants: Fayetteville Express Pipeline LLC.
Description: Fayetteville Express Pipeline LLC submits tariff filing per 154.204: FEP—CEMI K200001 Amendment Filing to be effective 12/30/2010.
Filed Date: 01/12/2011.
Accession Number: 20110112–5000.
Comment Date: 5 p.m. Eastern Time on Monday, January 24, 2011.

Any person desiring to intervene or to protest in any of the above proceedings must file in accordance with Rules 211 and 214 of the Commission's Rules of Practice and Procedure (18 CFR 385.211 and 385.214) on or before 5 p.m. Eastern time on the specified comment date. It is not necessary to separately intervene again in a subdocket related to a compliance filing if you have previously intervened in the same docket. Protests will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make protestants parties to the proceeding. Anyone filing a motion to intervene or protest must serve a copy of that document on the Applicant. In reference to filings initiating a new proceeding, interventions or protests submitted on or before the comment deadline need not be served on persons other than the Applicant.

The Commission encourages electronic submission of protests and interventions in lieu of paper, using the FERC Online links at *http://www.ferc.gov*. To facilitate electronic service, persons with Internet access who will eFile a document and/or be listed as a contact for an intervenor must create and validate an eRegistration account using the eRegistration link. Select the eFiling link to log on and submit the intervention or protests.

Persons unable to file electronically should submit an original and 14 copies of the intervention or protest to the Federal Energy Regulatory Commission, 888 First St. NE., Washington, DC 20426.

The filings in the above proceedings are accessible in the Commission's eLibrary system by clicking on the appropriate link in the above list. They are also available for review in the Commission's Public Reference Room in Washington, DC. There is an eSubscription link on the Web site that enables subscribers to receive e-mail notification when a document is added to a subscribed docket(s). For assistance with any FERC Online service, please e-mail *FERCOnlineSupport@ferc.gov* or call (866) 208–3676 (toll free). For TTY, call (202) 502–8659.

Nathaniel J. Davis, Sr.,
Deputy Secretary.

[FR Doc. 2011–2260 Filed 2–1–11; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

Combined Notice of Filings No. 1

January 18, 2011.

Take notice that the Commission has received the following Natural Gas Pipeline Rate and Refund Report filings:

Docket Numbers: RP11–1699–000.
Applicants: Guardian Pipeline, L.L.C.
Description: Guardian Pipeline, L.L.C. submits tariff filing per 154.203: Rate Schedule PAL Revisions Compliance filing to be effective 8/31/2010.
Filed Date: 01/12/2011.
Accession Number: 20110112–5097.
Comment Date: 5 p.m. Eastern Time on Monday, January 24, 2011.

Docket Numbers: RP11–1700–000.
Applicants: Dominion Cove Point LNG, LP.
Description: Dominion Cove Point LNG, LP submits tariff filing per 154.204: DCP—Off-System Capacity to be effective 2/12/2011.
Filed Date: 01/13/2011.
Accession Number: 20110113–5100.
Comment Date: 5 p.m. Eastern Time on Tuesday, January 25, 2011.

Docket Numbers: RP11–1701–000.
Applicants: Midcontinent Express Pipeline LLC.
Description: Annual Report of Operational Purchases and Sales.
Filed Date: 01/13/2011.
Accession Number: 20110113–5190.
Comment Date: 5 p.m. Eastern Time on Tuesday, January 25, 2011.

Docket Numbers: RP11–1702–000.
Applicants: Gas Transmission Northwest Corporation.
Description: Gas Transmission Northwest Refund Report.
Filed Date: 01/14/2011.
Accession Number: 20110114–5075.
Comment Date: 5 p.m. Eastern Time on Wednesday, January 26, 2011.

Docket Numbers: RP11–1703–000.
Applicants: CenterPoint Energy—Mississippi River Transmission LLC.
Description: CenterPoint Energy—Mississippi River Transmission, LLC submits tariff filing per 154.204: MRT LLC Name Change to be effective 1/1/2011.
Filed Date: 01/14/2011.
Accession Number: 20110114–5176.

Comment Date: 5 p.m. Eastern Time on Wednesday, January 26, 2011.

Docket Numbers: RP11–1704–000.

Applicants: Northern Border Pipeline Company.

Description: Northern Border Pipeline Company submits tariff filing per 154.601: T–1 Agreements to be effective 1/14/2011.

Filed Date: 01/14/2011.

Accession Number: 20110114–5190.

Comment Date: 5 p.m. Eastern Time on Wednesday, January 26, 2011.

Docket Numbers: RP11–1705–000.

Applicants: Dominion Cove Point LNG, LP.

Description: Dominion Cove Point LNG, LP submits tariff filing per 154.204: DCP—Contract Quantities to be effective 2/14/2011.

Filed Date: 01/14/2011.

Accession Number: 20110114–5191.

Comment Date: 5 p.m. Eastern Time on Wednesday, January 26, 2011.

Docket Numbers: RP11–1706–000.

Applicants: Dominion Transmission, Inc.

Description: Dominion Transmission, Inc. submits tariff filing per 154.204: DTI—Contract Quantities to be effective 2/14/2011.

Filed Date: 01/14/2011.

Accession Number: 20110114–5202.

Comment Date: 5 p.m. Eastern Time on Wednesday, January 26, 2011.

Docket Numbers: RP11–1707–000.

Applicants: CenterPoint Energy Gas Transmission Company, LLC.

Description: CenterPoint Energy Gas Transmission Company, LLC submits tariff filing per 154.204: CEGT LLC Name Change to be effective 7/22/2010.

Filed Date: 01/14/2011.

Accession Number: 20110114–5233.

Comment Date: 5 p.m. Eastern Time on Wednesday, January 26, 2011.

Docket Numbers: RP11–1708–000.

Applicants: Trailblazer Pipeline Company LLC.

Description: Penalty Revenue Crediting Report.

Filed Date: 01/14/2011.

Accession Number: 20110114–5237.

Comment Date: 5 p.m. Eastern Time on Wednesday, January 26, 2011.

Docket Numbers: RP11–1709–000.

Applicants: Algonquin Gas Transmission, LLC.

Description: Algonquin Gas Transmission, LLC submits tariff filing per 154.204: Termination of Fore River Agreement to be effective 2/18/2011.

Filed Date: 01/18/2011.

Accession Number: 20110118–5120.

Comment Date: 5 p.m. Eastern Time on Monday, January 31, 2011.

Any person desiring to intervene or to protest in any of the above proceedings must file in accordance with Rules 211 and 214 of the Commission's Rules of Practice and Procedure (18 CFR 385.211 and 385.214) on or before 5 p.m. Eastern time on the specified comment date. It is not necessary to separately intervene again in a subdocket related to a compliance filing if you have previously intervened in the same docket. Protests will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make protestants parties to the proceeding. Anyone filing a motion to intervene or protest must serve a copy of that document on the Applicant. In reference to filings initiating a new proceeding, interventions or protests submitted on or before the comment deadline need not be served on persons other than the Applicant.

The Commission encourages electronic submission of protests and interventions in lieu of paper, using the FERC Online links at *http://www.ferc.gov.* To facilitate electronic service, persons with Internet access who will eFile a document and/or be listed as a contact for an intervenor must create and validate an eRegistration account using the eRegistration link. Select the eFiling link to log on and submit the intervention or protests.

Persons unable to file electronically should submit an original and 14 copies of the intervention or protest to the Federal Energy Regulatory Commission, 888 First St., NE., Washington, DC 20426.

The filings in the above proceedings are accessible in the Commission's eLibrary system by clicking on the appropriate link in the above list. They are also available for review in the Commission's Public Reference Room in Washington, DC. There is an eSubscription link on the Web site that enables subscribers to receive e-mail notification when a document is added to a subscribed docket(s). For assistance with any FERC Online service, please e-mail *FERCOnlineSupport@ferc.gov.* or call (866) 208–3676 (toll free). For TTY, call (202) 502–8659.

Nathaniel J. Davis, Sr.,

Deputy Secretary.

[FR Doc. 2011–2259 Filed 2–1–11; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

Notice of Commissioners and Staff Attendance at FERC Leadership Development Program Induction Ceremony

January 26, 2011.

The Federal Energy Regulatory Commission (FERC or Commission) hereby gives notice that members of the Commission and/or Commission staff may attend the following event:

FERC Leadership Development Program Induction Ceremony: 888 First Street, NE., Washington, DC 20426. February 1, 2011 (2 p.m.–3 p.m.)

The event will introduce and welcome 16 employees selected for the 2011 Leadership Development Program.

Kimberly D. Bose,

Secretary.

[FR Doc. 2011–2220 Filed 2–1–11; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. EL11–16–000]

Prairie Power, Inc.; Notice of Filing

January 26, 2011.

Take notice that on January 25, 2011, Prairie Power, Inc., submitted a proposed revenue requirement filing under Midwest Independent Transmission System Operator, Inc. (Midwest ISO) Schedule 2, for reactive supply and voltage control service from certain of its owned generators [1], which is consistent with applicable Federal Energy Regulatory Commission (Commission) Orders and Midwest ISO requirements for the provision of reactive supply and voltage control under Schedule 2 of the Midwest ISO Open Access Transmission, Energy, and Operating Reserve Markets Tariff, including the Commission's Orders in Midwest Independent Transmission System Operator, Inc.[2]

[1] Prairie Power is also listed by the Midwest ISO as a Non-Transmission Owning Cooperative Member (see Midwest ISO, *Midwest ISO Members By Sector* (January 2011)).

[2] 113 FERC ¶ 61,046 at P 88 and n.13 (2005) ("October 2005 Order"), *reh'g denied,* 114 FERC ¶ 61,192 (2006) (the October 2005 Order relates to the Midwest ISO compliance filing submitted in response to the Commission's order on October 1, 2004 in *Midwest Indep. Transmission Sys. Operator, Inc.,* 109 FERC ¶ 61,005 at PP 39–40

Continued

Any person desiring to intervene or to protest this filing must file in accordance with Rules 211 and 214 of the Commission's Rules of Practice and Procedure (18 CFR 385.211, 385.214). Protests will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make protestants parties to the proceeding. Any person wishing to become a party must file a notice of intervention or motion to intervene, as appropriate. Such notices, motions, or protests must be filed on or before the comment date. On or before the comment date, it is not necessary to serve motions to intervene or protests on persons other than the Applicant.

The Commission encourages electronic submission of protests and interventions in lieu of paper using the "eFiling" link at *http://www.ferc.gov*. Persons unable to file electronically should submit an original and 14 copies of the protest or intervention to the Federal Energy Regulatory Commission, 888 First Street, NE., Washington, DC 20426.

This filing is accessible on-line at *http://www.ferc.gov*, using the "eLibrary" link and is available for review in the Commission's Public Reference Room in Washington, DC. There is an "eSubscription" link on the Web site that enables subscribers to receive e-mail notification when a document is added to a subscribed docket(s). For assistance with any FERC Online service, please e-mail *FERCOnlineSupport@ferc.gov*, or call (866) 208–3676 (toll free). For TTY, call (202) 502–8659.

Comment Date: 5 p.m. Eastern Time on February 15, 2011.

Kimberly D. Bose,

Secretary.

[FR Doc. 2011–2219 Filed 2–1–11; 8:45 am]

BILLING CODE 6717–01–P

(2004) ("October 2004 Order"), *order on reh'g,* 110 FERC ¶ 61,267 (2005)).

ENVIRONMENTAL PROTECTION AGENCY

[EPA–HQ–OAR–2007–0265; FRL–9261–2]

Agency Information Collection Activities: Proposed Collection; Comment Request

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: In compliance with the Paperwork Reduction Act (PRA) (44 U.S.C. 3501 *et seq.*), this document announces that EPA is planning to submit to the Office of Management and Budget (OMB) a request to renew an existing approved Information Collection Request (ICR) 2258.02—Implementation of the 1997 and the 2006 fine particle ($PM_{2.5}$) national ambient air quality standards (NAAQS). This ICR is scheduled to expire on May 31, 2011. Before submitting the ICR to OMB for review and approval, EPA is soliciting comments on specific aspects of the proposed information collection as described below.

DATES: Comments must be submitted on or before April 4, 2011.

ADDRESSES: Submit your comments, identified by Docket ID No. EPA–HQ–OAR–2007–0265, by one of the following methods:

- *http://www.regulations.gov:* Follow the on-line instructions for submitting comments.
- *E-mail: a-and-r-docket@epamail.epa.gov.*
- *Fax:* 202–566–1741
- *Mail:* Attention Docket ID No. EPA–HQ–OAR–2007–0265, U.S. Environmental Protection Agency, EPA West (Air Docket), 1200 Pennsylvania Avenue, Northwest, Mailcode: 6102T, Washington, DC 20460.
- *Hand Delivery:* U.S. Environmental Protection Agency, EPA West (Air Docket), 1301 Constitution Avenue, Northwest, Room 3334, Washington, DC 20004, Attention Docket ID No. EPA–HQ–OAR–2007–0265. Such deliveries are only accepted during the Docket's normal hours of operation, and special arrangements should be made for deliveries of boxed information.

Instructions: Direct your comments to Docket ID No. EPA–HQ–OAR–2007–0265. The EPA's policy is that all comments received will be included in the public docket without change and may be made available online at *http://www.regulations.gov,* including any personal information provided, unless the comment includes information claimed to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Do not submit information that you consider to be CBI or otherwise protected through *http://www.regulations.gov* or e-mail. 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. For additional information about EPA's public docket visit, the EPA Docket Center homepage at *http://www.epa.gov/epahome/dockets.htm.*

FOR FURTHER INFORMATION CONTACT: Butch Stackhouse, Air Quality Policy Division, Office of Air Quality Planning and Standards, Mail Code C539–01, Research Triangle Park, North Carolina 27711, telephone number (919) 541–5208, facsimile number (919) 541–0824, electronic mail e-mail address: *stackhouse.butch@epa.gov*; Karl Pepple, Air Quality Policy Division, Office of Air Quality Planning and Standards, Mail Code C539–01, Research Triangle Park, North Carolina 27711, telephone number (919) 541–2683, facsimile number (919) 541–0824, electronic mail e-mail address: *pepple.karl@epa.gov.*

SUPPLEMENTARY INFORMATION:

How can I access the docket and/or submit comments?

The EPA has established a public docket for this ICR under Docket ID No. EPA–HQ–OAR–2007–0265, which is available for online viewing at *http://www.regulations.gov*, or in person viewing at the Air Docket in the EPA Docket Center (EPA/DC), EPA West, Room 3334, 1301 Constitution Ave., NW., Washington, DC. The EPA/DC 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 Air Docket is 202–566–1742.

Use *http://www.regulations.gov* to obtain a copy of the draft collection of information, submit or view public comments, access the index listing of the contents of the docket, and to access those documents in the public docket that are available electronically. Once in the system, select "search," then key in the docket ID number identified in this document.

What information is EPA particularly interested in?

Pursuant to section 3506(c)(2)(A) of the PRA, EPA specifically solicits

comments and information to enable it to:

(i) Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the Agency, including whether the information will have practical utility;

(ii) evaluate the accuracy of the Agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;

(iii) enhance the quality, utility, and clarity of the information to be collected; and

(iv) minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated electronic, mechanical, or other technological collection techniques or other forms of information technology, e.g., permitting electronic submission of responses.

What should I consider when I prepare my comments for EPA?

You may find the following suggestions helpful for preparing your comments:

1. Explain your views as clearly as possible and provide specific examples.
2. Describe any assumptions that you used.
3. Provide copies of any technical information and/or data you used that support your views.
4. If you estimate potential burden or costs, explain how you arrived at the estimate that you provide.
5. Offer alternative ways to improve the collection activity.
6. Make sure to submit your comments by the deadline identified under **DATES**.
7. To ensure proper receipt by EPA, be sure to identify the docket ID number assigned to this action in the subject line on the first page of your response. You may also provide the name, date, and **Federal Register** citation.

What information collection activity or ICR does this apply to?

Affected entities: Entities potentially affected by this action are states and Regional Offices. There are other entities that may be indirectly affected, as they may comment on the draft submissions before they are forwarded to EPA's Regional Offices. These include potentially regulated entities, representatives of special interest groups, and individuals.

Title: $PM_{2.5}$ National Ambient Air Quality Standard Implementation Rule.

ICR number: EPA ICR No. 2258.02, OMB Control No. 2060–0611.

ICR status: This ICR is currently scheduled to expire on May 31, 2011. 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 Code of Federal Register (CFR), after appearing in the **Federal Register** when approved, are listed in 40 CFR part 9, 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: The Paperwork Reduction Act requires the information found in this ICR number 2258.02 to assess the burden (in hours and dollars) of the 1997 and 2006 $PM_{2.5}$ NAAQS Implementation Rule as well as the periodic reporting and recordkeeping necessary to maintain the rule. The rule was proposed November 1, 2005 (70 FR 65983) and promulgated April 25, 2007 (71 FR 61145). The preamble to the proposed and final regulation addressed the administrative burden in general terms. The preamble to the final rule stated that an ICR would be prepared. The rule includes requirements that involve collecting information from states with areas that have been designated nonattainment for the $PM_{2.5}$ NAAQS.

The time period covered in this ICR is a 3 year period from June 1, 2011 through May 31, 2014. The milestones for the State or local air agency respondents will include the required State Implementation Plan (SIP) elements prescribed in the Clean Air Act (CAA) sections 110 and part D, subpart 1 of title I for implementation plans and the requirements in the $PM_{2.5}$ NAAQS Implementation Rule (40 CFR 51.1000–51.1012). The $PM_{2.5}$ SIP will contain rules and other requirements designed to achieve the NAAQS by the deadlines established under the CAA, and it also contains a demonstration that the state's requirements will in fact result in attainment. The SIP must meet the requirements in subpart 1 to adopt Reasonable Available Control Measures, Reasonable Available Control Technology, and provide for Reasonable Further Progress toward attainment for the period prior to the area's attainment date. However, not all of the milestones and associated burden and administrative cost estimates apply to every designated $PM_{2.5}$ nonattainment area. Areas with cleaner air quality have fewer requirements.

Burden Statement: The annual public reporting and recordkeeping burden for this collection of information is estimated to average 317 hours per response for states with nonattainment areas for the 1997 $PM_{2.5}$ standard, and 4,243 hours per response for states with nonattainment areas for the 2006 $PM_{2.5}$ standard. 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.

The ICR provides a detailed explanation of the Agency's estimate, which is only briefly summarized here:

Estimated total number of potential respondents: 1997 $PM_{2.5}$

Standard: 21; 2006 $PM_{2.5}$ Standard: 18.

Frequency of response: Annual.

Estimated total average number of responses for each respondent: 1997 $PM_{2.5}$ Standard: 2.7; 2006 $PM_{2.5}$ Standard: 2.

Estimated total annual burden hours: 1997 $PM_{2.5}$ Standard: 18,400; 2006 $PM_{2.5}$ Standard: 157,000 hours.

Estimated total average annual costs per respondent: 1997 $PM_{2.5}$ standard: $52,600; 2006 $PM_{2.5}$ Standard: $523,700. This includes an estimated burden cost of $0 for capital investment or maintenance and operational costs.

There is a decrease of 34,600 hours to 175,400 hours (from a sum of 210,000 hours in the 2007 ICR) in the total estimated respondent burden compared with that identified in the ICR currently approved by OMB. This decrease reflects EPA's information that the number of non-attainment areas for the 1997 $PM_{2.5}$ standard has decreased as areas have come into compliance with the standards and that the burden associated with the remaining non-attainment areas is less because of the work they have done previously to comply with the standards. At the same time, promulgation of the 2006 $PM_{2.5}$ standard led to designations of new areas as non-attainment, leading to an increased burden on those respondents.

Additional Background on Burden Estimation Method

The methodology and draft estimates of incremental administrative burden for this ICR are documented in a separate supporting statement in the docket. The methodology and draft estimates in the $PM_{2.5}$ Implementation Rule ICR are based on the ICR developed for the 8-hour ozone Implementation Rule ICR (EPA ICR No. 2236.02, OMB Control No. 2060–0594). The 8-hour ozone Implementation Rule ICR methodology and draft estimates were submitted to EPA's Ozone NAAQS Implementation Workgroup for their review and comment. This workgroup is comprised of representatives from EPA Regional Offices I through IX, as well as EPA's Offices of General Counsel, Office of Policy, and Air and Radiation (including the Offices of Transportation and Air Quality, Air Quality Planning and Standards, and Policy Analysis and Review).

The workgroup provided constructive criticism on earlier drafts which resulted in clarifications to the methodology section, revisions to the categorization of non-attainment areas by Regional Office, and changes to the temporal allocation of Regional Office administrative burden. The workgroup reviewed the June 2006 ICR supporting statement which was forwarded to OMB's Office of Information and Regulatory Affairs. The workgroup believed there would be differences between the realized incremental administrative burden of the states and Regional Offices versus what was in the supporting statement. However, the estimates in the ICR supporting statement were judged to be appropriate.

What is the next step in the process for this ICR?

The EPA will consider the comments received and amend the ICR as appropriate. The final ICR package will then be submitted to OMB for review and approval pursuant to 5 CFR 1320.12. At that time, EPA will issue another **Federal Register** notice pursuant to 5 CFR 1320.5(a)(1)(iv) to announce the submission of the ICR to OMB and the opportunity to submit additional comments to OMB. If you have any questions about this ICR or the approval process, please contact the technical person listed under **FOR FURTHER INFORMATION CONTACT**.

Dated: January 28, 2011.

Mary E. Henigin,

Acting Director, Office of Air Quality Planning and Standards, Office of Air and Radiation.

[FR Doc. 2011–2271 Filed 2–1–11; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

[EPA–HQ–OEI–2011–0096; FRL–9261–1]

Agency Information Collection Activities; Proposed Collection; Comment Request; Cross-Media Electronic Reporting Rule (Renewal); EPA ICR No. 2002.05, OMB Control No. 2025–0003

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: In compliance with the Paperwork Reduction Act (PRA) (44 U.S.C. 3501 *et seq.*), this document announces that EPA is planning to submit a request to renew an existing approved Information Collection Request (ICR) to the Office of Management and Budget (OMB). This ICR is scheduled to expire on July 31, 2011. Before submitting the ICR to OMB for review and approval, EPA is soliciting comments on specific aspects of the proposed information collection as described below.

DATES: Comments must be submitted on or before April 4, 2011.

ADDRESSES: Submit your comments, identified by Docket ID No. EPA–HQ–OEI–2011–0096 by one of the following methods:

http://www.regulations.gov: Follow the on-line instructions for submitting comments.

E-mail: oei-docket@epa.gov.

Fax: 202–566–1753.

Mail: Office of Environmental Information Docket, Environmental Protection Agency, Mailcode: 2822T, 1200 Pennsylvania Avenue, NW., Washington, DC 20460. For hand delivery: Office of Environmental Information (OEI) Docket in the EPA Docket Center (EPA/DC), EPA West, Room 3334, 1301 Constitution Ave., NW., Washington, DC. Such deliveries are only accepted during the Docket's normal hours of operation, and special arrangements should be made for deliveries of boxed information. Please include a total of four copies.

Instructions: Direct your comments to Docket ID No. EPA–HQ–OEI–2011–0096. EPA's policy is that all comments received will be included in the public docket without change and may be made available online at *http://www.regulations.gov,* including any personal information provided, unless the comment includes information claimed to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Do not submit information that you consider to be CBI or otherwise protected through *www.regulations.gov* or e-mail. The *www.regulations.gov* Web site is an "anonymous access" system, which means EPA will not know your identity or contact information unless you provide it in the body of your comment. If you send an e-mail comment directly to EPA without going through *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. For additional information about EPA's public docket visit the EPA Docket Center homepage at *http://www.epa.gov/epahome/dockets.htm.*

FOR FURTHER INFORMATION CONTACT: Cross-Media Electronic Reporting Rule (CROMERR) ICR, Information Exchange & Services Division, Office of Environmental Information, 2823T, Environmental Protection Agency, 1200 Pennsylvania Avenue, NW., Washington, DC 20460. For questions regarding authorized programs burden and costs contact Evi Huffer, telephone number: 202–566–1697; fax number: 202–566–1685; e-mail address: *huffer.evi@epa.gov* or Karen Seeh, telephone number: 202–566–1175; fax number: 202–566–1685; e-mail address: *Seeh.Karen@epa.gov.* For questions regarding the Central Data Exchange (CDX) burden and costs contact Charles Freeman, telephone number: 202–566–1694; fax number: 202–566–1684; e-mail address: *freeman.charles@epa.gov.*

SUPPLEMENTARY INFORMATION:

How can I access the docket and/or submit comments?

EPA has established a public docket for this ICR under Docket ID No. EPA–HQ–OEI–2011–0096, which is available for online viewing at *www.regulations.gov,* or in person

viewing at the Office of Environmental Information (OEI) Docket in the EPA Docket Center (EPA/DC), EPA West, Room 3334, 1301 Constitution Ave., NW., Washington, DC. The EPA/DC 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 OEI Docket is 202–566–1752.

Use *www.regulations.gov* to obtain a copy of the draft collection of information, submit or view public comments, access the index listing of the contents of the docket, and to access those documents in the public docket that are available electronically. Once in the system, select "search," then key in the docket ID number identified in this document.

What information is EPA particularly interested in?

Pursuant to section 3506(c)(2)(A) of the PRA, EPA specifically solicits comments and information to enable it to:

(i) Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the Agency, including whether the information will have practical utility;

(ii) Evaluate the accuracy of the Agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;

(iii) Enhance the quality, utility, and clarity of the information to be collected; and

(iv) Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.,* permitting electronic submission of responses. In particular, EPA is requesting comments from very small businesses (those that employ less than 25) on examples of specific additional efforts that EPA could make to reduce the paperwork burden for very small businesses affected by this collection.

What should I consider when I prepare my comments for EPA?

You may find the following suggestions helpful for preparing your comments:

1. Explain your views as clearly as possible and provide specific examples.
2. Describe any assumptions that you used.
3. Provide copies of any technical information and/or data you used that support your views.
4. If you estimate potential burden or costs, explain how you arrived at the estimate that you provide.
5. Offer alternative ways to improve the collection activity.
6. Make sure to submit your comments by the deadline identified under **DATES**.
7. To ensure proper receipt by EPA, be sure to identify the docket ID number assigned to this action in the subject line on the first page of your response. You may also provide the name, date, and **Federal Register** citation.

What information collection activity or ICR does this apply to?

Affected entities: Entities potentially affected by this action are direct and indirect reporters and state and local government authorized programs.

Title: Cross-Media Electronic Reporting Rule (Renewal).

ICR numbers: EPA ICR No. 2002.05, OMB Control Number 2025–0003.

ICR status: This ICR is currently scheduled to expire on July 31, 2011. 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, 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: The scope of this Information Collection Request is the final electronic reporting components of CROMERR, which is designed to: Allow EPA to comply with the Government Paperwork Elimination Act of 1998; provide a uniform, technology-neutral framework for electronic reporting across all EPA programs; allow EPA programs to offer electronic reporting as they become ready for CROMERRR; and provide states with a streamlined process—together with uniform set of standards—for approval of their electronic reporting provisions for all their EPA-authorized programs. Responses to the collection of information are voluntary. In order to accommodate CBI, the information collected must be in accordance with the confidentiality regulations set forth in 40 CFR Part 2, Subpart B. Additionally, EPA will ensure that the information collection procedures comply with the Privacy Act of 1974 and the OMB Circular 108.

Burden Statement: The annual public reporting burden for facilities for this collection of information is estimated to average: about 10 minutes for an individual reporting electronically to EPA's CDX to prepare and submit the on-line subscriber agreement application and call the CDX Help Desk; 15 minutes for an individual that prepares and submits a subscriber agreement to a State/Local agency; 5 minutes for an individual that prepares and files a subscriber agreement on site at the facility under a Local Registration Authority (LRA) arrangement; and 30 minutes for each facility LRA, including the time for preparing and submitting the certification of receipt and secure storage of on-site subscriber agreements to EPA or the State/Local agency. The annual public recordkeeping burden for facilities for this collection of information is estimated to average about 30 minutes for the LRA, including time for compiling subscriber agreements from employee registrants within the LRA's firm, placing and maintaining them in secure storage. The public reporting burden in this ICR is estimated to range from 210 hours for a Local government to 330 hours for State EPA seeking to implement an electronic receiving system. This includes time for preparing and submitting the program modification application to EPA.

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.

The ICR provides a detailed explanation of the Agency's estimate, which is only briefly summarized here:

Respondents/Affected Entities: Facilities reporting electronically to EPA and state or local government authorized programs; and state and local government authorized programs implementing electronic.

Estimated total number of potential respondents: EPA estimates 20,391 facilities on average to register for electronic reporting to EPA or State/Local authorized program electronic document receiving systems each year, with an average total of 67,902 employee registrants each year. EPA estimates that 15 state agencies and 46 other local government jurisdictions will submit CROMERR applications for their electronic reporting programs each year.

Frequency of response: On occasion.

Estimated total average number of responses for each respondent: 1.

Estimated total annual burden hours: 48,292 hours for facilities and 14,717 hours for state and local authorized programs.

Estimated total annual costs: $5,401,250 for facilities and $4,868,889 for state and local authorized programs. This includes an estimated burden cost of $5,199,840 for facilities and $417,926 for state and local authorized programs, and an estimated cost of $201,410 for facilities and $4,450,963 for state and local authorized programs for capital investment or maintenance and operational costs.

Are there changes in the estimates from the last approval?

EPA does not expect a significant change in the ICR renewal compared to the previous ICR, as the basic requirements are the same. There is an adjustment in the labor cost estimates due to the inflation of the labor rates over the past three years. Also, EPA expects the total estimated respondent burden for state and local government authorized programs identified in the ICR currently approved by OMB, to decrease over the next three year because most authorized programs with existing electronic document receiving systems submitted CROMERR applications to EPA, in compliance with the January 13, 2010 regulatory deadline. EPA expects a further reduction in the total number of respondents based on a decrease in the number of affected facilities.

What is the next step in the process for this ICR?

EPA will consider the comments received and amend the ICR as appropriate. The final ICR package will then be submitted to OMB for review and approval pursuant to 5 CFR 1320.12. At that time, EPA will issue another **Federal Register** notice pursuant to 5 CFR 1320.5(a)(1)(iv) to announce the submission of the ICR to OMB and the opportunity to submit additional comments to OMB. If you have any questions about this ICR or the approval process, please contact the technical person listed under **FOR FURTHER INFORMATION CONTACT**.

Dated: January 26, 2011.

Connie Dwyer,

Director, Information Exchange and Services Division.

[FR Doc. 2011–2270 Filed 2–1–11; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

[EPA–HQ–OAR–2010–0682; FRL–9260–9]

Agency Information Collection Activities; Submission to OMB for Review and Approval; Comment Request; NSPS and NESHAP for Petroleum Refinery Sector Residual Risk and Technology Review (RTR) (New Collection); EPA ICR No. 2411.01, OMB Control No. 2060–NEW

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: In compliance with the Paperwork Reduction Act (PRA)(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 new collection. The ICR, which is abstracted below, describes the nature of the information collection and its estimated burden and cost.

DATES: Additional comments may be submitted on or before March 4, 2011.

ADDRESSES: Submit your comments, identified by Docket ID No. EPA–HQ–OAR–2010–0682, 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, 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, Attention: Desk Officer for EPA, 725 17th Street, NW., Washington, DC 20503.

FOR FURTHER INFORMATION CONTACT: Ms. Brenda Shine, Sector Policies and Programs Division (E143–01), Office of Air Quality Planning and Standards, Environmental Protection Agency, Research Triangle Park, NC 27711; telephone number: (919) 541–3608; fax number: (919) 541–0246; e-mail address: *shine.brenda@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 September 29, 2010 (75 FR 60107), EPA sought comments on this ICR pursuant to 5 CFR 1320.8(d). EPA received seven comment letters during the comment period. Any additional comments on the 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–2010–0682, which is available for online viewing at *http://www.regulations.gov,* or in person viewing at the Air and Radiation Docket in the EPA Docket Center (EPA/DC), EPA West, Room 3334, 1301 Constitution Ave., NW., Washington, DC. The EPA/DC Public Reading Room is open from 8 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 Air and Radiation Docket is (202) 566–1742.

Use EPA's electronic docket and comment system at *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: NSPS and NESHAP for Petroleum Refinery Sector Residual Risk and Technology Review (RTR) (New Collection).

ICR numbers: EPA ICR No. 2411.01, OMB Control No. 2060–NEW.

ICR status: This ICR is for a new information collection activity. 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 Code of Federal Regulations (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: This information collection is being conducted by EPA's Office of Air and Radiation (OAR) to assist the EPA Administrator, as required by sections 111(b), 112(d), and 112(f)(6) of the Clean Air Act (CAA), as amended, to reevaluate emission standards for this source category. The non-confidential information from this information collection request (ICR) would also be made available to the public.

The proposed ICR has four components. To obtain the information necessary to identify and categorize all units potentially affected by any future revision to a standard, the first component of this ICR will solicit information from all potentially affected units at all 152 refineries in the format of an electronic survey under authority of section 114 of the CAA. This survey will include questions about the facility and individual emissions sources, and it will ask the owners/operators to submit cost data and provide copies of recent emissions test reports and continuous emission monitoring system (CEMS)/ continuous monitoring system (CMS) data. The second component will ask the owners/operators to develop and provide an emissions inventory. The third component will ask the owners/ operators to conduct sampling and analysis of the feed to the distillation columns at their refinery over a specific time period. The first three components will be submitted to all facilities listed in the *Energy Information Administration's Refinery Capacity Report 2009.* The fourth component will consist of requiring emissions testing, again pursuant to the authority of section 114 of the CAA.

EPA is issuing a single collection of information for sources covered under 40 CFR part 63, subparts CC and UUU and 40 CFR part 60, subpart J so that EPA can, at one time, assess whether additional control strategies are necessary and, if so, which are the most effective for hazardous air pollutants (HAP), regulated under CAA section 112, and criteria air pollutants (such as particulate matter, sulfur dioxide, and nitrogen oxide), regulated under CAA section 111. The data would also allow EPA to evaluate compliance options for startup and shutdown periods and consider ways to consolidate monitoring, reporting and recordkeeping requirements for the different rules under review. The data may also help EPA conduct reviews of other rules specific to petroleum refineries, including Standards of Performance for Equipment Leaks of VOC in Petroleum Refineries (40 CFR part 60, subpart GGG), Standards of Performance for VOC Emissions from Petroleum Refinery Wastewater Systems (40 CFR part 60, subpart QQQ), and the National Emission Standard for Benzene Waste Operations (40 CFR part 61, subpart FF).

The data collected will be used to update and augment facility and emissions source information already available to the Agency, develop new estimates of the population of affected units, and identify the control measures and alternative emission limits being used for compliance with the existing rules that are under review. This information, along with existing emission limits, will be used to establish the baseline emissions and control levels for purposes of the regulatory reviews. The emissions test data (test reports, CEMS data, and CMS data) collected will be used to assess the effectiveness of existing control measures, examine variability in emissions, evaluate the stringency of existing emission limits, identify the most effective control measures considered for purposes of reducing residual risk, and provide a basis for estimating nationwide emissions from emissions sources for which EPA has little information. Emissions data will also be used, along with process and emissions unit details, to consider options for best demonstrated technology under the NSPS review, to consider subcategories for further regulation, and to estimate the environmental and cost impacts associated with any regulatory options considered.

Burden Statement: The annual public reporting and recordkeeping burden for this collection of information is estimated to average 256 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 use 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: Respondents affected by this action are owners/operators of petroleum refineries, all of which are expected to have the potential to be subject to one of the regulatory standards being reviewed or developed by EPA. Petroleum refineries are facilities engaged in refining and producing products made from crude oil or unfinished petroleum derivatives.

Estimated Number of Respondents: 152.

Frequency of response: Once.

Estimated total annual burden hours: 69,342 hours.

Estimated total annual burden costs: $30,924,069, which includes $912 in O&M costs.

Dated: January 26, 2011.

John Moses,

Director, Collection Strategies Division.

[FR Doc. 2011–2273 Filed 2–1–11; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

[EPA–HQ–OPP–2011–0004; FRL–8862–1]

Pesticide Products; Registration Applications

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: EPA has received applications to register pesticide products containing active ingredients not included in any previously registered pesticide products. Pursuant to the provisions of section 3(c)(4) of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), EPA is hereby providing notice of receipt and opportunity to comment on these applications.

DATES: Comments must be received on or before March 4, 2011.

ADDRESSES: Submit your comments, identified by docket identification (ID) number and the file symbol(s) for the product(s) of interest as listed in Unit II, 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 ID number and the file symbol(s) for the product(s) of interest as listed in Unit II. 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 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 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: The Regulatory Action Leader listed in the table in this unit:

Regulatory action leader	Telephone number and e-mail address	Mailing address	File symbol
Susanne Cerrelli	(703) 308–8077 *cerrelli.susanne@epa.gov*	Biopesticides and Pollution Prevention Division (7511P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania, Ave., NW., Washington, DC 20460–0001.	70051–RNT, 70051–RNI.
Anna Gross	(703) 305–5614 *gross.anna@epa.gov*	Do	84059–RG, 84059–RU.
Chris Pfeifer	(703) 308–0031 *pfeifer.chris@epa.gov*	Do	34704–RNLL, 34704–RNLA, 34704–RNLT.
Jeannine Kausch	(703) 347–8920 *kausch.jeannine@epa.gov*	Do	84059–RA, 85004–I, 85004–O.
Abigail Downs	(703) 305–5259 *downs.abigail@epa.gov*	Antimicrobials Division (7510P). Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania, Ave., NW., Washington, DC 20460–0001.	707–GEN, 707–GRO.
Jacqueline Campbell-McFarlane	(703) 308–6416 *campbell-mcfarlane.jacqueline@epa.gov*	Do	5383–RUE, 5383–RUN.
Tracy Lantz	(703) 308–6415 *Lantz.tracy@epa.gov*	Do	1706–EUN, 1706–EUR, 1706–EGO.

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. Registration Applications

EPA has received applications to register pesticide products containing active ingredients not included in any previously registered pesticide products. Pursuant to the provisions of section 3(c)(4) of FIFRA, EPA is hereby providing notice of receipt and opportunity to comment on these applications. Notice of receipt of these applications does not imply a decision by the Agency on these applications.

1. *File Symbol:* 707–GEN. *Docket Number:* EPA–HQ–OPP–2010–1037. *Applicant:* Rohm and Hass Company, 100 Independence Mall West, Philadelphia, PA 19106. *Product name:* Bioban MB 100 Technical. *Active ingredient:* microbiocide and 2-methyl-1, 2-benzisothiazolin-3-one at 98.90%. *Proposed classification/Use:* Technical. (Abigail Downs)

2. *File Symbol:* 707–GRO. *Docket Number:* EPA–HQ–OPP–2010–1037. *Applicant:* Rohm and Hass Company, 100 Independence Mall West, Philadelphia, PA 19106. *Product name:* Bioban MB 25 Antimicrobial. *Active ingredient:* Microbiocide and 2-methyl-1, 2-benzisothiazolin-3-one at 25%. *Proposed classification/Use:* For use in formulation of emulsion products, paints, building materials, adhesives and sealants, ink, textiles, paper coating, functional chemicals, household and I&I, oil process water and recovery system, metalworking fluids. (Abigail Downs)

3. *File Symbol:* 1706–EUN. *Docket Number:* EPA–HQ–OPP–2011–0019. *Applicant:* Nalco Company, 1601 West Diehl Road, Naperville, IL 60563. *Product name:* Nalco 60620. *Active ingredient:* Antimicrobial and Ammonium Sulfate at 20%. *Proposed classification/Use:* Pulp and paper mill water systems. (Tracy Lantz)

4. *File Symbol:* 1706–EUR. *Docket Number:* EPA–HQ–OPP–2011–0020. *Applicant:* Nalco Company, 1601 West Diehl Road, Naperville, IL 60563. *Product name:* Nalco 60630. *Active ingredient:* Antimicrobial and Urea at 30%. *Proposed classification/Use:* Pulp and paper mill water systems. (Tracy Lantz)

5. *File Symbol:* 1706–EGO. *Docket Number:* EPA–HQ–OPP–2011–0020. *Applicant:* Nalco Company, 1601 West Diehl Road, Naperville, IL 60563. *Product name:* Nalco 60615. *Active ingredient:* Antimicrobial and Urea at 15%. *Proposed classification/Use:* Pulp and paper mill water systems. (Tracy Lantz)

6. *File Symbol:* 5383–RUE. *Docket Number:* EPA–HQ–OPP–2009–1000. *Applicant:* Troy Chemical, Inc., 8 Vreeland Rd., P.O. Box 955, Florham Park, NJ 07932–4200. *Product name:* TROYSAN V662. *Active ingredient:* Antimicrobial and Terbutryn at 48%. *Proposed classification/Use:* Materials preservation of coatings, stuccos, roof coatings, joint cements, and sealants. (Jacqueline Campbell-McFarlane)

7. *File Symbol:* 5383–RUN. *Docket Number:* EPA–HQ–OPP–2009–1000. *Applicant:* Troy Chemical, Inc., 8 Vreeland Rd., P.O. Box 955, Florham Park, NJ 07932–4200. *Product name:* POLYPHASE ® 710 S. *Active ingredient:* Antimicrobial and Terbutryn at 8%. *Proposed classification/Use:* Materials preservation of joint cements, coatings, sealants, stuccos, and plastics. (Jacqueline Campbell-McFarlane)

8. *File Symbol:* 34704–RNLL. *Docket number:* EPA–HQ–OPP–2011–0009. *Applicant:* Loveland Products, Inc., c/o Pyxis Consulting, Inc., 4110 136th St., NW., Gig Harbor, WA 98332. *Product name:* LPI 6194 Concentrate Seed Treatment. *Active ingredient:* Plant growth regulator, Salicylic Acid, at 0.04%. *Proposed classification/Use:* Biochemical pesticide/plant growth regulator intended for seed treatment. (Chris Pfeifer)

9. *File Symbol:* 34704–RNLA. *Docket number:* EPA–HQ–OPP–2011–0009. *Applicant:* Loveland Products, Inc., c/o Pyxis Consulting, Inc., 4110 136th St., NW., Gig Harbor, WA 98332. *Product name:* LPI 6194 RTU Seed Treatment. *Active ingredient:* Plant growth regulator, Salicylic Acid, at 0.0067%. *Proposed classification/Use:* Biochemical pesticide/plant growth regulator intended for seed treatment. (Chris Pfeifer)

10. *File Symbol:* 34704–RNLT. *Docket number:* EPA–HQ–OPP–2011–0009. *Applicant:* Loveland Products, Inc., c/o Pyxis Consulting, Inc., 4110 136th St., NW., Gig Harbor, WA 98332. *Product name:* Salicylic Acid Technical. *Active ingredient:* Plant growth regulator, Salicylic Acid, at 98.7%. *Proposed classification/Use:* Biochemical pesticide/manufacturing use product containing a plant growth regulator intended for incorporation into end use products for seed treatment. (Chris Pfeifer)

11. *File Symbol:* 70051–RNT. *Docket number:* EPA–HQ–OPP–2010–0944. *Applicant:* Certis U.S.A., L.L.C., 9145 Guilford Road, Suite 175, Columbia, MD 21046. *Product name:* CX–9032. *Active ingredient:* Fungicide and *Bacillus subtilis var. amyloliquefaciens strain D747* at 98.35%. *Proposed classification/Use:* Fungicide on vegetable, melons, tree fruit and nuts, strawberry, berries, grapes, tropical fruits, herbs, coffee, mint, hops, tobacco, nurseries, greenhouses, shade house, ornamental plants and turf. (Susanne Cerrelli)

12. *File Symbol:* 70051–RNI. *Docket number:* EPA–HQ–OPP–2010–0944. *Applicant:* Certis U.S.A., L.L.C., 9145 Guilford Road, Suite 175, Columbia, MD 21046. *Product name:* CX–9030. *Active ingredient:* Fungicide and *Bacillus subtilis var. amyloliquefaciens strain D747* at 25.0%. *Proposed classification/Use:* Fungicide on vegetable, melons, tree fruit and nuts, strawberry, berries, grapes, tropical fruits, herbs, coffee, mint, hops, tobacco, nurseries, greenhouses, shade house, ornamental plants and turf. (Susanne Cerrelli)

13. *File Symbol:* 84059–RA. *Docket Number:* EPA–HQ–OPP–2010–0058. *Applicant:* Marrone Bio Innovations, Inc., 2121 Second St., Suite B–107, Davis, CA 95618. *Product Name:* MBI–203 SC. *Active Ingredient:* Insecticide and *Chromobacterium subtsugae* strain PRAA4–1^{T} at 86.50%. *Proposed classification/Use:* For control of foliar-feeding pests, such as caterpillars, foliage-feeding coleopteran, aphids, whiteflies, and plant-sucking mites, on ornamental plants, turf, and various edible crops. **Note:** In the **Federal Register** of March 10, 2010 (75 FR 11175) (FRL–8811–6), EPA announced

receipt of two other applications to register pesticide products containing this new active ingredient. (J. Kausch)

14. *File Symbol:* 84059–RG. *Docket Number:* EPA–HQ–OPP–2011–0010. *Applicant:* Marrone Bio Innovations, 2121 Second Street, Suite B–107, Davis, CA 95618. *Product name:* MBI–206 TGAI. *Active ingredient:* Insecticide and *Burkholderia sp.* strain A396 at 100%. *Proposed classification/Use:* Ornamental plants, turf and edible crops. (Anna Gross)

15. *File Symbol:* 84059–RU. *Docket Number:* EPA–HQ–OPP–2011–0010. *Applicant:* Marrone Bio Innovations, 2121 Second Street, Suite B–107, Davis, CA 95618. *Product name:* MBI–206 EP. *Active ingredient:* Insecticide and *Burkholderia sp.* strain A396 at 94.46%. *Proposed classification/Use:* Ornamental plants, turf and edible crops. (Anna Gross)

16. *File Symbol:* 85004–I. *Docket Number:* EPA–HQ–OPP–2010–0808. *Applicant:* MacIntosh and Associates, Inc., 1203 Hartford Ave., Saint Paul, MN 55116–1622 (on behalf of Pasteuria Bioscience, Inc., 12085 Research Dr., Suite 185, Alachua, FL 32615) *Product Name: Pasteuria reniformis*—Liquid Formulation. *Active Ingredient:* Nematicide and *Pasteuria reniformis*—Pr3 [SD–5834] at 0.0033%. *Proposed Classification/Use:* For control of reniform nematode (*Rotylenchulus reniformis)* on various food and nonfood crops. **Note:** In the **Federal Register** of November 24, 2010 (75 FR 71697) (FRL–8837–3), EPA announced receipt of two other applications to register pesticide products containing this new active ingredient. (J. Kausch)

17. *File Symbol:* 85004–O. *Docket Number:* EPA–HQ–OPP–2010–0806. *Applicant:* MacIntosh and Associates, Inc., 1203 Hartford Ave., Saint Paul, MN 55116–1622 (on behalf of Pasteuria Bioscience, Inc., 12085 Research Dr., Suite 185, Alachua, FL 32615.) *Product Name: Pasteuria nishizawae*—Liquid Formulation. *Active Ingredient:* Nematicide and *Pasteuria nishizawae*—Pn1 [SD–5833] at 0.0033%. *Proposed Classification/Use:* For control of soybean cyst nematode (*Heterodera glycines)* on soybean. **Note:** In the **Federal Register** of November 24, 2010 (75 FR 71697) (FRL–8837–3), EPA announced receipt of two other applications to register pesticide products containing this new active ingredient. (J. Kausch)

List of Subjects

Environmental protection, Agricultural Commodities, Pesticides and pest.

Dated: January 20, 2011.

Keith A. Matthews,

Acting Director, Biopesticides Pollution Prevention Division, Office of Pesticide Programs.

[FR Doc. 2011–2156 Filed 2–1–11; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

[EPA–HQ–OPP–2010–0548; FRL–8863–6]

Petition for a Ban on Triclosan; Notice of Availability; Extension of Comment Period

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice; extension of comment period.

SUMMARY: EPA issued a notice in the **Federal Register** of December 8, 2010 concerning the availability of a petition submitted by Beyond Pesticides and Food & Water Watch to the Environmental Protection Agency for review and public comment. The petition asks EPA to use its authority under various statutes to regulate triclosan. In a letter to the EPA dated January 22, 2011, Beyond Pesticides and Food & Water Watch requested a 60 day extension to the comment period. In response to this request, this document extends the comment period for 60 days, from February 7, 2011 to April 8, 2011.

DATES: Comments, identified by docket identification (ID) number EPA–HQ–OPP–2010–0548, must be received on or before April 8, 2011.

ADDRESSES: Follow the detailed instructions as provided under **ADDRESSES** in the **Federal Register** document of December 8, 2010.

FOR FURTHER INFORMATION CONTACT: Timothy F. McMahon, Antimicrobials Division (7510P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001; telephone number: (703) 308–6342; e-mail address: *mcmahon.tim@epa.gov.*

SUPPLEMENTARY INFORMATION: This document extends the public comment period established in the **Federal Register** of December 8, 2010 (75 FR 764613) (FRL–8852–8). In that document, the Agency made available for review and public comment a petition submitted by Beyond Pesticides and Food & Water Watch (hereafter referred to as "the petitioners") to the Environmental Protection Agency (hereafter referred to as "EPA" or "the Agency"), asking EPA to use its authority under various statutes to regulate triclosan. Triclosan is an antimicrobial substance used in pesticide products, hand sanitizers, toothpaste, and other consumer products. The petitioners claim that the "pervasive and widespread use" of triclosan poses significant risks to human health and the environment. In addition, the petitioners claim that the "agency failed to address the impacts posed by triclosan's degradation products on human health and the environment, failed to conduct separate assessments for triclosan residues in contaminated drinking water and food, and is complacent in seriously addressing concerns related to antibacterial resistance and endocrine disruption." Under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) and the Federal Food, Drug, and Cosmetic Act (FFDCA), the petitioners ask EPA to act to cancel and suspend the registration of pesticides containing triclosan. Under the Clean Water Act (CWA), the petitioners request that the Administrator impose technology-based effluent limitations, health-based toxic pollutant water quality pretreatment requirements, and biosolids regulation for triclosan. Under the Safe Drinking Water Act (SDWA), the petitioners request that the Administrator conduct a comprehensive assessment of the appropriateness of regulating triclosan under SDWA. Under the Endangered Species Act (ESA), the petitioners request that the Administrator comply fully with ESA, including consultation and biological assessment requirements. In a letter submitted to the Agency dated January 22, 2011, Beyond Pesticides and Food & Water Watch requested a 60 day extension to the comment period. EPA is hereby extending the comment period, which was set to end on February 7, 2011, to April 8, 2011.

To submit comments, or access the docket, please follow the detailed instructions as provided under **ADDRESSES** in the December 8, 2010 **Federal Register** document. If you have questions, consult the person listed under **FOR FURTHER INFORMATION CONTACT**.

List of Subjects

Environmental protection, Antimicrobial, Pesticides and pest, Triclosan, Endocrine.

Dated: January 26, 2011.

Joan Harrigan Farrelly,

Director, Antimicrobials Division, Office of Pesticide Programs.

[FR Doc. 2011–2267 Filed 2–1–11; 8:45 am]

BILLING CODE 6560–50–P

FEDERAL COMMUNICATIONS COMMISSION

Notice of Public Information Collection(s) Being Submitted for Review and Approval to the Office of Management and Budget (OMB), Comments Requested

January 28, 2011.

SUMMARY: The Federal Communications Commission, as part of its continuing effort to reduce paperwork burden invites the general public and other Federal agencies to take this opportunity to comment on the following information collection(s), as required by the Paperwork Reduction Act (PRA) of 1995, 44 U.S.C. 3501–3520. Comments are requested concerning: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the Commission, including whether the information shall have practical utility; (b) the accuracy of the Commission's burden estimate; (c) ways to enhance the quality, utility, and clarity of the information collected; (d) ways to minimize the burden of the collection of information on the respondents, including the use of automated collection techniques or other forms of information technology; and (e) ways to further reduce the information collection burden for small business concerns with fewer than 25 employees.

The FCC may not conduct or sponsor a collection of information unless it displays a currently valid control number. No person shall be subject to any penalty for failing to comply with a collection of information subject to the Paperwork Reduction Act (PRA) that does not display a currently valid OMB control number.

DATES: Written Paperwork Reduction Act (PRA) comments should be submitted on or before March 4, 2011. If you anticipate that you will be submitting PRA comments, but find it difficult to do so within the period of time allowed by this notice, you should advise the FCC contact listed below as soon as possible.

ADDRESSES: Direct all PRA comments to Nicholas A. Fraser, Office of Management and Budget, via fax at 202–395–5167 or via email to *Nicholas_A._Fraser@omb.eop.gov* and to the Federal Communications Commission via email to *PRA@fcc.gov* and *Cathy.Williams@fcc.gov.* To view a copy of this information collection request (ICR) submitted to OMB: (1) Go to the web page *http://reginfo.gov/public/do/PRAMain,* (2) look for the section of the web page called "Currently Under Review", (3) click on the downward-pointing arrow in the "Select Agency" box below the "Currently Under Review" heading, (4) select "Federal Communications Commission" from the list of agencies presented in the "Select Agency" box, (5) click the "Submit" button to the right of the "Select Agency" box, and (6) when the list of FCC ICRs currently under review appears, look for the title of this ICR (or its OMB Control Number, if there is one) and then click on the ICR Reference Number to view detailed information about this ICR.

FOR FURTHER INFORMATION CONTACT: For additional information or copies of the information collection(s), contact Cathy Williams on (202) 418–2918.

SUPPLEMENTARY INFORMATION:

OMB Control Number: 3060–0653.

Title: Sections 64.703(b) and (c), Consumer Information—Posting by Aggregators.

Form Number: N/A.

Type of Review: Extension of a currently approved collection.

Respondents: Business or other for-profit entities.

Number of Respondents and Responses: 56,075 respondents and 5,339,038 responses.

Estimated Time per Response: .017 to 3 hours.

Frequency of Response: On occasion reporting requirement; Third party disclosure requirement.

Obligation to Respond: Required to obtain or retain benefits. The statutory authority for this information collection is found at section 226 [47 U.S.C. 226] Telephone Operator Services codified at 47 CFR 64.703(b) Consumer Information.

Total Annual Burden: 174,401 hours.

Total Annual Cost: $1,688,168.

Nature and Extent of Confidentiality: An assurance of confidentiality is not offered because this information collection does not require the collection of personally identifiable information (PII) from individuals.

Privacy Impact Assessment: No impact(s).

Needs and Uses: The information collection requirements included under this OMB Control Number 3060–0653, requires aggregators (providers of telephones to the public or to transient users of their premises) under 47 U.S.C. 226(c)(1)(A), 47 CFR 64.703(b) of the Commission's rules, to post in writing, on or near such phones, information about the pre-subscribed operator services, rates, carrier access, and the FCC address to which consumers may direct complaints. Section 64.703(c) of the Commission's rules requires the posted consumer information to be added when an aggregator has changed the pre-subscribed operator service provider (OSP) no later than 30 days following such change. Consumers will use this information to determine whether they wish to use the services of the identified OSP.

OMB Control Number: 3060–1104.

Title: Section 73.682(d), DTV Transmission and Program System and Information Protocol ("PSIP") Standards.

Form Number: N/A.

Type of Review: Extension of a currently approved collection.

Respondents: Business or other for-profit entities; not for-profit institutions.

Number of Respondents and Responses: 1,812 respondents and 1,812 respondents.

Estimated Hours per Response: 0.50 hours.

Frequency of Response: Third Party Disclosure requirement; Weekly reporting requirement.

Total Annual Burden: 47,112 hours.

Total Annual Cost: None.

Obligation to Respond: Required to obtain or retain benefits—the statutory authority for this collection is contained in Sections 309 and 337 of the Communications Act of 1934, as amended.

Nature and Extent of Confidentiality: Confidentiality is not required with this collection of information.

Privacy Impact Assessment: No impact(s).

Needs and Uses: Section 73.682(d) of the Commission's rules incorporates by reference the Advanced Television Systems Committee, Inc. ("ATSC") Program System and Information Protocol ("PSIP") standard "A/65C." PSIP data is transmitted along with a TV broadcast station's digital signal and provides viewers (via their DTV receivers) with information about the station and what is being broadcast, such as program information. The Commission has recognized the utility that the ATSC PSIP standard offers for both broadcasters and consumers (or viewers) of digital television ("DTV").

ATSC PSIP standard A/65C requires broadcasters to provide detailed programming information when transmitting their broadcast signal. This standard enhances consumers' viewing experience by providing detailed information about digital channels and programs, such as how to find a program's closed captions, multiple streams and V-chip information. This standard requires broadcasters to populate the Event Information Tables ("EITs") (or program guide) with accurate information about each event (or program) and to update the EIT if more accurate information becomes

available. The previous ATSC PSIP standard A/65–B did not require broadcasters to provide such detailed programming information but only general information.

Federal Communications Commission.

Bulah P. Wheeler,

Deputy Manager, Office of the Secretary, Office of Managing Director.

[FR Doc. 2011–2282 Filed 2–1–11; 8:45 am]

BILLING CODE 6712–01–P

FEDERAL COMMUNICATIONS COMMISSION

[IB Docket No. 04–286; DA 11–156]

Seventh Meeting of the Advisory Committee for the 2012 World Radiocommunication Conference

AGENCY: Federal Communications Commission.

ACTION: Notice.

SUMMARY: In accordance with the Federal Advisory Committee Act, as amended, this notice advises interested persons that the seventh meeting of the WRC–12 Advisory Committee will be held at the Federal Communications Commission. The purpose of the meeting is to continue preparations for the 2012 World Radiocommunication Conference. The WRC–12 Advisory Committee will consider any preliminary views and draft proposals introduced by the WRC–12 Advisory Committee's Informal Working Groups.

DATES: March 8, 2011, 11 a.m. to 12 noon.

ADDRESSES: Federal Communications Commission, 445 12th Street, SW., Room TW–C305, Washington DC 20554.

FOR FURTHER INFORMATION CONTACT: Alexander Roytblat, Designated Federal Official, WRC–12 Advisory Committee, FCC International Bureau, Strategic Analysis and Negotiations Division, at (202) 418–7501.

SUPPLEMENTARY INFORMATION: The Federal Communications Commission established the WRC–12 Advisory Committee to provide advice, technical support and recommendations relating to the preparation of United States proposals and positions for the 2012 World Radiocommunication Conference (WRC–12).

In accordance with the Federal Advisory Committee Act, Public Law 92–463, as amended, this notice advises interested persons of the seventh meeting of the WRC–12 Advisory Committee. The WRC–12 Advisory Committee has an open membership. All interested parties are invited to participate in the WRC–12 Advisory Committee and to attend its meetings. The proposed agenda for the seventh meeting is as follows:

Agenda

Seventh Meeting of the WRC–12 Advisory Committee, Federal Communications Commission, 445 12th Street, SW., Room TW–C305, Washington, DC 20554, March 8, 2011, 11 a.m. to 12 noon.

1. Opening Remarks
2. Approval of Agenda
3. Approval of the Minutes of the Sixth Meeting
4. Informal Working Group Reports and Documents Relating to Preliminary Views and Draft Proposals
5. Future Meetings
6. Other Business

Federal Communications Commission.

Mindel De La Torre,

Chief, International Bureau.

[FR Doc. 2011–2306 Filed 2–1–11; 8:45 am]

BILLING CODE 6712–01–P

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.: 012116.

Title: NYK/Hanjin/Hyundai-Americas North South Service Vessel Sharing Agreement.

Parties: Hanjin Shipping Co., Ltd; Hyundai Merchant Marine Co., Ltd; and Nippon Yusen Kaisha.

Filing Party: Patricia M. O'Neill, Esq.; Corporate Counsel; NYK Line (North America) Inc.; 300 Lighting Way, 5th Floor; Secaucus, NJ 07094.

Synopsis: The agreement authorizes the parties to charter space to each other in the trade between ports on Atlantic Coast of North America and ports in East Coast of South America, Jamaica, Mexico, and Dominican Republic.

Agreement No.: 201201–001.

Title: Port of Seattle/Terminal Operator Agreement.

Parties: Port of Seattle; Eagle Marine Services, Ltd; SSA Terminals LLC; SSA Terminals (Seattle), LLC; and Total Terminals International, LLC.

Filing Party: Wayne R. Rohde, Esq.; Cozen O'Connor; 1627 I Street, NW., Suite 1100; Washington, DC 20006.

Synopsis: The amendment updates the address of Eagle Marine Services, Ltd.

By Order of the Federal Maritime Commission.

Dated: January 28, 2011.

Karen V. Gregory,

Secretary.

[FR Doc. 2011–2302 Filed 2–1–11; 8:45 am]

BILLING CODE 6730–01–P

FEDERAL RESERVE SYSTEM

Change in Bank Control Notices; Acquisitions of Shares of a Bank or Bank Holding Company

The notificants listed below have applied under the Change in Bank Control Act (12 U.S.C. 1817(j)) and § 225.41 of the Board's Regulation Y (12 CFR 225.41) to acquire shares of a bank or bank holding company. The factors that are considered in acting on the notices are set forth in paragraph 7 of the Act (12 U.S.C. 1817(j)(7)).

The notices are available for immediate inspection at the Federal Reserve Bank indicated. The notices also will be available for inspection at the offices of the Board of Governors. Interested persons may express their views in writing to the Reserve Bank indicated for that notice or to the offices of the Board of Governors. Comments must be received not later than February 17, 2011.

A. Federal Reserve Bank of Dallas (E. Ann Worthy, Vice President) 2200 North Pearl Street, Dallas, Texas 75201–2272:

1. *James Edward Campbell; Rick Lane Campbell, individually, and as Trustee for the Collin McElroy Trust; Angela Lee Koonce, individually, and as Trustee for the Collin McElroy Trust; and Cameron James McElroy, all in Center, Texas (the* "*Campbell Family Group*"*); Aaron Weldon Boles and Lisa Gayle McAdams, both in Center, Texas (the* "*Boles Family Group*"*); Clyde Donald Monroe, Center, Texas; and Brenda Monroe Humble, Shelbyville, Texas (the* "*Monroe Family Group*"*); Sammy Dean Dance and Connie Mettauer, both in Center, Texas (the Dance Family Group);* to retain voting shares of Shelby Bancshares, Inc., and thereby indirectly retain control of Shelby Savings Bank, SSB, both in Center, Texas.

Board of Governors of the Federal Reserve System, January 28, 2011.

Robert deV. Frierson,

Deputy Secretary of the Board.

[FR Doc. 2011–2263 Filed 2–1–11; 8:45 am]

BILLING CODE 6210–01–P

FEDERAL RESERVE SYSTEM

Formations of, Acquisitions by, and Mergers of Bank Holding Companies

The companies listed in this notice have applied to the Board for approval, pursuant to the Bank Holding Company Act of 1956 (12 U.S.C. 1841 *et seq.*) (BHC Act), Regulation Y (12 CFR part 225), and all other applicable statutes and regulations to become a bank holding company and/or to acquire the assets or the ownership of, control of, or the power to vote shares of a bank or bank holding company and all of the banks and nonbanking companies owned by the bank holding company, including the companies listed below.

The applications listed below, as well as other related filings required by the Board, are available for immediate inspection at the Federal Reserve Bank indicated. The application also will be available for inspection at the offices of the Board of Governors. Interested persons may express their views in writing on the standards enumerated in the BHC Act (12 U.S.C. 1842(c)). If the proposal also involves the acquisition of a nonbanking company, the review also includes whether the acquisition of the nonbanking company complies with the standards in section 4 of the BHC Act (12 U.S.C. 1843). Unless otherwise noted, nonbanking activities will be conducted throughout the United States.

Unless otherwise noted, comments regarding each of these applications must be received at the Reserve Bank indicated or the offices of the Board of Governors not later than February 28, 2011.

A. Federal Reserve Bank of Atlanta (Clifford Stanford, Vice President) 1000 Peachtree Street, NE., Atlanta, Georgia 30309:

1. *Peoples Bancshares, Inc.,* Mendenhall, Mississippi; to become a bank holding company by acquiring 100 percent of the outstanding voting shares of Peoples Bank, Mendenhall, Mississippi.

B. Federal Reserve Bank of St. Louis (Glenda Wilson, Community Affairs Officer) P.O. Box 442, St. Louis, Missouri 63166–2034:

1. *Cabool State Bank Employee Stock Ownership Plan,* Cabool, Missouri; to acquire an additional 1.02 percent, for a total of 32.44 percent, of the outstanding voting shares of Cabool Bancshares, Inc., and thereby indirectly acquire additional voting shares of Cabool State Bank, both in Cabool, Missouri.

Board of Governors of the Federal Reserve System, January 28, 2011.

Robert deV. Frierson,

Deputy Secretary of the Board.

[FR Doc. 2011–2262 Filed 2–1–11; 8:45 am]

BILLING CODE 6210–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Adjusted Federal Medical Assistance Percentage (FMAP) Rate for the First Quarter of Fiscal Year 2011 (FY11)

Implementation of Section 5001 of the American Recovery and Reinvestment Act of 2009 (Pub. L. 111–5) for Adjustments to the First Quarter of Fiscal Year 2011 Federal Medical Assistance Percentage Rates for Federal Matching Shares for Medicaid and Title IV–E Foster Care, Adoption Assistance and Guardianship Assistance Programs.

AGENCY: Office of the Secretary, DHHS.

ACTION: Notice.

SUMMARY: This notice provides the adjusted Federal Medical Assistance Percentage (FMAP) rate for the first quarter of Fiscal Year 2011 (FY11) as required under Section 5001 of the American Recovery and Reinvestment Act of 2009 (ARRA). Section 5001 of the ARRA provides for temporary increases in the FMAP rates to provide fiscal relief to states and to protect and maintain state Medicaid and certain other assistance programs in a period of economic downturn. The increased FMAP rates apply during a recession adjustment period that was originally defined in ARRA as the period beginning October 1, 2008 and ending December 31, 2010. Public Law 111–226 amended ARRA to extend the recession adjustment period to June 30, 2011 and to extend the hold harmless provision that prevents a state's FMAP rate from decreasing due to a lower unemployment rate from the calendar quarter ending before July 1, 2010 to the calendar quarter ending before January 1, 2011. Public Law 111–226 also provided for a phase-down of the general FMAP increase in the last two quarters of the extended recession adjustment period, and changed the look back period for calculating the unemployment adjustment for those quarters, which will be addressed in a future Notice.

DATES: *Effective Date:* The percentages listed are for the first quarter of FY11 beginning October 1, 2010 through December 31, 2010.

A. Background

The FMAP is used to determine the amount of federal matching for specified state expenditures for assistance payments under programs under the Social Security Act ("the Act"). Sections 1905(b) and 1101(a)(8)(B) of the Act require the Secretary of Health and Human Services to publish the FMAP rates each year. The Secretary calculates the percentages using formulas in sections 1905(b) and 1101(a)(8)(B), and statistics from the Department of Commerce of average income per person in each state and for the Nation as a whole. The percentages must be within the upper and lower limits given in section 1905(b) of the Act. The percentages to be applied to the District of Columbia, Puerto Rico, the Virgin Islands, Guam, American Samoa, and the Northern Mariana Islands are specified separately in the Act, and thus are not based on the statutory formula that determines the percentages for the 50 states.

Section 1905(b) of the Act specifies the formula for calculating the FMAP as follows:

> The FMAP for any State shall be 100 per centum less the State percentage; and the State percentage shall be that percentage which bears the same ratio to 45 per centum as the square of the per capita income of such State bears to the square of the per capita income of the continental United States (including Alaska) and Hawaii; except that (1) the FMAP shall in no case be less than 50 per centum or more than 83 per centum, and (2) the FMAP for Puerto Rico, the Virgin Islands, Guam, the Northern Mariana Islands, and American Samoa shall be 50 per centum.

Section 4725 of the Balanced Budget Act of 1997 amended section 1905(b) to provide that the FMAP for the District of Columbia for purposes of titles XIX (Medicaid) and XXI (CHIP) shall be 70 percent. The Medicare Improvements for Patients and Providers Act of 2008 (MIPPA) (Pub. L. 110–275) amended the FMAP applied to the District of Columbia for maintenance payments under title IV–E programs to make it consistent with the 70 percent Medicaid match rate.

Section 5001 of Division B of the ARRA provides for a temporary increase in FMAP rates for Medicaid and title IV–E Foster Care, Adoption Assistance and Guardianship Assistance programs. The purpose of the increases to the FMAP rates is to provide fiscal relief to states and to protect and maintain State Medicaid and certain other assistance

programs in a period of economic downturn, referred to as the "recession adjustment period." The recession adjustment period is defined as the period beginning October 1, 2008 and ending December 31, 2010. Public Law 111–226 extends the recession adjustment period to June 30, 2011.

B. Calculation of the Increased FMAP Rates Under ARRA

Section 5001 of the ARRA specifies that the FMAP rates shall be temporarily increased for the following: (1) Maintenance of FMAP rates for FY09, FY10, and first three calendar quarters of FY11, so that the FMAP rate will not decrease from the prior year, determined by using as the FMAP rate for the current year, the greater of any prior fiscal year FMAP rates between 2008–2010 or the rate calculated for the current fiscal year; (2) in addition to any maintenance increase, the application of a general percentage point increase in each state's FMAP of 6.2 percentage points (decreasing during the last two quarters of the extended recession adjustment period); and (3) an additional percentage point increase based on the state's increase in unemployment during the recession adjustment period. The resulting increased FMAP cannot exceed 100 percent. Each state's FMAP will be recalculated each fiscal quarter beginning October 2008. Availability of certain components of the increased FMAP is conditioned on states meeting statutory programmatic requirements, such as the maintenance of effort requirement, which are not part of the calculation process.

Expenditures for which the increased FMAP is not available under title XIX include expenditures for disproportionate share hospital payments, certain eligibility expansions, services received through an IHS or tribal facility (which are already paid at a rate of 100 percent and therefore not subject to increase), and expenditures that are paid at an enhanced FMAP rate. The increased FMAP is available for expenditures under part E of title IV (including Foster Care, Adoption Assistance and Guardianship Assistance programs) only to the extent of a maintenance increase (hold harmless), if any, and the general percentage point increase. The increased FMAP does not apply to other parts of title IV, including part D (Child Support Enforcement Program).

For title XIX purposes only, for each qualifying state with an unemployment rate that has increased at a rate above the statutory threshold percentage, ARRA provides additional relief above the general percentage point increase in FMAP through application of a separate increase calculation. For those states, the FMAP for each qualifying state is increased by the number of percentage points equal to the product of the state matching percentage (as calculated under section 1905(b) and adjusted if necessary for the maintenance of FMAP without reduction from the prior year, and after applying half of the general percentage point increase in the federal percentage) and the applicable percent determined from the state unemployment increase percentage for the quarter.

The unemployment increase percentage for calendar quarters other than the last two quarters of the recession adjustment period is equal to the number of percentage points (if any) by which the average monthly unemployment rate for the state in the most recent previous 3-consecutive-month period for which data are available exceeds the lowest average monthly unemployment rate for the state for any 3-consecutive-month period beginning on or after January 1, 2006. A state qualifies for additional relief based on an increase in unemployment if that state's unemployment increase percentage is at least 1.5 percentage points. A different but related methodology for an unemployment adjustment applies for the last two quarters of the recession adjustment period.

The applicable percent is: (1) 5.5 percent if the state unemployment increase percentage is at least 1.5 percentage points but less than 2.5 percentage points; (2) 8.5 percent if the state unemployment increase percentage is at least 2.5 percentage points but less than 3.5 percentage points; and (3) 11.5 percent if the state unemployment increase percentage is at least 3.5 percentage points.

If the state's applicable percent is less than the applicable percent for the preceding quarter, then the higher applicable percent shall continue in effect for any calendar quarter beginning on or after January 1, 2009 and ending before January 1, 2011, as amended by Public Law 111–226. This hold harmless provision is not in effect from January 1, 2011 to June 30, 2011.

Under section 5001(b)(2) of ARRA, Puerto Rico, the Virgin Islands, Guam, the Commonwealth of the Northern Mariana Islands, and America Samoa were given the option to make a special one-time election between (1) a 30 percent increase in their cap on Medicaid payments (as determined under subsections (f) and (g) of section 1108 of the Act), or (2) applying the general 6.2 percentage point increase in the FMAP plus a 15 percent increase in the cap on Medicaid payments. There is no quarterly unemployment adjustment for territories. All territories and the Commonwealth of the Northern Mariana Islands elected the 30 percent increase in their spending cap on Medicaid payments; therefore there is no recalculation of their FMAP rate.

D. Adjusted FMAPs for the First Quarter of FY2011

ARRA adjustments to FMAPs are shown by state in the accompanying table. The hold harmless FY11 FMAP is the higher of the original FY08, FY09, FY10 or FY11 FMAP. The 6.2 percentage point increase is added to the hold harmless FY11 FMAP. The unemployment adjustment is calculated according to the unemployment tier and added to the hold harmless FY11 FMAP with the 6.2 percentage point increase.

For the first quarter of FY11, the unemployment tier is determined by comparing the average unemployment rate for the three consecutive months preceding the start of the fiscal quarter to the lowest consecutive 3-month average unemployment rate beginning January 1, 2006. If the state's applicable percent is less than the applicable percent for the fourth quarter of FY10, then the higher applicable percent shall continue for the first quarter of FY11.

As indicated in the August 4, 2009 **Federal Register** Notice that proposed the methodology for the FMAP unemployment adjustment calculations (74 FR 38630), we utilize annual updates to the historical Bureau of Labor Statistics (BLS) data to make changes to the States' lowest unemployment rate beginning with the fourth quarter FMAP rate adjustment calculation each year. As such, the rates calculated and presented in the accompanying table are based on updates to the historical BLS data used to determine the States' average lowest unemployment rate for any 3 consecutive months beginning January 1, 2006.

FOR FURTHER INFORMATION CONTACT: Rose Chu or Thomas Musco, Office of Health Policy, Office of the Assistant Secretary for Planning and Evaluation, Room 447D—Hubert H. Humphrey Building, 200 Independence Avenue, SW., Washington, DC 20201, (202) 690–6870.

(Catalog of Federal Domestic Assistance Program Nos. 93.778: Medical Assistance Program; 93.658: Foster Care; 93.659: Adoption Assistance; 93.090: Guardianship Assistance)

Dated: January 26, 2010.

Kathleen Sebelius,

Secretary.

ARRA ADJUSTMENTS TO Q1 FY11

State	Hold harmless FY11	Hold harmless FY11 FMAP with 6.2% pt increase	Unemployment tier	Unemployment adjustment Q1 FY11	1st Quarter FY11 FMAP unemployment adjustment	Final 1st quarter FY11 FMAP unemployment adjustment
Alabama	68.54	74.74	11.50	3.26	78.00	78.00
Alaska	52.48	58.68	5.50	2.44	61.12	62.46
Arizona	66.20	72.40	11.50	3.53	75.93	75.93
Arkansas	72.94	79.14	8.50	2.04	81.18	81.18
California	50.00	56.20	11.50	5.39	61.59	61.59
Colorado	50.00	56.20	11.50	5.39	61.59	61.59
Connecticut	50.00	56.20	11.50	5.39	61.59	61.59
Delaware	53.15	59.35	11.50	5.03	64.38	64.38
Dist of Columbia	70.00	76.20	11.50	3.09	79.29	79.29
Florida	56.83	63.03	11.50	4.61	67.64	67.64
Georgia	65.33	71.53	11.50	3.63	75.16	75.16
Hawaii	56.50	62.70	11.50	4.65	67.35	67.35
Idaho	69.87	76.07	11.50	3.11	79.18	79.18
Illinois	50.32	56.52	11.50	5.36	61.88	61.88
Indiana	66.52	72.72	11.50	3.49	76.21	76.21
Iowa	63.51	69.71	8.50	2.84	72.55	72.55
Kansas	60.38	66.58	8.50	3.10	69.68	69.68
Kentucky	71.49	77.69	11.50	2.92	80.61	80.61
Louisiana	72.47	78.67	11.50	2.81	81.48	81.48
Maine	64.99	71.19	8.50	2.71	73.90	74.86
Maryland	50.00	56.20	11.50	5.39	61.59	61.59
Massachusetts	50.00	56.20	11.50	5.39	61.59	61.59
Michigan	65.79	71.99	11.50	3.58	75.57	75.57
Minnesota	50.00	56.20	8.50	3.99	60.19	61.59
Mississippi	76.29	82.49	11.50	2.37	84.86	84.86
Missouri	64.51	70.71	11.50	3.72	74.43	74.43
Montana	68.53	74.73	11.50	3.26	77.99	77.99
Nebraska	60.56	66.76	5.50	2.00	68.76	68.76
Nevada	52.64	58.84	11.50	5.09	63.93	63.93
New Hampshire	50.00	56.20	5.50	2.58	58.78	61.59
New Jersey	50.00	56.20	11.50	5.39	61.59	61.59
New Mexico	71.35	77.55	11.50	2.94	80.49	80.49
New York	50.00	56.20	11.50	5.39	61.59	61.59
North Carolina	65.13	71.33	11.50	3.65	74.98	74.98
North Dakota	63.75	69.95	0.00	0.00	69.95	69.95
Ohio	63.69	69.89	11.50	3.82	73.71	73.71
Oklahoma	67.10	73.30	11.50	3.43	76.73	76.73
Oregon	62.85	69.05	11.50	3.92	72.97	72.97
Pennsylvania	55.64	61.84	11.50	4.74	66.58	66.58
Rhode Island	52.97	59.17	11.50	5.05	64.22	64.22
South Carolina	70.32	76.52	11.50	3.06	79.58	79.58
South Dakota	62.72	68.92	5.50	1.88	70.80	70.8
Tennessee	65.85	72.05	11.50	3.57	75.62	75.62
Texas	60.56	66.76	11.50	4.18	70.94	70.94
Utah	71.68	77.88	11.50	2.90	80.78	80.78
Vermont	59.45	65.65	5.50	2.06	67.71	69.96
Virginia	50.00	56.20	11.50	5.39	61.59	61.59
Washington	51.52	57.72	11.50	5.22	62.94	62.94
West Virginia	74.25	80.45	11.50	2.60	83.05	83.05
Wisconsin	60.21	66.41	11.50	4.22	70.63	70.63
Wyoming	50.00	56.20	11.50	5.39	61.59	61.59

[FR Doc. 2011–2283 Filed 2–1–11; 8:45 am]

BILLING CODE 4150–05–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of the Assistant Secretary for Financial Resources, Office of Grants and Acquisition Policy and Accountability, Division of Acquisition; Public Availability of the Department of Health and Human Services FY 2010 Service Contract Inventory

AGENCY: Department of Health and Human Services.

ACTION: Notice of public availability of FY 2010 Service Contract Inventories.

SUMMARY: In accordance with Section 743 of Division C of the Consolidated Appropriations Act of 2010 (Pub. L. 111–117), Department of Health and Human Services (HHS) is publishing this notice to advise the public of the availability of its FY 2010 Service Contract inventory. This inventory provides information on service contract actions over $25,000 that were made in FY 2010. The information is organized by function to show how contracted resources are distributed throughout the agency. The inventory has been developed in accordance with guidance issued on November 5, 2010 by the Office of Management and Budget's Office of Federal Procurement Policy (OFPP). OFPP's guidance is available at *http://www.whitehouse.gov/sites/default/files/omb/procurement/memo/service-contract-inventories-guidance-11052010.pdf.* HHS has posted its inventory and a summary of the inventory on the HHS homepage at the following link: *http://www.hhs.gov/grants/servicecontractsfy10.html.*

FOR FURTHER INFORMATION CONTACT: Questions regarding the service contract inventory should be directed to Cheryl Howe in the HHS/Office of the Secretary, Assistant Secretary for Financial Resources, Office of Grants and Acquisition Policy and Accountability, Division of Acquisition at 202–690–5552 or *cheryl.howe@hhs.gov.*

Dated: January 27, 2011.

Debbie H. Ridgely,

Acting Deputy Assistant Secretary for Grants and Acquisition Policy and Accountability, Assistant Secretary for Financial Resources, Office of the Secretary.

[FR Doc. 2011–2253 Filed 1–28–11; 11:15 am]

BILLING CODE 4150–24–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Advisory Board on Radiation and Worker Health (ABRWH or Advisory Board), National Institute for Occupational Safety and Health (NIOSH)

In accordance with section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92–463), and pursuant to the requirements of 42 CFR 83.15(a), the Centers for Disease Control and Prevention (CDC), announces the following meeting of the aforementioned committee:

Board Public Meeting Times and Dates (All times are Eastern Time):

8:15 a.m.–3:45 p.m., February 23, 2011.

8:15 a.m.–5:00 p.m., February 24, 2011.

8:15 a.m.–10:30 a.m., February 25, 2011

Public Comment Times and Dates (All times are Eastern Time):

6:30 p.m.–7:30 p.m.*, February 23, 2011.

5:30 p.m.–7 p.m.*, February 24, 2011.

* Please note that the public comment periods may end before the times indicated, following the last call for comments. Members of the public who wish to provide public comments should plan to attend public comment sessions at the start times listed.

Place: Augusta Marriott Hotel and Suites, Two Tenth Street, Augusta, Georgia 30901; Phone: 800–868–5354; Fax: 404–377–1587. Audio Conference Call via FTS Conferencing. The USA toll-free dial-in number is 1–866–659–0537 with a pass code of 9933701.

Status: Open to the public, limited only by the space available. The meeting space accommodates approximately 150 people.

Background: The Advisory Board was established under the Energy Employees Occupational Illness Compensation Program (EEOICP) Act of 2000 to advise the President on a variety of policy and technical functions required to implement and effectively manage the new compensation program. Key functions of the Advisory Board include providing advice on the development of probability of causation guidelines which have been promulgated by the Department of Health and Human Services (HHS) as a final rule, advice on methods of dose reconstruction which have also been promulgated by HHS as a final rule, advice on the scientific validity and quality of dose estimation and reconstruction efforts being performed for purposes of the compensation program, and advice on petitions to add classes of workers to the Special Exposure Cohort (SEC).

In December 2000, the President delegated responsibility for funding, staffing, and operating the Advisory Board to HHS, which subsequently delegated this authority to the CDC. NIOSH implements this responsibility for CDC. The charter was issued on August 3, 2001, renewed at appropriate intervals, and will expire on August 3, 2011.

Purpose: This Advisory Board is charged with (a) providing advice to the Secretary, HHS, on the development of guidelines under Executive Order 13179; (b) providing advice to the Secretary, HHS, on the scientific validity and quality of dose reconstruction efforts performed for this program; and (c) upon request by the Secretary, HHS, advise the Secretary on whether there is a class of employees at any Department of Energy facility who were exposed to radiation but for whom it is not feasible to estimate their radiation dose, and on whether there is reasonable likelihood that such radiation doses may have endangered the health of members of this class.

Matters To Be Discussed: The agenda for the Advisory Board meeting includes: NIOSH Program Update and Program Evaluation Update; Department of Labor (DOL) Program Update; Department of Energy (DOE) Program Update; Savannah River Site Work Group Update; NIOSH Savannah River Site Activities Update; Use of Co-worker Data; the Application of OTIB–70 for Residual Contamination Periods; SEC petitions for: Linde Ceramics Plant (Tonawanda, New York), Dow Chemical (Madison, Illinois), Chapman Valve (Indian Orchard, Massachusetts), Wah Chang (Albany, OR), Grand Junction Operations Office (Grand Junction, CO), Bliss and Laughlin Steel (Buffalo, NY), Feed Materials Production Center (Fernald, OH), Norton Company (Worcester, MA), and Vitro Manufacturing (Canonsburg, PA); SEC Petition Status Updates; Subcommittee and Work Group Reports; Board Work Sessions, and an Administrative Session.

The agenda is subject to change as priorities dictate.

In the event an individual cannot attend, written comments may be submitted in accordance with the redaction policy provided below. Any written comments received will be provided at the meeting and should be submitted to the contact person below well in advance of the meeting.

Policy on Redaction of Board Meeting Transcripts (Public Comment): (1) If a person making a comment gives his or her name, no attempt will be made to redact that name. (2) NIOSH will take reasonable steps to ensure that individuals making public comment are aware of the fact that their comments (including their name, if provided) will appear in a transcript of the meeting posted on a public website. Such reasonable steps include: (a) A statement read at the start of each public comment period stating that transcripts will be posted and names of speakers will not be redacted; (b) A printed copy of the statement mentioned in (a) above will be displayed on the table where individuals sign up to make public comments; (c) A statement such as outlined in (a) above will also appear with the agenda for a Board Meeting when it is posted on the NIOSH website; (d) A statement such as in (a) above will appear in the **Federal Register** Notice that announces Board and Subcommittee meetings. (3) If an individual in making a statement reveals personal information (e.g., medical information) about themselves that information will not usually be redacted. The NIOSH Freedom of Information Act (FOIA) coordinator will, however, review such revelations in accordance with the FOIA and the Federal Advisory Committee Act and if deemed appropriate, will redact such information. (4) All disclosures of information concerning third parties will be redacted. (5) If it comes to the attention of the DFO that an individual wishes to share information with the Board but objects to doing so in a public forum, the DFO will work with that individual, in accordance with the Federal Advisory Committee Act, to find a way that the Board can hear such comments.

Contact Person for More Information: Theodore Katz, M.P.A., Executive Secretary, NIOSH, CDC, 1600 Clifton Road, MS E–20, Atlanta GA 30333, telephone: (513) 533–6800, toll free: 1–800–CDC–INFO, e-mail: *dcas@cdc.gov.*

The Director, Management Analysis and Services Office, has been delegated the authority to sign **Federal Register** Notices pertaining to announcements of meetings and other committee management activities, for both the Centers for Disease Control and Prevention, and the Agency for Toxic Substances and Disease Registry.

Dated: January 26, 2011.

Elaine L. Baker,

Director, Management Analysis and Services Office, Centers for Disease Control and Prevention.

[FR Doc. 2011–2261 Filed 2–1–11; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

[USCG–2011–0016; OMB Control numbers: 1625–0005, 1625–0024, 1625–0036 and 1625–0061]

Information Collection Request to Office of Management and Budget

AGENCY: Coast Guard, DHS.

ACTION: Sixty-day notice requesting comments.

SUMMARY: In compliance with the Paperwork Reduction Act of 1995, the U.S. Coast Guard intends to submit Information Collection Requests (ICRs) to the Office of Management and Budget (OMB), Office of Information and Regulatory Affairs (OIRA), requesting approval of revisions to the following collections of information: 1625–0005, Application and Permit to Handle Hazardous Materials, 1625–0024, Safety Approval of Cargo Containers, 1625–0036, Plan Approval and Records for U.S. and Foreign Tank Vessels Carrying Oil in Bulk, and 1625–0061, Commercial Fishing Industry Vessel Safety Regulations.

Our ICRs describe the information we seek to collect from the public. Before submitting these ICRs to OIRA, the Coast Guard is inviting comments as described below.

DATES: Comments must reach the Coast Guard on or before April 4, 2011.

ADDRESSES: You may submit comments identified by Coast Guard docket number [USCG–2011–0016] to the Docket Management Facility (DMF) at the U.S. Department of Transportation (DOT). To avoid duplicate submissions, please use only one of the following means:

(1) *Online: http://www.regulations.gov.*

(2) *Mail:* DMF (M–30), DOT, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue, SE., Washington, DC 20590–0001.

(3) *Hand delivery:* Same as mail address above, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The telephone number is 202–366–9329.

(4) *Fax:* 202–493–2251. To ensure your comments are received in a timely manner, mark the fax, to attention Desk Officer for the Coast Guard.

The DMF maintains the public docket for this Notice. Comments and material received from the public, as well as documents mentioned in this Notice as being available in the docket, will become part of the docket and will be available for inspection or copying at room W12–140 on the West Building Ground Floor, 1200 New Jersey Avenue, SE., Washington, DC, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. You may also find the docket on the Internet at *http://www.regulations.gov.*

Copies of the ICRs are available through the docket on the Internet at *http://www.regulations.gov.* Additionally, copies are available from: COMMANDANT (CG–611), ATTN PAPERWORK REDUCTION ACT MANAGER, U.S. COAST GUARD, 2100 2ND ST., SW. STOP 7101, WASHINGTON DC 20593–7101.

FOR FURTHER INFORMATION CONTACT: Contact Ms. Kenlinishia Tyler, Office of Information Management, telephone 202–475–3652, or fax 202–475–3929, for questions on these documents. Contact Ms. Renee V. Wright, Program Manager, Docket Operations, 202–366–9826, for questions on the docket.

SUPPLEMENTARY INFORMATION:

Public Participation and Request for Comments

This Notice relies on the authority of the Paperwork Reduction Act of 1995; 44 U.S.C. Chapter 35, as amended. An ICR is an application to OIRA seeking the approval, extension, or renewal of a Coast Guard collection of information (Collection). The ICR contains information describing the Collection's purpose, the Collection's likely burden on the affected public, an explanation of the necessity of the Collection, and other important information describing the Collections. There is one ICR for each Collection.

The Coast Guard invites comments on whether these ICRs should be granted based on the Collections being necessary for the proper performance of Departmental functions. In particular, the Coast Guard would appreciate comments addressing: (1) The practical utility of the Collections; (2) the accuracy of the estimated burden of the Collections; (3) ways to enhance the quality, utility, and clarity of information subject to the Collections; and (4) ways to minimize the burden of the Collections on respondents, including the use of automated collection techniques or other forms of information technology. In response to

your comments, we may revise these ICRs or decide not to seek approval for the Collections. We will consider all comments and material received during the comment period.

We encourage you to respond to this request by submitting comments and related materials. Comments must contain the OMB Control Number of the ICR and the docket number of this request, [USCG–2011–0016], and must be received by April 4, 2011. We will post all comments received, without change, to *http://www.regulations.gov.* They will include any personal information you provide. We have an agreement with DOT to use their DMF. Please see the "Privacy Act" paragraph below.

Submitting Comments

If you submit a comment, please include the docket number [USCG–2011–0016], indicate the specific section of the document to which each comment applies, providing a reason for each comment. You may submit your comments and material online (*via http://www.regulations.gov*), by fax, mail, or hand delivery, but please use only one of these means. If you submit a comment online via *http://www.regulations.gov,* it will be considered received by the Coast Guard when you successfully transmit the comment. If you fax, hand deliver, or mail your comment, it will be considered as having been received by the Coast Guard when it is received at the DMF. We recommend you include your name, mailing address, an e-mail address, or other contact information in the body of your document so that we can contact you if we have questions regarding your submission.

You may submit your comments and material by electronic means, mail, fax, or delivery to the DMF at the address under **ADDRESSES**; but please submit them by only one means. To submit your comment online, go to *http://www.regulations.gov*, and type "USCG–2011–0016" in the "Keyword" box. If you submit your comments by mail or hand delivery, submit them in an unbound format, no larger than 8½ by 11 inches, suitable for copying and electronic filing. If you submit comments by mail and would like to know that they reached the Facility, please enclose a stamped, self-addressed postcard or envelope. We will consider all comments and material received during the comment period and will address them accordingly.

Viewing comments and documents: To view comments, as well as documents mentioned in this Notice as being available in the docket, go to *http://www.regulations.gov,* click on the "read comments" box, which will then become highlighted in blue. In the "Keyword" box insert "USCG–2011–0016" and click "Search." Click the "Open Docket Folder" in the "Actions" column. You may also visit the DMF in Room W12–140 on the ground floor of the DOT West Building, 1200 New Jersey Avenue, SE., Washington, DC 20590, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

Privacy Act

Anyone can search the electronic form of comments received in dockets by the name of the individual submitting the comment (or signing the comment, if submitted on behalf of an association, business, labor union, *etc.*). You may review a Privacy Act statement regarding Coast Guard public dockets in the January 17, 2008, issue of the **Federal Register** (73 FR 3316).

Information Collection Requests

1. *Title:* Application and Permit to Handle Hazardous Materials.

OMB Control Number: 1625–0005.

Summary: The information sought by this collection, which includes form CG–4260, ensures the safe handling of explosives and other hazardous materials around ports and aboard vessels.

Need: Sections 1225 and 1231 of 33 U.S.C. authorize the Coast Guard to establish standards for the handling, storage, and movement of hazardous materials on a vessel and waterfront facility. Regulations in 33 CFR 126.17, 49 CFR 176.100, and 176.415 prescribe the rules for facilities and vessels.

Forms: CG–4260.

Respondents: Shipping agents and terminal operators that handle hazardous materials.

Frequency: On occasion.

Burden Estimate: The estimated burden has increased from 185 hours to 205 hours a year.

2. *Title:* Safety Approval of Cargo Containers.

OMB Control Number: 1625–0024.

Summary: This information collection is associated with requirements for owners and manufacturers of cargo containers to submit information and keep records associated with the approval and inspection of those containers. This information is required to ensure compliance with the International Convention for Safe Containers (CSC), 29 U.S.T. 3707; T.I.A.S. 9037.

Need: This collection of information addresses the reporting and recordkeeping requirements for containers in 49 CFR parts 450 through 453. These rules are necessary since the U.S. is signatory to the CSC. The CSC requires all containers to be safety approved prior to being used in trade. These rules prescribe only the minimum requirements of the CSC.

Forms: None.

Respondents: Owners and manufacturers of containers, and organizations that the Coast Guard delegates to act as an approval authority.

Frequency: On occasion.

Burden Estimate: The estimated burden has decreased from 105,920 hours to 104,096 hours a year.

3. *Title:* Plan Approval and Records for U.S. and Foreign Tank Vessels Carrying Oil in Bulk.

OMB Control Number: 1625–0036.

Summary: This information collection aids the Coast Guard in determining if a vessel complies with certain safety and environmental protection standards. Plans, to include records, for construction or modification of U.S. or foreign vessels submitted and maintained on board are required for compliance with these standards.

Need: Title 46 U.S.C. 3703 provides the Coast Guard with the authority to regulate design, construction, alteration, repair, maintenance, operation, equipping, personnel qualification, and manning of vessels carrying oil in bulk. See e.g., 33 CFR part 157, Rules for the Protection of the Marine Environment Relating to Tank Vessels Carrying Oil in Bulk, and 46 CFR chapter I, subchapter D, Tank Vessels.

Forms: Not applicable.

Respondents: Owners and operators of vessels.

Frequency: On occasion.

Burden Estimate: The estimated burden has increased from 1,253 hours to 1,357 hours a year.

4. *Title:* Commercial Fishing Industry Vessel Safety Regulations.

OMB Control Number: 1625–0061.

Summary: This information collection is intended to improve safety on board vessels in the commercial fishing industry. The requirements apply to those vessels and to seamen on them.

Need: Under the authority of 46 U.S.C. 6104, the U.S. Coast Guard has promulgated regulations in 46 CFR Part 28 to reduce the unacceptably high level of fatalities and accidents in the commercial fishing industry. The rules allowing the collection also provide means of verifying compliance and enhancing safe operation of fishing vessels.

Forms: None.

Respondents: Owners, agents, individuals-in-charge of commercial

fishing vessels, and insurance underwriters.

Frequency: On occasion.

Burden Estimate: The estimated burden has increased from 5,917 hours to 5,945 hours a year.

Dated: January 28, 2011.

R. E. Day,

Rear Admiral, U.S. Coast Guard, Assistant Commandant for Command, Control, Communications, Computers and Information Technology.

[FR Doc. 2011–2300 Filed 2–1–11; 8:45 am]

BILLING CODE 9110–04–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

[USCG–2010–0978]

Collection of Information Under Review by Office of Management and Budget: OMB Control Number: 1625–0008

AGENCY: Coast Guard, DHS.

ACTION: Thirty-day notice requesting comments.

SUMMARY: In compliance with the Paperwork Reduction Act of 1995 the U.S. Coast Guard is forwarding an Information Collection Request (ICR), abstracted below, to the, Office of Management and Budget (OMB), Office of Information and Regulatory Affairs (OIRA), requesting approval of a revision to the following collection of information: 1625–0008, Regattas and Marine Parades. Our ICR describes the information we seek to collect from the public. Review and comments by OIRA ensure we only impose paperwork burdens commensurate with our performance of duties.

DATES: Comments must reach the Coast Guard and OIRA on or before March 4, 2011.

ADDRESSES: You may submit comments identified by Coast Guard docket number [USCG–2010–0978] to the Docket Management Facility (DMF) at the U.S. Department of Transportation (DOT) and/or to OIRA. To avoid duplicate submissions, please use only one of the following means:

(1) *Online:* (a) To Coast Guard docket at *http://www.regulation.gov.* (b) To OIRA by e-mail via: *OIRA-submission@omb.eop.gov.*

(2) *Mail:* (a) DMF (M–30), DOT, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue, SE., Washington, DC 20590–0001. (b) To OIRA, 725 17th Street, NW., Washington, DC 20503, attention Desk Officer for the Coast Guard.

(3) *Hand Delivery:* To DMF address above, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The telephone number is 202–366–9329.

(4) *Fax:* (a) To DMF, 202–493–2251. (b) To OIRA at 202–395–6566. To ensure your comments are received in a timely manner, mark the fax, attention Desk Officer for the Coast Guard.

The DMF maintains the public docket for this Notice. Comments and material received from the public, as well as documents mentioned in this Notice as being available in the docket, will become part of the docket and will be available for inspection or copying at room W12–140 on the West Building Ground Floor, 1200 New Jersey Avenue, SE., Washington, DC, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. You may also find the docket on the Internet at *http://www.regulations.gov.*

A copy of the ICR is available through the docket on the Internet at *http://www.regulations.gov.* Additionally, copies are available from: Commandant (CG–611), Attn: Paperwork Reduction Act Manager, U.S. Coast Guard, 2100 2nd St., SW., Stop 7101, Washington DC 20593–7101.

FOR FURTHER INFORMATION CONTACT: Ms. Kenlinishia Tyler, Office of Information Management, telephone 202–475–3652 or fax 202–475–3929, for questions on these documents. Contact Ms. Renee V. Wright, Program Manager, Docket Operations, 202–366–9826, for questions on the docket.

SUPPLEMENTARY INFORMATION:

Public Participation and Request for Comments

This Notice relies on the authority of the Paperwork Reduction Act of 1995; 44 U.S.C. chapter 35, as amended. An ICR is an application to OIRA seeking the approval, extension, or renewal of a Coast Guard collection of information (Collection). The ICR contains information describing the Collection's purpose, the Collection's likely burden on the affected public, an explanation of the necessity of the Collection, and other important information describing the Collections. There is one ICR for each Collection.

The Coast Guard invites comments on whether this ICR should be granted based on the Collection being necessary for the proper performance of Departmental functions. In particular, the Coast Guard would appreciate comments addressing: (1) The practical utility of the collections; (2) the accuracy of the estimated burden of the collection; (3) ways to enhance the quality, utility, and clarity of information subject to the collection; and (4) ways to minimize the burden of collections on respondents, including the use of automated collection techniques or other forms of information technology. These comments will help OIRA determine whether to approve the ICR referred to in this Notice.

We encourage you to respond to this request by submitting comments and related materials. Comments to Coast Guard or OIRA must contain the OMB Control Number of the ICR. They must also contain the docket number of this request, [USCG 2010–0978], and must be received by March 4, 2011. We will post all comments received, without change, to *http://www.regulations.gov.* They will include any personal information you provide. We have an agreement with DOT to use their DMF. Please see the "Privacy Act" paragraph below.

Submitting Comments

If you submit a comment, please include the docket number [USCG–2010–0978], indicate the specific section of the document to which each comment applies, providing a reason for each comment. You may submit your comments and material online (via *http://www.regulations.gov*), by fax, mail, or hand delivery, but please use only one of these means. If you submit a comment online via *http://www.regulations.gov,* it will be considered received by the Coast Guard when you successfully transmit the comment. If you fax, hand deliver, or mail your comment, it will be considered as having been received by the Coast Guard when it is received at the DMF. We recommend you include your name, mailing address, an e-mail address, or other contact information in the body of your document so that we can contact you if we have questions regarding your submission.

You may submit comments and material by electronic means, mail, fax, or delivery to the DMF at the address under **ADDRESSES**, but please submit them by only one means. To submit your comment online, go to *http://www.regulations.gov*, and type "USCG–2010–0978" in the "Keyword" box. If you submit your comments by mail or hand delivery, submit them in an unbound format, no larger than 8½ by 11 inches, suitable for copying and electronic filing. If you submit comments by mail and would like to know that they reached the Facility, please enclose a stamped, self-addressed postcard or envelope. We will consider all comments and material received

during the comment period and will address them accordingly.

Viewing Comments and Documents

To view comments, as well as documents mentioned in this Notice as being available in the docket, go to *http://www.regulations.gov,* click on the "read comments" box, which will then become highlighted in blue. In the "Keyword" box insert "USCG–2010–0978" and click "Search." Click the "Open Docket Folder" in the "Actions" column. You may also visit the DMF in Room W12–140 on the ground floor of the DOT West Building, 1200 New Jersey Avenue, SE., Washington, DC 20590, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

OIRA posts its decisions on ICRs online at *http://www.reginfo.gov/public/do/PRAMain* after the comment period for each ICR. An OMB Notice of Action on each ICR will become available via a hyperlink in the OMB Control Number: USCG–2010–0978.

Privacy Act

Anyone can search the electronic form of comments received in dockets by the name of the individual submitting the comment (or signing the comment, if submitted on behalf of an association, business, labor union, etc.). You may review a Privacy Act statement regarding Coast Guard public dockets in the January 17, 2008, issue of the **Federal Register** (73 FR 3316).

Previous Request for Comments

This request provides a 30-day comment period required by OIRA. The Coast Guard has published the 60-day notice (75 FR 67991, November 4, 2010) required by 44 U.S.C. 3506(c)(2). That Notice elicited no comments.

Information Collection Request

Title: Regattas and Marine Parades.

OMB Control Number: 1625–0008.

Type of Request: Revision of a previously approved collection.

Respondents: Sponsors of marine events.

Abstract: Title 46 U.S.C. 1233 authorizes the Coast Guard to issue rules promoting safety of life on navigable waters during regattas or marine events. Title 33 CFR 100.17 and 100.18 include the rules for providing notice of, and additional information for permitting regattas/marine events to the Coast Guard.

Forms: CG–4423.

Burden Estimate: The estimated burden has increased from 3,000 to 5,271 hours a year.

Authority: The Paperwork Reduction Act of 1995; 44 U.S.C. chapter 35, as amended.

Dated: January 28, 2011.

R. E. Day,

Rear Admiral, U.S. Coast Guard, Assistant Commandant for Command, Control, Communications, Computers and Information Technology.

[FR Doc. 2011–2301 Filed 2–1–11; 8:45 am]

BILLING CODE 9110–04–P

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

[Docket No. FR–5480–N–09]

Notice of Submission of Proposed Information Collection to OMB Home Equity Conversion Mortgage (HECM) Insurance Application for Reverse Mortgages and Related Documents

AGENCY: Office of the Chief Information Officer, HUD.

ACTION: Notice.

SUMMARY: The proposed information collection requirement described below has been submitted to the Office of Management and Budget (OMB) for review, as required by the Paperwork Reduction Act. The Department is soliciting public comments on the subject proposal.

The HECM reverse mortgage application and related documents are used to determine the eligibility of the borrower and proposed mortgage transaction for FHA insurance endorsement. This submission is a consolidation of additional consumer notification requirements formerly approved under 2502–0534 and 2502–0546.

DATES: *Comments Due Date:* March 4, 2011.

ADDRESSES: Interested persons are invited to submit comments regarding this proposal. Comments should refer to the proposal by name and/or OMB approval Number (2502–0524) and should be sent to: HUD Desk Officer at, *OIRA–Submission@omb.eop.gov,* Office of Management and Budget, New Executive Office Building, Washington, DC 20503; fax: 202–395–5806.

FOR FURTHER INFORMATION CONTACT: Colette Pollard, Reports Management Officer, QDAM, Department of Housing and Urban Development, 451 Seventh Street, SW., Washington, DC 20410; e-mail Colette Pollard at *Colette.Pollard@hud.gov;* or telephone (202) 402–3400. This is not a toll-free number. Copies of available documents submitted to OMB may be obtained from Ms. Pollard.

SUPPLEMENTARY INFORMATION: This notice informs the public that the Department of Housing and Urban Development has submitted to OMB a request for approval of the information collection described below. This notice is soliciting comments from members of the public and affecting agencies concerning the proposed collection of information to: (1) Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility; (2) Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information; (3) Enhance the quality, utility, and clarity of the information to be collected; and (4) Minimize the burden of the collection of information on those who are to respond; including through the use of appropriate automated collection techniques or other forms of information technology, *e.g.,* permitting electronic submission of responses.

This notice also lists the following information:

Title of Proposal: Home Equity Conversion Mortgage (HECM) Insurance Application for Reverse Mortgages and Related Documents.

OMB Approval Number: 2502–0524.

Form Numbers: HUD–92800–5b, HUD–92051, HUD–92900–A, FANNIE–MAE–1009, HUD–92901, HUD–92902, Fannie Mae 1073, fnma–1004, fnma–1025, HUD–92561, HUD–1a, fnma–1003, fnma–1004c, HUD–1.

Description of the Need for the Information and Its Proposed Use:

The HECM reverse mortgage application and related documents are used to determine the eligibility of the borrower and proposed mortgage transaction for FHA insurance endorsement. This submission is a consolidation of additional consumer notification requirements formerly approved under 2502–0534 and 2502–0546.

Frequency of Submission: On-occasion, Annually.

	Number of respondents	Annual responses	×	Hours per response	=	Burden hours
Reporting Burden:	129,000	3.490		0.0024		1,100

Total Estimated Burden Hours: 1,100.

Status: Extension without change of a currently approved collection.

Authority: Section 3507 of the Paperwork Reduction Act of 1995, 44 U.S.C. 35, as amended.

Dated: January 26, 2011.

Colette Pollard,

Departmental Reports Management Officer.

[FR Doc. 2011–2297 Filed 2–1–11; 8:45 am]

BILLING CODE 4210–67–P

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

[Docket No. FR–5480–N–10]

Notice of Submission of Proposed Information Collection to OMB; HUD-Owned Real Estate—Dollar Home Sales Program

AGENCY: Office of the Chief Information Officer, HUD.

ACTION: Notice.

SUMMARY: The proposed information collection requirement described below has been submitted to the Office of Management and Budget (OMB) for review, as required by the Paperwork Reduction Act. The Department is soliciting public comments on the subject proposal.

The information collected will be used in binding contracts between the purchaser and HUD. The respondents are purchasers of HUD-owned properties, community development corporations, nonprofit organizations, and government entities. The sale of these properties under this program makes it possible for local governments to rehabilitate the homes and make them available as low- and moderate-income housing at a considerable savings.

DATES: *Comments Due Date:* March 4, 2011.

ADDRESSES: Interested persons are invited to submit comments regarding this proposal. Comments should refer to the proposal by name and/or OMB approval Number (2502–0569) and should be sent to: HUD Desk Officer, Office of Management and Budget, New Executive Office Building, Washington, DC 20503; e-mail OIRA–Submission@omb.eop.gov fax: 202–395–5806.

FOR FURTHER INFORMATION CONTACT: Colette Pollard, Reports Management Officer, QDAM, Department of Housing and Urban Development, 451 Seventh Street, SW., Washington, DC 20410; e-mail Colette Pollard at *Colette.Pollard@hud.gov;* or telephone (202) 402–3400. This is not a toll-free number. Copies of available documents submitted to OMB may be obtained from Ms. Pollard.

SUPPLEMENTARY INFORMATION: This notice informs the public that the Department of Housing and Urban Development has submitted to OMB a request for approval of the Information collection described below. This notice is soliciting comments from members of the public and affecting agencies concerning the proposed collection of information to: (1) Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility; (2) Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information; (3) Enhance the quality, utility, and clarity of the information to be collected; and (4) Minimize the burden of the collection of information on those who are to respond; including through the use of appropriate automated collection techniques or other forms of information technology, e.g., permitting electronic submission of responses.

This notice also lists the following information:

Title of Proposal: HUD-Owned Real Estate—Dollar Home Sales Program.

OMB approval number: 2502–0569.

Form Numbers: None.

Description of the Need for the Information and Its Proposed Use: The information collected will be used in binding contracts between the purchaser and HUD. The respondents are purchasers of HUD-owned properties, community development corporations, nonprofit organizations, and government entities. The sale of these properties under this program makes it possible for local governments to rehabilitate the homes and make them available as low- and moderate-income housing at a considerable savings.

Frequency of Submission: On-occasion, annually.

	Number of respondents	Annual responses	×	Hours per response	=	Burden hours
Reporting Burden:	560	0.892		0.076		38

Total Estimated Burden Hours: 38.

Status: Extension without change of a currently approved collection.

Authority: Section 3507 of the Paperwork Reduction Act of 1995, 44 U.S.C. 35, as amended.

Dated: January 26, 2011.

Colette Pollard,

Departmental Reports Management Officer.

[FR Doc. 2011–2298 Filed 2–1–11; 8:45 am]

BILLING CODE 4210–67–P

DEPARTMENT OF THE INTERIOR

Office of the Secretary

Availability of the Policy on Integrity of Scientific and Scholarly Activities of the Department of the Interior

AGENCY: Office of the Secretary, Interior.

ACTION: Notice of availability.

SUMMARY: We, the Department of the Interior, announce the availability of the Policy on Integrity of Scientific and Scholarly Activities of the Department of the Interior established in the Departmental Manual 305 DM 3.

ADDRESSES: You can obtain copies of the Policy on Integrity of Scientific and Scholarly Activities of the Department of the Interior by contacting Alan D. Thornhill, 1849 C Street, NW., MS 5438, Washington, DC 20240–0002, 202–208–6249, or by visiting our Web site at *http://elips.doi.gov/app_dm/index.cfm.*

FOR FURTHER INFORMATION CONTACT: Alan D. Thornhill, 1849 C Street, NW., MS 5438, Washington, DC 20240–0002, 202–208–6249.

SUPPLEMENTARY INFORMATION:

Background

The Presidential Memorandum on Scientific Integrity dated March 9, 2009, and the Office of Science and Technology Policy 2010 guidance memorandum on scientific integrity call for ensuring the highest level of integrity in all aspects of the executive branch's involvement with scientific and technological processes. On September 29, 2010, the Secretary issued Order No. 3305, Ensuring Scientific Integrity within the Department of the Interior. This Order required publication of a Departmental Manual Chapter that sets forth principles of scientific and scholarly integrity and clarifies the roles and responsibilities of all Department employees in upholding these principles. This policy is the implementation of the Secretary's directive. The policy covers all Department employees, including political appointees, when they engage in, supervise, manage, or influence scientific and scholarly activities, or communicate information about the Department's scientific and scholarly activities, or utilize scientific and scholarly information in making agency policy, management, or regulatory decisions. The policy also covers all volunteers, contractors, cooperators, partners, permittees, leasees, and grantees who assist with developing or applying the results of scientific and scholarly activities.

Dated: January 28, 2011.

David J. Hayes,

Deputy Secretary.

[FR Doc. 2011–2366 Filed 1–31–11; 11:15 am]

BILLING CODE 4310–MR–P

DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

[FWS–R9–MB–2011–N016; [91100–3740–GRNT 7C]

Meeting Announcements: North American Wetlands Conservation Council; Neotropical Migratory Bird Conservation Advisory Group

AGENCY: Fish and Wildlife Service, Interior.

ACTION: Notice of meetings.

SUMMARY: The North American Wetlands Conservation Council (Council) will meet to select North American Wetlands Conservation Act (NAWCA) grant proposals for recommendation to the Migratory Bird Conservation Commission (Commission). This meeting is open to the public. The Advisory Group for the Neotropical Migratory Bird Conservation Act (NMBCA) grants program (Advisory Group) will also meet. This meeting is also open to the public, and interested persons may present oral or written statements.

DATES: *Council:* Meeting is March 9, 2011, 10:30 a.m. through 12 p.m. and 1–4 p.m. If you are interested in presenting information at this public meeting, contact the Council Coordinator no later than March 1, 2011.

Advisory Group: Meeting is March 10, 2011, 8:30 a.m. through 4 p.m. If you are interested in presenting information at this public meeting, contact the Council Coordinator no later than March 1, 2011.

ADDRESSES: The Council meeting will be held at the Department of the Interior, 1849 C Street NW., North Penthouse, Room 7000 A and B, Washington, DC 20240. The Advisory Group meeting will be held at the Melrose Hotel, 2430 Pennsylvania Avenue NW., Washington, DC 20037.

FOR FURTHER INFORMATION CONTACT: Michael J. Johnson, Council Coordinator, by phone at (703) 358–1784; by e-mail at *dbhc@fws.gov;* or by U.S. mail at U.S. Fish and Wildlife Service, 4401 N. Fairfax Drive, Mail Stop MBSP 4075, Arlington, VA 22203.

SUPPLEMENTARY INFORMATION: In accordance with NAWCA (Pub. L. 101–233, 103 Stat. 1968, December 13, 1989, as amended), the State-private-Federal Council meets to consider wetland acquisition, restoration, enhancement, and management projects for recommendation to, and final funding approval by, the Commission. Project proposal due dates, application instructions, and eligibility requirements are available on the NAWCA Web site at *http://www.fws.gov/birdhabitat/Grants/NAWCA/Standard/US/Overview.shtm.* Proposals require a minimum of 50 percent non-Federal matching funds. The Council will consider Canadian and U.S. small grant proposals at the meeting. The Commission will consider the Council's recommendations at its meeting tentatively scheduled for June 9, 2010.

The Advisory Group, named by the Secretary of the Interior under NMBCA (Pub. L. 106–247, 114 Stat. 593, July 20, 2000), will hold its meeting to discuss the strategic direction and management of the NMBCA program and provide advice to the Director of the Fish and Wildlife Service. If you are interested in presenting information at either of these public meetings, contact the Council Coordinator no later than the date under **DATES**.

Dated: January 26, 2011.

Jerome Ford,

Acting Assistant Director, Migratory Birds.

[FR Doc. 2011–2305 Filed 2–1–11; 8:45 am]

BILLING CODE 4310–55–P

DEPARTMENT OF THE INTERIOR

National Park Service

[5017–7155–409]

Record of Decision for the General Management Plan for the Cumberland Gap National Historical Park, KY, TN, and VA

AGENCY: National Park Service, Interior.

ACTION: Notice of Availability of the Record of Decision for the General Management Plan Environmental Impact Statement for the Cumberland Gap National Historical Park.

SUMMARY: Pursuant to the National Environmental Policy Act of 1969, the National Park Service (NPS) announces the availability of the Record of Decision (ROD) for the General Management Plan, Cumberland Gap National Historical Park in Kentucky, Tennessee, and Virginia. On September 13, 2010, the Regional Director, Southeast Region, approved the ROD for the project.

FOR FURTHER INFORMATION CONTACT: Mark Woods, Superintendent, Cumberland Gap National Historical Park, U.S. 25E South, P.O. Box 1848, Middlesboro, KY 40965–1848; telephone 606–248–2817. *Mark_Woods@nps.gov.*

SUPPLEMENTARY INFORMATION: Three alternatives were evaluated in the Environmental Impact Statement. These include: Alternative A, No Action—Continue Current Management; Alternative B—Increase opportunities for visitor access by providing additional park facilities as compared to Alternative A; Alternative C—the selected alternative, provides slightly expanded visitor access to the Park while minimizing the potential for adverse effects on resources and would feature increased levels of education, outreach, and formalized partnering.

The ROD includes a statement of the decision made, synopses of other alternatives considered, the basis for the decision, a description of the environmentally preferable alternative, a finding of no impairment of Park resources and values, a listing of measures to minimize environmental harm, and an overview of public

involvement in the decision-making process.

Copies of the Record of Decision may be obtained from the contact listed above or online at *http://parkplanning.nps.gov/CUGA.*

Authority: The authority for publishing this notice is 40 C.F.R. 1506.6.

The responsible official for this Record of Decision is the Regional Director, Southeast Region, National Park Service, 100 Alabama Street, SW., 1924 Building, Atlanta, Georgia 30303.

Dated: January 24, 2011.

Gordon Wissinger,

Acting, Regional Director, Southeast Region.

[FR Doc. 2011–2308 Filed 2–1–11; 8:45 am]

BILLING CODE 4310–NX–P

INTERNATIONAL TRADE COMMISSION

[Investigation No. 332–503]

Earned Import Allowance Program: Evaluation of the Effectiveness of the Program for Certain Apparel From the Dominican Republic; Second Annual Report

AGENCY: United States International Trade Commission.

ACTION: Notice of public hearing and opportunity to provide testimony and written comments in connection with the Commission's second annual report.

SUMMARY: The U.S. International Trade Commission (Commission) has announced its schedule, including the date for the public hearing and deadlines for filing briefs and other written submissions, in connection with the preparation of its second annual report in investigation No. 332–503, *Earned Import Allowance Program: Evaluation of the Effectiveness of the Program for Certain Apparel from the Dominican Republic.*

DATES:

March 3, 2011: Deadline for filing requests to appear at the public hearing.

March 8, 2011: Deadline for filing pre-hearing briefs and statements.

March 22, 2011: Public hearing.

April 1, 2011: Deadline for filing post-hearing briefs and statements and all other written submissions.

July 22, 2011: Transmittal of second report to House Committee on Ways and Means and Senate Committee on Finance.

ADDRESSES: All Commission offices, including the Commission's hearing rooms, are located in the United States International Trade Commission Building, 500 E Street, SW., Washington, DC. All written submissions, including requests to appear at the hearing, statements, and briefs, should be addressed to the Secretary, United States International Trade Commission, 500 E Street SW., Washington, DC 20436. The public record for this investigation may be viewed on the Commission's electronic docket (EDIS) at *http://www.usitc.gov/secretary/edis.htm.*

FOR FURTHER INFORMATION CONTACT: Project Leader Kimberlie Freund (202–708–5402 or *kimberlie.freund@usitc.gov*) for information specific to this investigation. For information on the legal aspects of this investigation, contact William Gearhart of the Commission's Office of the General Counsel (202–205–3091 or *william.gearhart@usitc.gov*). The media should contact Margaret O'Laughlin, Office of External Relations (202–205–1819 or *margaret.olaughlin@usitc.gov*). Hearing-impaired individuals may obtain information on this matter by contacting the Commission's TDD terminal at 202–205–1810. General information concerning the Commission may also be obtained by accessing its Internet server (*http://www.usitc.gov*). Persons with mobility impairments who will need special assistance in gaining access to the Commission should contact the Office of the Secretary at 202–205–2000.

Background: Section 404 of the Dominican Republic-Central America-United States Free Trade Agreement Implementation Act (DR–CAFTA Act) (19 U.S.C. 4112) required the Secretary of Commerce to establish an Earned Import Allowance Program (EIAP) and directed the Commission to conduct annual reviews of the program for the purpose of evaluating its effectiveness and making recommendations for improvements. Section 404 of the DR–CAFTA Act authorizes certain apparel articles wholly assembled in an eligible country to enter the United States free of duty if accompanied by a certificate that shows evidence of the purchase of certain U.S. fabric. The term "eligible country" is defined to mean the Dominican Republic. More specifically, the program allows producers (in the Dominican Republic) that purchase a certain quantity of qualifying U.S. fabric for use in the production of certain bottoms of cotton in the Dominican Republic to receive a credit that can be used to ship a certain quantity of eligible apparel using third country fabrics from the Dominican Republic to the United States duty free.

Section 404(d) directs the Commission to conduct an annual review of the program for the purpose of evaluating the effectiveness of the program and making recommendations for improvements. The Commission is required to submit its reports to the House Committee on Ways and Means and the Senate Committee on Finance. The Commission submitted its first annual report (USITC Publication 4175) on July 28, 2010 and expects to submit its second report to the committees by July 22, 2011.

The Commission instituted this investigation pursuant to section 332(g) of the Tariff Act of 1930 to facilitate docketing of submissions and also to facilitate public access to Commission records through the Commission's EDIS electronic records system.

Public Hearing: A public hearing in connection with this second report will be held at the U.S. International Trade Commission Building, 500 E Street, SW., Washington, DC beginning at 9:30 a.m. on March 22, 2011. Requests to appear at the public hearing should be filed with the Secretary no later than 5:15 p.m., March 3, 2011, in accordance with the requirements in the "Submissions" section below. All pre-hearing briefs and statements should be filed not later than 5:15 p.m., March 8, 2011; and all post-hearing briefs and statements responding to matters raised at the hearing should be filed not later than 5:15 p.m., April 1, 2011. If, at of the close of business on March 3, 2011, no witnesses are scheduled to appear at the hearing, the hearing will be canceled. Any person interested in attending the hearing as an observer or non-participant may call the Secretary (202–205–2000) after March 3, 2011, to determine whether the hearing will be held.

Submissions: In lieu of or in addition to participating in the hearing, interested parties are invited to file written submissions concerning this investigation. All written submissions, including requests to appear at the hearing, statements, and briefs, should be addressed to the Secretary and must conform to the provisions of section 201.8 of the Commission's *Rules of Practice and Procedure* (19 CFR 201.8). Section 201.8 requires that a signed original (or a copy so designated) and fourteen (14) copies of each document be filed. If confidential treatment of a document is requested, at least four (4) additional copies must be filed, in which the confidential information must be deleted (*see* the following paragraph for further information regarding confidential business information). The Commission's rules

authorize filing submissions with the Secretary by facsimile or electronic means only to the extent permitted by section 201.8 of the rules (*see* Handbook for Electronic Filing Procedures, *http://www.usitc.gov/secretary/fed_reg_notices/rules/documents/handbook_on_electronic_filing.pdf*). Persons with questions regarding electronic filing should contact the Secretary (202–205–2000).

Any submissions that contain confidential business information must also conform to the requirements of section 201.6 of the Commission's *Rules of Practice and Procedure* (19 CFR 201.6). Section 201.6 of the rules requires that the cover of the document and the individual pages be clearly marked as to whether they are the "confidential" or "non-confidential" version, and that the confidential business information is clearly identified by means of brackets. All written submissions, except for confidential business information, will be made available for inspection by interested parties.

The Commission intends to publish only a public report in this investigation. Consequently, the report that the Commission sends to the committees will not contain any confidential business information. Any confidential business information received by the Commission in this investigation and used in preparing its report will not be published in a manner that would reveal the operations of the firm supplying the information.

By order of the Commission.

Issued: January 26, 2011.

Marilyn R. Abbott,

Secretary to the Commission.

[FR Doc. 2011–2217 Filed 2–1–11; 8:45 am]

BILLING CODE 7020–02–P

INTERNATIONAL TRADE COMMISSION

[Investigation No. 731–TA–1089 (Review)]

Orange Juice From Brazil

AGENCY: United States International Trade Commission.

ACTION: Institution of a five-year review concerning the antidumping duty order on certain orange juice from Brazil.

SUMMARY: The Commission hereby gives notice that it has instituted a review pursuant to section 751(c) of the Tariff Act of 1930 (19 U.S.C. 1675(c)) (the Act) to determine whether revocation of the antidumping duty order on certain orange juice from Brazil would be likely to lead to continuation or recurrence of material injury. Pursuant to section 751(c)(2) of the Act, interested parties are requested to respond to this notice by submitting the information specified below to the Commission; [1] to be assured of consideration, the deadline for responses is March 3, 2011. Comments on the adequacy of responses may be filed with the Commission by April 18, 2011. For further information concerning the conduct of this review and rules of general application, consult the Commission's Rules of Practice and Procedure, part 201, subparts A through E (19 CFR part 201), and part 207, subparts A, D, E, and F (19 CFR part 207), as most recently amended at 74 FR 2847 (January 16, 2009).

DATES: *Effective Date:* February 1, 2011.

FOR FURTHER INFORMATION CONTACT: Mary Messer (202–205–3193), Office of Investigations, U.S. International Trade Commission, 500 E Street, SW., Washington, DC 20436. Hearing-impaired persons can obtain information on this matter by contacting the Commission's TDD terminal on 202–205–1810. Persons with mobility impairments who will need special assistance in gaining access to the Commission should contact the Office of the Secretary at 202–205–2000. General information concerning the Commission may also be obtained by accessing its Internet server (*http://www.usitc.gov*). The public record for this review may be viewed on the Commission's electronic docket (EDIS) at *http://edis.usitc.gov.*

SUPPLEMENTARY INFORMATION:

Background.—On March 9, 2006, the Department of Commerce issued an antidumping duty order on imports of certain orange juice from Brazil (71 FR 12183). The Commission is conducting a review to determine whether revocation of the order would be likely to lead to continuation or recurrence of material injury to the domestic industry within a reasonably foreseeable time. It will assess the adequacy of interested party responses to this notice of institution to determine whether to conduct a full review or an expedited review. The Commission's determination in any expedited review will be based on the facts available, which may include information provided in response to this notice.

Definitions.—The following definitions apply to this review:

(1) *Subject Merchandise* is the class or kind of merchandise that is within the scope of the five-year review, as defined by the Department of Commerce.

(2) The *Subject Country* in this review is Brazil.

(3) The *Domestic Like Product* is the domestically produced product or products which are like, or in the absence of like, most similar in characteristics and uses with, the *Subject Merchandise.* In its original determination, the Commission defined the *Domestic Like Product* as consisting of conventional FCOJM, conventional NFC, organic FCOJM, and organic NFC, coextensive with Commerce's scope.[2]

(4) The *Domestic Industry* is the U.S. producers as a whole of the *Domestic Like Product,* or those producers whose collective output of the *Domestic Like Product* constitutes a major proportion of the total domestic production of the product. In its original determination, the Commission defined the *Domestic Industry* as both orange growers and all domestic extractors/processors of certain orange juice.

(5) The *Order Date* is the date that the antidumping duty order under review became effective. In this review, the *Order Date* is March 9, 2006.

(6) An *Importer* is any person or firm engaged, either directly or through a parent company or subsidiary, in importing the *Subject Merchandise* into the United States from a foreign manufacturer or through its selling agent.

Participation in the review and public service list.—Persons, including industrial users of the *Subject Merchandise* and, if the merchandise is sold at the retail level, representative consumer organizations, wishing to participate in the review as parties must file an entry of appearance with the Secretary to the Commission, as provided in section 201.11(b)(4) of the Commission's rules, no later than 21 days after publication of this notice in the **Federal Register.** The Secretary will maintain a public service list containing the names and addresses of all persons, or their representatives, who are parties to the review.

Former Commission employees who are seeking to appear in Commission five-year reviews are advised that they may appear in a review even if they

[1] No response to this request for information is required if a currently valid Office of Management and Budget (OMB) number is not displayed; the OMB number is 3117–0016/USITC No. 11–5–238, expiration date June 30, 2011. Public reporting burden for the request is estimated to average 15 hours per response. Please send comments regarding the accuracy of this burden estimate to the Office of Investigations, U.S. International Trade Commission, 500 E Street, SW., Washington, DC 20436.

[2] FCOJM stands for frozen concentrated orange juice for further manufacturing and NFC stands for conventional pasteurized single strength orange juice which has not been concentrated, typically referred to as not-from-concentrate.

participated personally and substantially in the corresponding underlying original investigation. The Commission's designated agency ethics official has advised that a five-year review is not considered the "same particular matter" as the corresponding underlying original investigation for purposes of 18 U.S.C. 207, the post employment statute for Federal employees, and Commission rule 201.15(b) (19 CFR 201.15(b)), 73 FR 24609 (May 5, 2008). This advice was developed in consultation with the Office of Government Ethics. Consequently, former employees are not required to seek Commission approval to appear in a review under Commission rule 19 CFR 201.15, even if the corresponding underlying original investigation was pending when they were Commission employees. For further ethics advice on this matter, contact Carol McCue Verratti, Deputy Agency Ethics Official, at 202–205–3088.

Limited disclosure of business proprietary information (BPI) under an administrative protective order (APO) and APO service list.—Pursuant to section 207.7(a) of the Commission's rules, the Secretary will make BPI submitted in this review available to authorized applicants under the APO issued in the review, provided that the application is made no later than 21 days after publication of this notice in the **Federal Register**. Authorized applicants must represent interested parties, as defined in 19 U.S.C. 1677(9), who are parties to the review. A separate service list will be maintained by the Secretary for those parties authorized to receive BPI under the APO.

Certification.—Pursuant to section 207.3 of the Commission's rules, any person submitting information to the Commission in connection with this review must certify that the information is accurate and complete to the best of the submitter's knowledge. In making the certification, the submitter will be deemed to consent, unless otherwise specified, for the Commission, its employees, and contract personnel to use the information provided in any other reviews or investigations of the same or comparable products which the Commission conducts under Title VII of the Act, or in internal audits and investigations relating to the programs and operations of the Commission pursuant to 5 U.S.C. Appendix 3.

Written submissions.—Pursuant to section 207.61 of the Commission's rules, each interested party response to this notice must provide the information specified below. The deadline for filing such responses is March 3, 2011. Pursuant to section 207.62(b) of the Commission's rules, eligible parties (as specified in Commission rule 207.62(b)(1)) may also file comments concerning the adequacy of responses to the notice of institution and whether the Commission should conduct an expedited or full review. The deadline for filing such comments is April 18, 2011. All written submissions must conform with the provisions of sections 201.8 and 207.3 of the Commission's rules and any submissions that contain BPI must also conform with the requirements of sections 201.6 and 207.7 of the Commission's rules. The Commission's rules do not authorize filing of submissions with the Secretary by facsimile or electronic means, except to the extent permitted by section 201.8 of the Commission's rules, as amended, 67 FR 68036 (November 8, 2002). Also, in accordance with sections 201.16(c) and 207.3 of the Commission's rules, each document filed by a party to the review must be served on all other parties to the review (as identified by either the public or APO service list as appropriate), and a certificate of service must accompany the document (if you are not a party to the review you do not need to serve your response).

Inability to provide requested information.—Pursuant to section 207.61(c) of the Commission's rules, any interested party that cannot furnish the information requested by this notice in the requested form and manner shall notify the Commission at the earliest possible time, provide a full explanation of why it cannot provide the requested information, and indicate alternative forms in which it can provide equivalent information. If an interested party does not provide this notification (or the Commission finds the explanation provided in the notification inadequate) and fails to provide a complete response to this notice, the Commission may take an adverse inference against the party pursuant to section 776(b) of the Act in making its determination in the review.

Information To Be Provided in Response to This Notice of Institution: As used below, the term "firm" includes any related firms.

(1) The name and address of your firm or entity (including World Wide Web address) and name, telephone number, fax number, and e-mail address of the certifying official.

(2) A statement indicating whether your firm/entity is a U.S. producer of the *Domestic Like Product,* a U.S. union or worker group, a U.S. importer of the *Subject Merchandise,* a foreign producer or exporter of the *Subject Merchandise,* a U.S. or foreign trade or business association, or another interested party (including an explanation). If you are a union/worker group or trade/business association, identify the firms in which your workers are employed or which are members of your association.

(3) A statement indicating whether your firm/entity is willing to participate in this review by providing information requested by the Commission.

(4) A statement of the likely effects of the revocation of the antidumping duty order on the *Domestic Industry* in general and/or your firm/entity specifically. In your response, please discuss the various factors specified in section 752(a) of the Act (19 U.S.C. 1675a(a)) including the likely volume of subject imports, likely price effects of subject imports, and likely impact of imports of *Subject Merchandise* on the *Domestic Industry.*

(5) A list of all known and currently operating U.S. producers of the *Domestic Like Product.* Identify any known related parties and the nature of the relationship as defined in section 771(4)(B) of the Act (19 U.S.C. 1677(4)(B)).

(6) A list of all known and currently operating U.S. importers of the *Subject Merchandise* and producers of the *Subject Merchandise* in the *Subject Country* that currently export or have exported *Subject Merchandise* to the United States or other countries since the *Order Date.*

(7) A list of 3–5 leading purchasers in the U.S. market for the *Domestic Like Product* and the *Subject Merchandise* (including street address, World Wide Web address, and the name, telephone number, fax number, and E-mail address of a responsible official at each firm).

(8) A list of known sources of information on national or regional prices for the *Domestic Like Product* or the *Subject Merchandise* in the U.S. or other markets.

(9) If you are a U.S. producer of the *Domestic Like Product,* provide the following information on your firm's operations on that product during crop year 2009/10, except as noted (report quantity data in millions of boxes (growers) or thousands of solids (processors) and value data in U.S. dollars, f.o.b. your production facility). If you are a union/worker group or trade/business association, provide the information, on an aggregate basis, for the firms in which your workers are employed/which are members of your association.

(a) Production (quantity) and, if known, an estimate of the percentage of total U.S. production of the *Domestic*

Like Product accounted for by your firm's(s') production;

(b) Capacity (quantity) of your firm to produce the *Domestic Like Product* (*i.e.,* the level of production that your establishment(s) could reasonably have expected to attain during the year, assuming normal operating conditions (using equipment and machinery in place and ready to operate), normal operating levels (hours per week/weeks per year), time for downtime, maintenance, repair, and cleanup, and a typical or representative product mix);

(c) The quantity and value of U.S. commercial shipments of the *Domestic Like Product* produced in your U.S. plant(s);

(d) The quantity and value of U.S. internal consumption/company transfers of the *Domestic Like Product* produced in your U.S. plant(s); and

(e) The value of (i) net sales, (ii) cost of goods sold (COGS), (iii) gross profit, (iv) selling, general and administrative (SG&A) expenses, and (v) operating income of the *Domestic Like Product* produced in your U.S. plant(s) (include both U.S. and export commercial sales, internal consumption, and company transfers) for your most recently completed fiscal year (identify the date on which your fiscal year ends).

(10) If you are a U.S. importer or a trade/business association of U.S. importers of the *Subject Merchandise* from the *Subject Country,* provide the following information on your firm's(s') operations on that product during crop year 2009/10 (report quantity data in thousands of solids and value data in U.S. dollars). If you are a trade/business association, provide the information, on an aggregate basis, for the firms which are members of your association.

(a) The quantity and value (landed, duty-paid but not including antidumping duties) of U.S. imports and, if known, an estimate of the percentage of total U.S. imports of *Subject Merchandise* from the *Subject Country* accounted for by your firm's(s') imports;

(b) The quantity and value (f.o.b. U.S. port, including antidumping duties) of U.S. commercial shipments of *Subject Merchandise* imported from the *Subject Country;* and

(c) The quantity and value (f.o.b. U.S. port, including antidumping duties) of U.S. internal consumption/company transfers of *Subject Merchandise* imported from the *Subject Country.*

(11) If you are a producer, an exporter, or a trade/business association of producers or exporters of the *Subject Merchandise* in the *Subject Country,* provide the following information on your firm's(s') operations on that product during crop year 2010 (report quantity data in millions of boxes (growers) or thousands of solids (processors) and value data in U.S. dollars, landed and duty-paid at the U.S. port but not including antidumping duties). If you are a trade/business association, provide the information, on an aggregate basis, for the firms which are members of your association.

(a) Production (quantity) and, if known, an estimate of the percentage of total production of *Subject Merchandise* in the *Subject Country* accounted for by your firm's(s') production;

(b) Capacity (quantity) of your firm to produce the *Subject Merchandise* in the *Subject Country* (*i.e.,* the level of production that your establishment(s) could reasonably have expected to attain during the year, assuming normal operating conditions (using equipment and machinery in place and ready to operate), normal operating levels (hours per week/weeks per year), time for downtime, maintenance, repair, and cleanup, and a typical or representative product mix); and

(c) The quantity and value of your firm's(s') exports to the United States of *Subject Merchandise* and, if known, an estimate of the percentage of total exports to the United States of *Subject Merchandise* from the *Subject Country* accounted for by your firm's(s') exports.

(12) Identify significant changes, if any, in the supply and demand conditions or business cycle for the *Domestic Like Product* that have occurred in the United States or in the market for the *Subject Merchandise* in the *Subject Country* since the *Order Date,* and significant changes, if any, that are likely to occur within a reasonably foreseeable time. Supply conditions to consider include technology; production methods; development efforts; ability to increase production (including the shift of production facilities used for other products and the use, cost, or availability of major inputs into production); and factors related to the ability to shift supply among different national markets (including barriers to importation in foreign markets or changes in market demand abroad). Demand conditions to consider include end uses and applications; the existence and availability of substitute products; and the level of competition among the *Domestic Like Product* produced in the United States, *Subject Merchandise* produced in the *Subject Country,* and such merchandise from other countries.

(13) (OPTIONAL) A statement of whether you agree with the above definitions of the *Domestic Like Product* and *Domestic Industry;* if you disagree with either or both of these definitions, please explain why and provide alternative definitions.

Authority: This review is being conducted under authority of title VII of the Tariff Act of 1930; this notice is published pursuant to section 207.61 of the Commission's rules.

By order of the Commission.

Issued: January 27, 2011.

Marilyn R. Abbott,

Secretary to the Commission.

[FR Doc. 2011–2215 Filed 2–1–11; 8:45 am]

BILLING CODE 7020–02–P

INTERNATIONAL TRADE COMMISSION

[Inv. No. 337–TA–758]

In the Matter of Certain Mobile Telephones and Modems; Notice of Investigation

AGENCY: U.S. International Trade Commission.

ACTION: Institution of investigation pursuant to 19 U.S.C. 1337

SUMMARY: Notice is hereby given that a complaint was filed with the U.S. International Trade Commission on December 28, 2010, under section 337 of the Tariff Act of 1930, as amended, 19 U.S.C. 1337, on behalf of Sony Corporation of Japan. The complaint alleges violations of section 337 based upon the importation into the United States, the sale for importation, and the sale within the United States after importation of certain mobile telephones and modems by reason of infringement of certain claims of U.S. Patent No. 6,311,092 ("the '092 patent"); U.S. Patent No. 5,907,604 ("the '604 patent"); U.S. Patent No. 6,263,205 ("the '205 patent"); U.S. Patent No. 6,507,611 ("the '611 patent"); U.S. Patent No. 6,674,464 ("the '464 patent"); U.S. Patent No. 7,839,477 ("the '477 patent"); and U.S. Patent No. 6,674,732 ("the '732 patent"). The complaint further alleges that an industry in the United States exists as required by subsection (a)(2) of section 337.

The complainant requests that the Commission institute an investigation and, after the investigation, issue an exclusion order and a cease and desist order.

ADDRESSES: The complaint, except for any confidential information contained therein, is 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., Room 112, Washington, DC 20436, telephone

202–205–2000. Hearing impaired individuals are advised that information on this matter can be obtained by contacting the Commission's TDD terminal on 202–205–1810. Persons with mobility impairments who will need special assistance in gaining access to the Commission should contact the Office of the Secretary at 202–205–2000. General information concerning the Commission may also be obtained by accessing its Internet server 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.*

FOR FURTHER INFORMATION CONTACT: Mareesa A. Frederick, Esq., Office of Unfair Import Investigations, U.S. International Trade Commission, telephone (202) 205–2055. *Authority:* The authority for institution of this investigation is contained in section 337 of the Tariff Act of 1930, as amended, and in section 210.10 of the Commission's Rules of Practice and Procedure, 19 CFR 210.10 (2010). *Scope Of Investigation:* Having considered the complaint, the U.S. International Trade Commission, on January 27, 2011, *ordered that*—

(1) Pursuant to subsection (b) of section 337 of the Tariff Act of 1930, as amended, an investigation be instituted to determine whether there is a violation of subsection (a)(1)(B) of section 337 in the importation into the United States, the sale for importation, or the sale within the United States after importation of certain mobile telephones and modems that infringe one or more of claims 1 and 2 of the '092 patent; claims 1 and 8 of the '604 patent; claims 7–10 of the '205 patent; claims 17, 18, 24, 25, 27, 32–34, 40, 41, 43, and 48 of the '611 patent; claims 1–3 of the '464 patent; claims 3, 4, 7, and 8 of the '447 patent; and claims 2, 3, 6, and 7 of the '732 patent, and whether an industry in the United States exists as required by subsection (a)(2) of section 337;

(2) For the purpose of the investigation so instituted, the following are hereby named as parties upon which this notice of investigation shall be served:

(a) The complainant is: Sony Corporation, 1–7–1 Konan, Minato-ku, Tokyo, 108–0075, Japan.

(b) The respondents are the following entities alleged to be in violation of section 337, and are the parties upon which the complaint is to be served:

LG Electronics, Inc., LG Twin Towers, 20 Yeouido-dong Yeongdeungpo-gu, Seoul, 150–721, South Korea;

LG Electronics U.S.A., Inc., 1000 Sylvan Avenue, Englewood Cliffs, NJ 07632;

LG Electronics Mobilecomm U.S.A., Inc., 10101 Old Grove Road, San Diego, CA 92131.

(c) The Commission investigative attorney, party to this investigation, is Mareesa A. Frederick, Esq., Office of Unfair Import Investigations, U.S. International Trade Commission, 500 E Street, SW., Suite 401, Washington, DC 20436; and

(3) For the investigation so instituted, the Honorable Paul J. Luckern, Chief Administrative Law Judge, U.S. International Trade Commission, shall designate the presiding Administrative Law Judge.

Responses to the complaint and the notice of investigation must be submitted by the named respondents in accordance with section 210.13 of the Commission's Rules of Practice and Procedure, 19 CFR 210.13. Pursuant to 19 CFR 201.16(d)–(e) and 210.13(a), such responses will be considered by the Commission if received not later than 20 days after the date of service by the Commission of the complaint and the notice of investigation. Extensions of time for submitting responses to the complaint and the notice of investigation will not be granted unless good cause therefor is shown.

Failure of a respondent to file a timely response to each allegation in the complaint and in this notice may be deemed to constitute a waiver of the right to appear and contest the allegations of the complaint and this notice, and to authorize the administrative law judge and the Commission, without further notice to the respondent, to find the facts to be as alleged in the complaint and this notice and to enter an initial determination and a final determination containing such findings, and may result in the issuance of an exclusion order or a cease and desist order or both directed against the respondent.

By order of the Commission.
Issued: January 27, 2011.

Marilyn R. Abbott,

Secretary to the Commission.

[FR Doc. 2011–2216 Filed 2–1–11; 8:45 am]

BILLING CODE 7020–02–P

INTERNATIONAL TRADE COMMISSION

[Investigation No. 332–523]

U.S.-Korea Free Trade Agreement: Passenger Vehicle Sector Update

AGENCY: United States International Trade Commission.

ACTION: Institution of investigation and request for written statements.

SUMMARY: Following receipt of a request dated January 27, 2011, from the U.S. House of Representatives Committee on Ways and Means (Committee) under section 332(g) of the Tariff Act of 1930 (19 U.S.C. 1332(g)), the U.S. International Trade Commission (Commission) instituted investigation No. 332–523, *U.S.-Korea Free Trade Agreement: Passenger Vehicle Sector Update.*

DATES: February 14, 2011: Deadline for filing written statements. March 15, 2011: Transmittal of Commission report to the Committee.

ADDRESSES: All Commission offices are located in the United States International Trade Commission Building, 500 E Street, SW., Washington, DC. All written submissions should be addressed to the Secretary, United States International Trade Commission, 500 E Street, SW., Washington, DC 20436. The public record for this investigation may be viewed on the Commission's electronic docket (EDIS) at *https://edis.usitc.gov/edis3-internal/app.*

FOR FURTHER INFORMATION CONTACT: Brian Allen, Co-Project Leader, Office of Industries (202–205–3034 or *brian.allen@usitc.gov*) or Deborah McNay, Co-Project Leader, Office of Industries (202–205–3425 or *deborah.mcnay@usitc.gov*) for information specific to this investigation. For information on the legal aspects of this investigation, contact William Gearhart of the Commission's Office of the General Counsel (202–205–3091 or *william.gearhart@usitc.gov*). The media should contact Margaret O'Laughlin, Office of External Relations (202–205–1819 or *margaret.olaughlin@usitc.gov*). Hearing-impaired individuals may obtain information on this matter by contacting the Commission's TDD terminal at 202–205–1810. General information concerning the Commission may also be obtained by accessing its Internet server (*http://www.usitc.gov*). Persons with mobility impairments who will need special assistance in gaining access to the Commission should contact the Office of the Secretary at 202–205–2000.

Background: In April 2007, the U.S. Trade Representative (USTR) requested that the Commission prepare a report, as specified in section 2104(f) of the Trade Act of 2002 (19 U.S.C. 3804(f)), assessing the likely impact of the U.S.-Korea Free Trade Agreement (FTA) on the U.S. economy as a whole and on

specific industry sectors and the interests of U.S. consumers. The Commission transmitted its report (*U.S.-Korea Free Trade Agreement: Potential Economy-wide and Selected Sectoral Effects,* inv. No. TA–2104–24, USITC pub. 3949) to the USTR in September 2007.

The United States and Korea recently concluded negotiations to modify the FTA, including certain provisions relating to the passenger vehicle sector. In its request letter, the Committee requested that the Commission, under section 332(g) of the Tariff Act of 1930, update its 2007 assessment with respect to the passenger vehicle sector. The Committee asked that the Commission use the most recent data available and include a modeling simulation of the effects of the auto nontariff measures in its assessment.

Written Submissions: Because of the short time frame requested by the Committee, the Commission will not hold a public hearing in connection with this investigation. However, interested parties are invited to submit written statements concerning this investigation. All written submissions should be addressed to the Secretary, and should be received not later than 5:15 p.m., February 14, 2011. All written submissions must conform with the provisions of section 201.8 of the *Commission's Rules of Practice and Procedure* (19 CFR 201.8). Section 201.8 requires that a signed original (or a copy so designated) and fourteen (14) copies of each document be filed. In the event that confidential treatment of a document is requested, at least four (4) additional copies must be filed, in which the confidential information must be deleted (see the following paragraph for further information regarding confidential business information). The Commission's rules authorize filing submissions with the Secretary by facsimile or electronic means only to the extent permitted by section 201.8 of the rules (see Handbook on Electronic Filing Procedures, *http://www.usitc.gov/docket_services/documents/handbook_on_electronic_filing.pdf*). Persons with questions regarding electronic filing should contact the Secretary (202–205–2000).

Any submissions that contain confidential business information (CBI) must also conform with the requirements of section 201.6 of the *Commission's Rules of Practice and Procedure* (19 CFR 201.6). Section 201.6 of the rules requires that the cover of the document and the individual pages be clearly marked as to whether they are the "confidential" or "non-confidential" version, and that the confidential business information be clearly identified by means of brackets. All written submissions, except for confidential business information, will be made available for inspection by interested parties.

In its request letter, the Committee stated that it intends to make the Commission's report available to the public in its entirety, and asked that the Commission not include any confidential business information in the report that the Commission sends to the Committee. Any confidential business information received by the Commission in this investigation and used in preparing this report will not be published in a manner that would reveal the operations of the firm supplying the information.

By order of the Commission.
Issued: January 28, 2011.

William R. Bishop,

Hearings and Meetings Coordinator.

[FR Doc. 2011–2286 Filed 2–1–11; 8:45 am]

BILLING CODE P

DEPARTMENT OF JUSTICE

Antitrust Division

Notice Pursuant to the National Cooperative Research and Production Act of 1993—Advanced Media Workflow Association, Inc.

Notice is hereby given that, on January 6, 2011, pursuant to Section 6(a) of the National Cooperative Research and Production Act of 1993, 15 U.S.C. 4301 *et seq.* ("the Act"), Advanced Media Workflow Association, Inc. has filed written notifications simultaneously with the Attorney General and the Federal Trade Commission disclosing changes in its membership. The notifications were filed for the purpose of extending the Act's provisions limiting the recovery of antitrust plaintiffs to actual damages under specified circumstances. Specifically, Front Porch Digital, Louisville, CO; MBC Group, Dubai, UNITED ARAB EMIRATES; TOSHIBA, Wayne, NJ; Tom Adamich (individual member), New Philadelphia, OH; Robert Gummesson, London, UNITED KINGDOM; Isak Jonsson (individual member), Sollentuna, SWEDEN; George Luff (individual member), Berkhamsted, UNITED KINGDOM; and Salvador Villa Vidaller, Madrid, SPAIN, have been added as parties to this venture.

Also, 3T Technology, Taipei City, TAIWAN; Blue Order Technologies, Kaiserslautern, GERMANY; Harmonic, Inc., Sunnyvale, CA; Integrated Media Technologies, Hollywood, CA; Open Text Media Group, Reading, Berkshire, UNITED KINGDOM; Signiant, Burlington, MA; Richard Eversley (individual member), Lakewood, CO; and Michael Karagosian (individual member), Calabasas, CA, have withdrawn as parties to this venture.

No other changes have been made in either the membership or planned activity of the group research project. Membership in this group research project remains open, and Advanced Media Workflow Association, Inc. intends to file additional written notifications disclosing all changes in membership.

On March 28, 2000, Advanced Media Workflow Association, Inc. filed its original notification pursuant to Section 6(a) of the Act. The Department of Justice published a notice in the **Federal Register** pursuant to Section 6(b) of the Act on June 29, 2000 (65 FR 40127).

The last notification was filed with the Department on September 23, 2010. A notice was published in the **Federal Register** pursuant to Section 6(b) of the Act on October 26, 2010 (75 FR 65656).

Patricia A. Brink,

Director of Civil Enforcement, Antitrust Division.

[FR Doc. 2011–2078 Filed 2–1–11; 8:45 am]

BILLING CODE 4410–11–M

DEPARTMENT OF JUSTICE

Antitrust Division

Notice Pursuant to the National Cooperative Research and Production Act of 1993—Institute of Electrical and Electronics Engineers

Notice is hereby given that, on January 3, 2011, pursuant to Section 6(a) of the National Cooperative Research and Production Act of 1993, 15 U.S.C. 4301 *et seq.* ("the Act"), Institute of Electrical and Electronics Engineers ("IEEE") has filed written notifications simultaneously with the Attorney General and the Federal Trade Commission disclosing additions or changes to its standards development activities. The notifications were filed for the purpose of extending the Act's provisions limiting the recovery of antitrust plaintiffs to actual damages under specified circumstances. Specifically, 34 new standards have been initiated and 21 existing standards are being revised. More details regarding these changes can be found at: *http://standards.ieee.org/about/sba/sep2010.html, http://standards.ieee.org/about/sba/oct2010.html, http://*

standards.ieee.org/about/sba/dec2010.html.

On September 17, 2004, IEEE filed its original notification pursuant to Section 6(a) of the Act. The Department of Justice published a notice in the **Federal Reqister** pursuant to Section 6(b) of the Act on November 3, 2004 (69 FR 64105).

The last notification was filed with the Department on July 22, 2010. A notice was published in the **Federal Register** pursuant to Section 6(b) of the Act on September 9, 2010 (75 FR 54915).

Patricia A. Brink,

Director of Civil Enforcement, Antitrust Division.

[FR Doc. 2011–2076 Filed 2–1–11; 8:45 am]

BILLING CODE 4410–11–M

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

Importer of Controlled Substances; Notice of Application

Pursuant to Title 21 Code of Federal Regulations 1301.34(a), this is notice that on November 9, 2010, Mallinckrodt Inc., 3600 North Second Street, St. Louis, Missouri 63147, made application by renewal to the Drug Enforcement Administration (DEA) for registration as an importer of the following basic classes of controlled substances:

Drug	Schedule
Phenylacetone (8501)	II
Coca Leaves (9040)	II
Opium, raw (9600)	II
Poppy Straw Concentrate (9670)	II

The company plans to import the listed controlled substances for the manufacture of controlled substances in bulk for distribution to its customers.

No comments, objections, or requests for any hearings will be accepted on any application for registration or re-registration to import crude opium, poppy straw, concentrate of poppy straw or coca leaves. As explained in the Correction to Notice of Application pertaining to Rhodes Technologies, 72 FR 3417 (2007), comments and requests for hearings on applications to import narcotic raw material are not appropriate.

Any bulk manufacturer who is presently, or is applying to be, registered with DEA to manufacture such basic classes of controlled substances listed in schedule I or II, which fall under the authority of section 1002(a)(2)(B) of the Act (21 U.S.C. 952(a)(2)(B)) may, in the circumstances set forth in 21 U.S.C. 958(i), file comments or objections to the issuance of the proposed registration and may, at the same time, file a written request for a hearing on such application pursuant to 21 CFR 1301.43 and in such form as prescribed by 21 CFR 1316.47.

Any such comments or objections should be addressed, in quintuplicate, to the Drug Enforcement Administration, Office of Diversion Control, **Federal Register** Representative (ODL), 8701 Morrissette Drive, Springfield, Virginia 22152; and must be filed no later than March 4, 2011.

This procedure is to be conducted simultaneously with, and independent of, the procedures described in 21 CFR 1301.34(b), (c), (d), (e), and (f). As noted in a previous notice published in the **Federal Register** on September 23, 1975, (40 FR 43745), all applicants for registration to import a basic class of any controlled substance in schedule I or II are, and will continue to be, required to demonstrate to the Deputy Assistant Administrator, Office of Diversion Control, Drug Enforcement Administration, that the requirements for such registration pursuant to 21 U.S.C. 958(a); 21 U.S.C. 823(a); and 21 CFR 1301.34(b), (c), (d), (e), and (f) are satisfied.

Dated: January 18, 2011.

Joseph T. Rannazzisi,

Deputy Assistant Administrator, Office of Diversion Control, Drug Enforcement Administration.

[FR Doc. 2011–2289 Filed 2–1–11; 8:45 am]

BILLING CODE 4410–09–P

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

Importer of Controlled Substances; Notice of Registration

By Notice dated June 17, 2010, and published in the **Federal Register** on June 28, 2010, (75 FR 36681), Research Triangle Institute, Kenneth H. Davis, Jr., Hermann Building, East Institute Drive, P.O. Box 12194, Research Triangle, North Carolina 27709, made application by renewal to the Drug Enforcement Administration (DEA) to be registered as an importer of the following basic classes of controlled substances:

Drug	Schedule
1-(1-Phenylcyclohexyl)pyrrolidine (7458).	I
1-[1-(2-Thienyl)cyclohexyl]piperidine (7470).	I
1-[1-(2-Thienyl)cyclohexyl]pyrrolidine (7473).	I
1-Methyl-4-phenyl-4-propionoxypiperidine (9661).	I
1-(2-Phenylethyl)-4-phenyl-4-acetoxypiperidine (9663).	I
2,5-Dimethoxy-4-(n)-propylthiophenethylamine (7348).	I
2,5-Dimethoxy-4-ethylamphetamine (7399).	I
2,5-Dimethoxyamphetamine (7396).	I
3,4,5-Trimethoxyamphetamine (7390).	I
3,4-Methylenedioxyamphetamine (7400).	I
3,4-Methylenedioxymethamphetamine (7405).	I
3,4-Methylenedioxy-N-ethylamphetamine (7404).	I
3-Methylfentanyl (9813)	I
3-Methylthiofentanyl (9833)	I
4-Bromo-2,5-dimethoxyamphetamine (7391).	I
4-Bromo-2,5-dimethoxyphenethylamine (7392).	I
4-Methyl-2,5-dimethoxyamphetamine (7395).	I
4-Methylaminorex (cis isomer) (1590).	I
4-Methoxyamphetamine (7411)	I
5-Methoxy-3,4-methylenedioxyamphetamine (7401).	I
5-Methoxy-N,N-diisopropyltryptamine (7439).	I
Acetorphine (9319)	I
Acetyl-alpha-methylfentanyl (9815).	I
Acetyldihydrocodeine (9051)	I
Acetylmethadol (9601)	I
Allylprodine (9602)	I
Alphacetylmethadol except levo-alphacetylmethadol (9603).	I
Alpha-ethyltryptamine (7249)	I
Alphameprodine (9604)	I
Alphamethadol (9605)	I
Alpha-methylfentanyl (9814)	I
Alpha-methylthiofentanyl (9832)	I
Alpha-methyltryptamine (7432)	I
Aminorex (1585)	I
Benzethidine (9606)	I
Benzylmorphine (9052)	I
Betacetylmethadol (9607)	I
Beta-hydroxy-3-methylfentanyl (9831).	I
Beta-hydroxyfentanyl (9830)	I
Betameprodine (9608)	I
Betamethadol (9609)	I
Betaprodine (9611)	I
Bufotenine (7433)	I
Cathinone (1235)	I
Clonitazene (9612)	I
Codeine methylbromide (9070)	I
Codeine-N-Oxide (9053)	I
Cyprenorphine (9054)	I
Desomorphine (9055)	I
Dextromoramide (9613)	I
Diampromide (9615)	I
Diethylthiambutene (9616)	I

Drug	Schedule
Diethyltryptamine (7434)	I
Difenoxin (9168)	I
Dihydromorphine (9145)	I
Dimenoxadol (9617)	I
Dimepheptanol (9618)	I
Dimethylthiambutene (9619)	I
Dimethyltryptamine (7435)	I
Dioxaphetyl butyrate (9621)	I
Dipipanone (9622)	I
Drotebanol (9335)	I
Ethylmethylthiambutene (9623)	I
Etonitazene (9624)	I
Etorphine except HCl (9056)	I
Etoxeridine (9625)	I
Fenethylline (1503)	I
Furethidine (9626)	I
Gamma Hydroxybutyric Acid (2010).	I
Heroin (9200)	I
Hydromorphinol (9301)	I
Hydroxypethidine (9627)	I
Ibogaine (7260)	I
Ketobemidone (9628)	I
Levomoramide (9629)	I
Levophenacylmorphan (9631)	I
Lysergic acid diethylamide (7315)	I
Marihuana (7360)	I
Mecloqualone (2572)	I
Mescaline (7381)	I
Methaqualone (2565)	I
Methcathinone (1237)	I
Methyldesorphine (9302)	I
Methyldihydromorphine (9304)	I
Morpheridine (9632)	I
Morphine methylbromide (9305)	I
Morphine methylsulfonate (9306)	I
Morphine-N-Oxide (9307)	I
Myrophine (9308)	I
N,N-Dimethylamphetamine (1480)	I
N-Benzylpiperazine (7493)	I
N-Ethyl-3-piperidyl benzilate (7482).	I
N-Ethylamphetamine (1475)	I
N-Ethyl-l-phenylcyclohexylamine (7455).	I
N-Hydroxy-3,4-methylenedioxyamphetamine (7402).	I
Nicocodeine (9309)	I
Nicomorphine (9312)	I
N-Methyl-3-piperidyl benzilate (7484).	I
Noracymethadol (9633)	I
Norlevorphanol (9634)	I
Normethadone (9635)	I
Normorphine (9313)	I
Norpipanone (9636)	I
Para-Fluorofentanyl (9812)	I
Parahexyl (7374)	I
Peyote (7415)	I
Phenadoxone (9637)	I
Phenampromide (9638)	I
Phenomorphan (9647)	I
Phenoperidine (9641)	I
Pholcodine (9314)	I
Piritramide (9642)	I
Proheptazine (9643)	I
Properidine (9644)	I
Propiram (9649)	I
Psilocybin (7437)	I
Psilocyn (7438)	I
Racemoramide (9645)	I
Tetrahydrocannabinols (7370)	I
Thebacon (9315)	I
Thiofentanyl (9835)	I
Tilidine (9750)	I
Trimeperidine (9646)	I
1-Phenylcyclohexylamine (7460)	II
1-Piperidinocyclohexanecarbonitrile (8603).	II
Alfentanil (9737)	II
Alphaprodine (9010)	II
Amobarbital (2125)	II
Amphetamine (1100)	II
Anileridine (9020)	II
Bezitramide (9800)	II
Carfentanil (9743)	II
Coca Leaves (9040)	II
Cocaine (9041)	II
Codeine (9050)	II
Dextropropoxyphene, bulk (non-dosage forms) (9273).	II
Dihydrocodeine (9120)	II
Dihydroetorphine (9334)	II
Diphenoxylate (9170)	II
Ethylmorphine (9190)	II
Etorphine Hcl (9059)	II
Fentanyl (9801)	II
Glutethimide (2550)	II
Hydrocodone (9193)	II
Hydromorphone (9150)	II
Isomethadone (9226)	II
Levo-alphacetylmethadol (9648)	II
Levomethorphan (9210)	II
Levorphanol (9220)	II
Lisdexamfetamine (1205)	II
Meperidine (9230)	II
Meperidine intermediate-A (9232)	II
Meperidine intermediate-B (9233)	II
Meperidine intermediate-C (9234)	II
Metazocine (9240)	II
Methadone (9250)	II
Methadone intermediate (9254)	II
Methamphetamine (1105)	II
Methylphenidate (1724)	II
Metopon (9260)	II
Moramide intermediate (9802)	II
Morphine (9300)	II
Nabilone (7379)	II
Opium, raw (9600)	II
Opium extracts (9610)	II
Opium fluid extract (9620)	II
Opium tincture (9630)	II
Opium, granulated (9640)	II
Oxycodone (9143)	II
Oxymorphone (9652)	II
Pentobarbital (2270)	II
Phenazocine (9715)	II
Phencyclidine (7471)	II
Phenmetrazine (1631)	II
Phenylacetone (8501)	II
Piminodine (9730)	II
Powdered opium (9639)	II
Racemethorphan (9732)	II
Racemorphan (9733)	II
Remifentanil (9739)	II
Secobarbital (2315)	II
Sufentanil (9740)	II
Thebaine (9333)	II

The company plans to import small quantities of the listed controlled substances for the National Institute on Drug Abuse (NIDA) for research activities.

In addition to the basic classes of controlled substances mentioned previously in this Notice of Registration, the Notice of Application (75 FR 36681), dated June 17, 2010, and published in the **Federal Register** on June 28, 2010, also stated that the Research Triangle Institute made application to be registered as an importer of the following schedule I controlled substances:

N-[1-benzyl-4-piperidyl]-N-phenylpropanamide (benzylfentanyl) (drug code: 9818)

N-[1-(2-thienyl)methyl-4-piperidyl]-N-phenylpropanamide (thenylfentanyl) (drug code: 9834)

By Notice dated June 19, 2010, and published in the **Federal Register** on June 29, 2010, (75 FR 37300), the DEA issued a rulemaking in the form of a Final Rule to correct Title 21, Code of Federal Regulations (CFR), specifically: 21 CFR 1308.11(g), by deleting regulations which listed benzylfentanyl (drug code: 9818) and thenylfentanyl (drug code: 9834) as being temporarily subject to schedule I controls under the emergency scheduling provisions of the Controlled Substances Act (CSA). DEA determined that these compounds were both essentially inactive, with no evidence of abuse potential. Pursuant to June 19th rulemaking (75 FR 37300), effective June 29, 2010, both benzylfentanyl (drug code: 9818) and thenylfentanyl (drug code: 9834) were no longer legally deemed to be controlled substances. Thus, neither benzylfentanyl (drug code: 9818) nor thenylfentanyl (drug code: 9834) is listed in this Notice of Registration despite being originally listed in the Notice of Application. (75 FR 36681)

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 Research Triangle Institute 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. DEA has investigated Research Triangle Institute 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: January 18, 2011.

Joseph T. Rannazzisi,

Deputy Assistant Administrator, Office of Diversion Control, Drug Enforcement Administration.

[FR Doc. 2011–2284 Filed 2–1–11; 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), Title 21 of the Code of Federal Regulations (CFR), this is notice that on May 25, 2010, AMRI Rensselaer, Inc., 33 Riverside Avenue, Rensselaer, New York 12144, made application by renewal to the Drug Enforcement Administration (DEA) to be registered as a bulk manufacturer of the following basic classes of controlled substances:

Drug	Schedule
Marihuana (7360)	I
Tetrahydrocannabinols (7370)	I
Amphetamine (1100)	II
Lisdexamfetamine (1205)	II
Methylphenidate (1724)	II
Pentobarbital (2270)	II
Meperidine (9230)	II
Fentanyl (9801)	II

The company plans to manufacture bulk controlled substances for use in product development and for distribution to its customers.

In reference to drug code 7360 (Marihuana), the company plans to bulk manufacture cannabidiol as a synthetic intermediate. This controlled substance will be further synthesized to bulk manufacture a synthetic THC (7370). No other activity for this drug code is authorized for this registration.

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 April 4, 2011.

Dated: January 18, 2011.

Joseph T. Rannazzisi,

Deputy Assistant Administrator, Office of Diversion Control, Drug Enforcement Administration.

[FR Doc. 2011–2288 Filed 2–1–11; 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), Title 21 of the Code of Federal Regulations (CFR), this is notice that on November 24, 2010, 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 following classes of controlled substances:

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.

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 April 4, 2011.

Dated: January 18, 2011.

Joseph T. Rannazzisi,

Deputy Assistant Administrator, Office of Diversion Control, Drug Enforcement Administration.

[FR Doc. 2011–2237 Filed 2–1–11; 8:45 am]

BILLING CODE 4410–09–P

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

Manufacturer of Controlled Substances; Notice of Registration

By Notice dated August 3, 2010, and published in the **Federal Register** on September 1, 2010, 75 FR 53719, Cambridge Isotope Lab, 50 Frontage Road, Andover, Massachusetts 01810, made application by renewal to the Drug Enforcement Administration (DEA) to be registered as a bulk manufacturer of Morphine (9300), a basic class of controlled substance listed in schedule II.

The company plans to utilize small quantities of the listed controlled substance in the preparation of analytical 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 Cambridge Isotope Lab to manufacture the listed basic class of controlled substance is consistent with the public interest at this time. DEA has

investigated Cambridge Isotope Lab 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(a), and in accordance with 21 CFR 1301.33, the above named company is granted registration as a bulk manufacturer of the basic class of controlled substance listed.

Dated: January 18, 2011.

Joseph T. Rannazzisi,

Deputy Assistant Administrator, Office of Diversion Control, Drug Enforcement Administration.

[FR Doc. 2011–2295 Filed 2–1–11; 8:45 am]

BILLING CODE 4410–09–P

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

Manufacturer of Controlled Substances; Notice of Registration

By Notice dated August 3, 2010, and published in the Federal Register on September 1, 2010, (75 FR 53720), American Radiolabeled Chemicals, Inc., 101 Arc Drive, St. Louis, Missouri 63146, made application by renewal to the Drug Enforcement Administration (DEA) to be registered as a bulk manufacturer of the following basic classes of controlled substances:

Drug	Schedule
Gamma Hydroxybutyric Acid (2010).	I
Ibogaine (7260)	I
Lysergic acid diethylamide (7315)	I
Tetrahydrocannabinols (7370)	I
Dimethyltryptamine (7435)	I
1-[1-(2-Thienyl)cyclohexyl]piperidine (7470).	I
Dihydromorphine (9145)	I
Normorphine (9313)	I
Amphetamine (1100)	II
Methamphetamine (1105)	II
Amobarbital (2125)	II
Phencyclidine (7471)	II
Phenylacetone (8501)	II
Cocaine (9041)	II
Codeine (9050)	II
Dihydrocodeine (9120)	II
Oxycodone (9143)	II
Hydromorphone (9150)	II
Ecgonine (9180)	II
Hydrocodone (9193)	II
Meperidine (9230)	II
Metazocine (9240)	II
Dextropropoxyphene, bulk (non-dosage forms) (9273).	II
Morphine (9300)	II
Oripavine (9330)	II
Thebaine (9333)	II
Oxymorphone (9652)	II
Phenazocine (9715)	II
Fentanyl (9801)	II

The company plans to manufacture small quantities of the listed controlled substances as radiolabeled compounds for biochemical research.

No comments or objections have been received. DEA has considered the factors in 21 U.S.C. 823(a) and determined that the registration of American Radiolabeled Chemicals, Inc. to manufacture the listed basic classes of controlled substances is consistent with the public interest at this time. DEA has investigated American Radiolabeled Chemicals 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(a), and in accordance with 21 CFR 1301.33, the above named company is granted registration as a bulk manufacturer of the basic classes of controlled substances listed.

Dated: January 18, 2011.

Joseph T. Rannazzisi,

Deputy Assistant Administrator, Office of Diversion Control, Drug Enforcement Administration.

[FR Doc. 2011–2294 Filed 2–1–11; 8:45 am]

BILLING CODE 4410–09–P

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

Manufacturer of Controlled Substances; Notice of Registration

By Notice dated August 2, 2010, and published in the **Federal Register** on September 1, 2010, 75 FR 53720, Cody Laboratories, 601 Yellowstone Avenue, Cody, Wyoming 82414, made application by renewal to the Drug Enforcement Administration (DEA) to be registered as a bulk manufacturer of the following basic classes of controlled substances:

Drug	Schedule
Dihydromorphine (9145)	I
Amphetamine (1100)	II
Methamphetamine (1105)	II
Amobarbital (2125)	II
Pentobarbital (2270)	II
Secobarbital (2315)	II
Phenylacetone (8501)	II
Cocaine (9041)	II
Codeine (9050)	II
Dihydrocodeine (9120)	II
Oxycodone (9143)	II
Hydromorphone (9150)	II
Diphenoxylate (9170)	II
Ecgonine (9180)	II
Hydrocodone (9193)	II
Meperidine (9230)	II
Methadone (9250)	II
Morphine (9300)	II
Oxymorphone (9652)	II
Alfentanil (9737)	II
Remifentanil (9739)	II
Sufentanil (9740)	II
Fentanyl (9801)	II

The company plans on manufacturing the listed controlled substances in bulk for sale to its customers.

No comments or objections have been received. DEA has considered the factors in 21 U.S.C. 823(a) and determined that the registration of Cody Laboratories to manufacture the listed basic classes of controlled substances is consistent with the public interest at this time. DEA has investigated Cody Laboratories to ensure that the company's registration is consistent with the public interest. The investigation has included inspection and testing of the company's physical security systems, verification of the company's compliance with state and local laws, and a review of the company's background and history. Therefore, pursuant to 21 U.S.C. 823(a), and in accordance with 21 CFR 1301.33, the above named company is granted registration as a bulk manufacturer of the basic classes of controlled substances listed.

Dated: January 18, 2011.

Joseph T. Rannazzisi,

Deputy Assistant Administrator, Office of Diversion Control, Drug Enforcement Administration.

[FR Doc. 2011–2291 Filed 2–1–11; 8:45 am]

BILLING CODE 4410–09–P

DEPARTMENT OF JUSTICE

Federal Bureau of Investigation

[Docket No. FBI 150]

FBI Records Management Division; National Name Check Program Section; New User Fees Schedule

AGENCY: Federal Bureau of Investigation (FBI), Justice.

ACTION: Notice.

SUMMARY: Pursuant to 28 CFR 20.31(e)(3), this notice establishes a new

user fee schedule for Federal agencies requesting name-based background checks of the FBI's Central Records System through the National Name Check Program for noncriminal justice purposes. The total resource costs associated with providing these name check services have been calculated to ensure full reimbursement to the FBI.

DATES: This fee schedule is effective March 4, 2011.

FOR FURTHER INFORMATION CONTACT: FBI, RMD, National Name Check Program Section, 170 Marcel Drive, Winchester, Virginia 22602, Attention: Michael Cannon, (540) 868–4400.

SUPPLEMENTARY INFORMATION:

Pursuant to the authority in Public Law 101–515, as amended, the FBI has established user fees for Federal agencies requesting noncriminal name-based background checks of the Central Records System (CRS) through the National Name Check Program (NNCP) of the Records Management Division (RMD). The regulations governing the revision of these user fees are set out at 28 CFR 20.31(e and f). In accordance with 28 CFR 20.31(e), the FBI is required to periodically review the amount of the fees it collects for the NNCP to determine the current cost of processing name checks for noncriminal justice purposes and publish any resulting fee adjustments in the **Federal Register**.

Accordingly, the FBI conducted a fee study to assess the proper fee amounts that should be collected by the FBI.

In accordance with 28 CFR 20.31(e)(2), the fee study employed the same Activity Based Cost (ABC) accounting method detailed in the Final Rule establishing the process for setting fees (75 FR 24796 (May 6, 2010)). The ABC methodology is consistent with widely accepted accounting principles and complies with the provisions of 31 U.S.C. 9701 and other applicable Federal law. The fee study identified all direct and indirect costs associated with the name-based background checks incurred by the FBI in fiscal year 2009. These costs were analyzed by the ABC model to project the total reimbursable costs, by fee category, for fiscal year 2011.

The fee study recommended several adjustments to the current user fees, which have been in effect since October 1, 2007. Pursuant to the fee study, the fees imposed for electronic submissions will be increased, while the fees for manual and expedited submissions will be decreased. The following table details the fee amounts for Federal agencies requesting name-based background checks of the FBI's CRS through the NNCP for noncriminal justice purposes.

Service	Fee currently in effect	Change in fee amount	Revised fee
Electronic Submission:			
Batch Process Only	$1.50	$0.50	$2.00
Batch + File Review	29.50	9.00	38.50
Manual Submission	56.00	(5.25)	50.75
Expedited Submission	56.00	(5.25)	50.75

This new fee schedule will become effective on March 4, 2011.

Dated: January 25, 2011.

Robert S. Mueller, III,

Director, Federal Bureau of Investigation.

[FR Doc. 2011–2212 Filed 2–1–11; 8:45 am]

BILLING CODE 4410–02–P

DEPARTMENT OF LABOR

Employment and Training Administration

[TA–W–74,689]

Amdocs, Inc., Global Support Services, Advertising And Media AT&T Division, New Haven, Connecticut; Notice of Affirmative Determination Regarding Application for Reconsideration

By application dated December 22, 2010, legal counsel of a member of the subject worker group requested administrative reconsideration of the negative determination regarding workers' eligibility to apply for Trade Adjustment Assistance (TAA) applicable to workers and former workers of Amdocs, Inc., Global Support Services, Advertising and Media AT&T Division, New Haven, Connecticut (subject firm). The negative determination was issued on November 9, 2010. The Notice of determination was published in the **Federal Register** on November 23, 2010 (75 FR 71461).

The negative determination was based on the findings that the worker separations are not attributable to increased imports or a shift of services by the workers' firm. Specifically, services shifted to a foreign country by Amdocs, Inc. did not contribute importantly to worker separations in Global Support Services, Advertising and Media AT&T Division.

The investigation also revealed that the firm is not a Supplier or Downstream Producer to a firm with a TAA-certified worker group.

In the request for reconsideration, the petitioner alleged that the workers of the Advertising and Media Division are eligible to apply for TAA because Section 222(a) and/or Section 222(c) of the Trade Act of 1974, as amended, has been met.

The Department has carefully reviewed the request for reconsideration and the existing record, and has determined that the Department will conduct further investigation to determine if the petitioning workers meet the eligibility requirements of the Trade Act of 1974, as amended.

Conclusion

After careful review of the application, I conclude that the claim is of sufficient weight to justify reconsideration of the U.S. Department of Labor's prior decision. The application is, therefore, granted.

Signed at Washington, DC, this 21st day of January, 2011.

Del Min Amy Chen,

Certifying Officer, Office of Trade Adjustment Assistance.

[FR Doc. 2011–2241 Filed 2–1–11; 8:45 am]

BILLING CODE 4510–FN–P

DEPARTMENT OF LABOR

Employment and Training Administration

[TA–W–74,700]

AT&T; Reynoldsburg, OH; Notice of Affirmative Determination Regarding Application for Reconsideration

By application dated January 6, 2011, by three petitioners requested administrative reconsideration of the negative determination regarding workers' eligibility to apply for Trade Adjustment Assistance (TAA) applicable to workers and former workers of AT&T, Reynoldsburg, Ohio

(subject firm). The determination was issued on December 9, 2010. The Department's Notice of Determination was published in the **Federal Register** on January 3, 2011 (76 FR 182). The workers supply customer care call services.

The negative determination was based on the findings that the worker separations are not attributable to increased imports or a shift of services to a foreign country. Rather, the investigation established that the worker separations are attributable to the workers' firm shifting customer care call services to other facilities within the United States. The investigation also revealed the firm is not a supplier or downstream producer to a firm with a TAA-certified worker group.

In the request for reconsideration, the petitioners alleged that the subject firm has shifted services to a foreign country.

The Department has carefully reviewed the request for reconsideration and the existing record, and has determined that the Department will conduct further investigation to determine if the petitioning workers meet the eligibility requirements of the Trade Act of 1974, as amended.

Conclusion

After careful review of the application, I conclude that the claim is of sufficient weight to justify reconsideration of the U.S. Department of Labor's prior decision. The application is, therefore, granted.

Signed at Washington, DC, this 21st day of January, 2011.

Del Min Amy Chen,

Certifying Officer, Office of Trade Adjustment Assistance.

[FR Doc. 2011–2242 Filed 2–1–11; 8:45 am]

BILLING CODE 4510–FN–P

DEPARTMENT OF LABOR

Employment and Training Administration

[TA–W–74,554]

International Business Machines (IBM), Software Group Business Unit, Optim Data Studio Tools QA, San Jose, CA; Notice of Affirmative Determination Regarding Application for Reconsideration

By application dated November 29, 2010, a worker and a state workforce official requested administrative reconsideration of the Department of Labor's negative determination regarding eligibility to apply for Trade Adjustment Assistance (TAA), applicable to workers and former workers of the subject firm. The denial notice was signed on October 29, 2010, and was published in the **Federal Register** on November 17, 2010 (75 FR 70296).

The negative determination of the TAA petition filed on behalf of workers at International Business Machines (IBM), Software Group Business Unit, Optim Data Studio Tools QA, San Jose, California was based on the finding that that Criterion (1) has not been met because fewer than three workers were separated from Optim Data Studio Tools QA and further separations are not threatened.

In the request for reconsideration the petitioner stated that there were three more additional IBM employees working on the relevant product within the Data Studio Tools QA on a part-time basis and that the development for this product was shifted to a foreign country.

The Department has carefully reviewed the request for reconsideration and the existing record, and has determined that the Department will conduct further investigation to determine if the petitioning workers meet the eligibility requirements of the Trade Act of 1974, as amended.

Conclusion

After careful review of the application, I conclude that the claim is of sufficient weight to justify reconsideration of the U.S. Department of Labor's prior decision. The application is, therefore, granted.

Signed at Washington, DC, this 21st day of January 2011.

Del Min Amy Chen,

Certifying Officer, Office of Trade Adjustment Assistance.

[FR Doc. 2011–2240 Filed 2–1–11; 8:45 am]

BILLING CODE 4510–FN–P

DEPARTMENT OF LABOR

Employment and Training Administration

[TA–W–73,351]

Sandy Alexander; Clifton, NJ; Notice of Affirmative Determination Regarding Application for Reconsideration

By application dated January 6, 2011, by a petitioner requested administrative reconsideration of the negative determination regarding workers' eligibility to apply for Trade Adjustment Assistance (TAA) applicable to workers and former workers of Sandy Alexander, Clifton, New Jersey (subject firm). The determination was issued on November 24, 2010. The Department's Notice of Determination was published in the **Federal Register** on December 8, 2010 (75 FR 76489). The workers are engaged in activities related to the production of printed materials.

The negative determination was based on the findings that the petitioning worker group did not meet the eligibility criteria set forth in the Trade Act of 1974, as amended.

In the request for reconsideration, the petitioner supplied new information regarding an alleged shift in production to China.

The Department has carefully reviewed the request for reconsideration and the existing record, and has determined that the Department will conduct further investigation to determine if the petitioning workers meet the eligibility requirements of the Trade Act of 1974, as amended.

Conclusion

After careful review of the application, I conclude that the claim is of sufficient weight to justify reconsideration of the U.S. Department of Labor's prior decision. The application is, therefore, granted.

Signed at Washington, DC, this 21st day of January, 2011.

Del Min Amy Chen,

Certifying Officer, Office of Trade Adjustment Assistance.

[FR Doc. 2011–2239 Filed 2–1–11; 8:45 am]

BILLING CODE 4510–FN–P

DEPARTMENT OF LABOR

Employment and Training Administration

[TA–W–70,123]

Electrolux Home Products, Inc., Electrolux Major Appliances Division, Including On-Site Leased Workers From Per Mar Security, Webster City, IA; Amended Certification Regarding Eligibility To Apply for Worker Adjustment Assistance

In accordance with Section 223 of the Trade Act of 1974, as amended ("Act"), 19 U.S.C. 2273, the Department of Labor issued a Certification of Eligibility to Apply for Worker Adjustment Assistance on June 25, 2009, applicable to workers of Electrolux Home Products, Inc., Electrolux Major Appliances Division, Webster City, Iowa. The notice as published in the **Federal Register** on August 19, 2009 (74 FR 41935). The workers produce laundry equipment.

At the request of the State agency, the Department reviewed the certification for workers of the subject firm. The company reports that workers leased from Per Mar Security were employed

on-site at the Webster City, Iowa location of Electrolux Home Products, Inc., Electrolux Major Appliances Division. The Department has determined that these workers were sufficiently under the control of Electrolux Home Products, Inc., Electrolux Major Appliances Division to be considered leased workers.

Based on these findings, the Department is amending this certification to include workers leased from Per Mar Security working on-site at the Webster City, Iowa location of Electrolux Home Products, Inc., Electrolux Major Appliances Division.

The amended notice applicable to TA–W–70,123 is hereby issued as follows:

All workers of Electrolux Home Products, Inc., Electrolux Major Appliances Division, including on-site leased workers from Per Mar Security, Webster City, Iowa, who became totally or partially separated from employment on or after May 18, 2008, through June 25, 2011, and all workers in the group threatened with total or partial separation from employment on the date of certification through two years from the date of certification, are eligible to apply for adjustment assistance under Chapter 2 of Title II of the Trade Act of 1974, as amended.

Signed at Washington, DC this 21st day of January 2011.

Elliott S. Kushner,

Certifying Officer, Division of Trade Adjustment Assistance.

[FR Doc. 2011–2238 Filed 2–1–11; 8:45 am]

BILLING CODE 4510–FN–P

DEPARTMENT OF LABOR

Employment and Training Administration

[TA–W–74,336]

Polaris Industries, Including On-Site Leased Workers From Westaff, Supply Technologies, Aerotek, and Securitas Security Services, Osceola, WI; Amended Certification Regarding Eligibility To Apply for Worker Adjustment Assistance

In accordance with Section 223 of the Trade Act of 1974, as amended ("Act"), 19 U.S.C. 2273, the Department of Labor issued a Certification of Eligibility to Apply for Worker Adjustment Assistance on August 26, 2010, applicable to workers of Polaris Industries, including on-site leased workers from Westaff, Osceola, Wisconsin. The notice was published in the **Federal Register** on September 15, 2010 (75 FR 56143). The notice was amended on December 6, 2010 to include on-site leased workers from Supply Technologies. The notice as published in the **Federal Register** on December 13, 2010 (75 FR 77666).

At the request of the State agency, the Department reviewed the certification for workers of the subject firm. The workers are engaged in activities related to the production of components for recreational vehicles.

The company reports that workers leased from Aerotek and Securitas Security Services were employed on-site at the Osceola, Wisconsin location of Polaris Industries. The Department has determined that these workers were sufficiently under the control of Polaris Industries to be considered leased workers.

Based on these findings, the Department is amending this certification to include workers leased from Aerotek and Securitas Security Services working on-site at the Osceola, Wisconsin location of Polaris Industries.

The amended notice applicable to TA–W–74,336 is hereby issued as follows:

All workers of Polaris Industries, including on-site leased workers from Westaff, Supply Technologies, Aerotek and Securitas Security Services, Osceola, Wisconsin, who became totally or partially separated from employment on or after June 28, 2009 through August 26, 2012, and all workers in the group threatened with total or partial separation from employment on the date of certification through two years from the date of certification, are eligible to apply for adjustment assistance under Chapter 2 of Title II of the Trade Act of 1974, as amended.

Signed at Washington, DC, this 21st day of January 2011.

Elliott S. Kushner,

Certifying Officer, Division of Trade Adjustment Assistance.

[FR Doc. 2011–2252 Filed 2–1–11; 8:45 am]

BILLING CODE 4510–FN–P

DEPARTMENT OF LABOR

Employment and Training Administration

[TA–W–72,972; TA–W–72,972A; TA–W–72,972B]

Amended Certification Regarding Eligibility to Apply for Worker Adjustment Assistance

TA–W–72,972
SUNGARD HIGHER EDUCATION, INC., DEVELOPMENT DIVISION INCLUDING ON–SITE LEASED WORKERS OF INTUITIVE INCLUDING OFF–SITE WORKERS ACROSS THE UNITED STATES, MALVERN, PENNSYLVANIA
TA–W–72,972A
SUNGARD HIGHER EDUCATION, INC., CONSULTING PRACTICES DIVISION INCLUDING ON–SITE LEASED WORKERS OF CICCARIELLO CONSULTING, INSTAMATION, INC., DYNAMIC METHODS, COLLEGIATE, CORNELIUS PROFESSIONAL SERVICES, CIBER, UC4 AND ENVISIONS INCLUDING OFF–SITE WORKERS ACROSS THE UNITED STATES, MALVERN, PENNSYLVANIA
TA–W–72,972B
SUNGARD HIGHER EDUCATION, INC., ACTIONLINE DIVISION INCLUDING ON–SITE LEASED WORKERS OF SICOM INCLUDING OFF–SITE WORKERS ACROSS THE UNITED STATES, MALVERN, PENNSYLVANIA

In accordance with Section 223 of the Trade Act of 1974, as amended ("Act"), 19 U.S.C. 2273, the Department of Labor issued a Certification of Eligibility to Apply for Worker Adjustment Assistance on March 3, 2010, applicable to workers of SunGard Higher Education, Inc., Malvern, Pennsylvania. The Department's notice of determination was published in the **Federal Register** on April 23, 2010 (75 FR 21361).

At the request of State agency, the Department reviewed the certification for workers of the subject firm. The workers are engaged in employment related to the supply of computer systems design and support services for colleges and universities.

New information shows that worker separations have occurred involving off-site employees of the Development Division, the Consulting Practices Division and the Actionline Division of SunGard Higher Education, Inc., Malvern, Pennsylvania. Employees working off-site across the United States are under the control of the subject firm and the supply of computer systems design and support services for the subject firm.

The intent of the Department's certification is to include all workers of the subject firm who were adversely affected by shift in services of employment related to the supply of computer systems design and support services to India.

Based on these findings, the Department is amending this certification to include employees of the subject firm's Malvern, Pennsylvania, facility working off-site across the United States.

The amended notice applicable to TA–W–72,972, TA–W–72972A, and TA–W–72,972B, are hereby issued as follows:

All workers of SunGard Higher Education, Inc., Development Division, including on-site leased workers of Intuitive, including off-site workers across the United States, Malvern, Pennsylvania (TA–W–72,972); SunGard Higher Education, Inc., Consulting Practices

Division, including on-site leased workers of Ciccariello Consulting, Instamation, Inc., Dynamic Methods, Collegiate, Cornelius Professional Services, Ciber, UC4 and Envisions, including off-site workers across the United States, Malvern, Pennsylvania (TA–W–72,972A); SunGard Higher Education, Inc., Actionline Division, including on-site leased workers of SICOM, including off-site workers across the United States, Malvern, Pennsylvania (TA–W–72,972B) who became totally or partially separated from employment on or after November 25, 2008, through March 3, 2012, and all workers in the group threatened with total or partial separation from employment on the date of certification through two years from the date of certification, are eligible to apply for adjustment assistance under Chapter 2 of Title II of the Trade Act of 1974, as amended.

Signed in Washington, DC, this 24th day of January, 2011.

Elliott S. Kushner,

Certifying Officer, Office of Trade Adjustment Assistance.

[FR Doc. 2011–2250 Filed 2–1–11; 8:45 am]

BILLING CODE 4510–FN–P

DEPARTMENT OF LABOR

Employment and Training Administration

[TA–W–71,248]

International Business Machines Corporation, Global Technology Services Business Unit, Integrated Technology Services, Cost and Expense Team, Payroll, Travel and Mobility Services Team, Working From Various States In the United States, Reporting to Armonk, New York, Including On-Site Leased Workers From Datrose, Inc., Armonk, New York; Amended Certification Regarding Eligibility To Apply for Worker Adjustment Assistance

In accordance with Section 223 of the Trade Act of 1974, as amended ("Act"), 19 U.S.C. 2273, the Department of Labor issued a Certification of Eligibility to apply for Worker Adjustment Assistance on July 31, 2009, applicable to workers of International Business Machines Corporation, Global Technology Services Business Unit, Integrated Technology Services, Cost and Expense Team, working from various states in the United States and reporting to Armonk, New York. The Department's notice was published in the **Federal Register** on April 23, 2010 (75 FR 21355).

The certification was amended on April 8, 2010 to leased workers from Datrose, Inc. working on-site at the Armonk, New York facility. The Department's notice was published in the **Federal Register** on April 19, 2010 (75 FR 20388–20389).

At the request of a company official, the Department reviewed the certification for workers of the subject firm. The workers are engaged in activities related to support for the Global Technology Services Business Unit.

The company reports that workers of the Payroll, Travel, and Mobility Services Team were part of the International Business Machines Corporation, Global Technology Services Business Unit, Integrated Technology Services, reporting to the Armonk, New York facility. The Department has determined that workers of the Payroll, Travel, and Mobility Services Team were affected by the subject firm's shift in supply of like or directly competitive services to India.

Based on these findings, the Department is amending this certification to include workers in the Payroll, Travel, and Mobility Services Team of International Business Machines Corporation, Global Technology Services Business Unit, Integrated Technology Services, reporting to the Armonk, New York facility.

The amended notice applicable to TA–W–71,248 is hereby issued as follows:

All workers of International Business Machines Corporation, Global Technology Services Business Unit, Integrated Technology Services, Cost and Expense Team, Payroll, Travel, and Mobility Services Team, working in various states but reporting to Armonk, New York, including on-site leased workers from Datrose, Inc., Armonk, New York, who became totally or partially separated from employment on or after June 1, 2008, through July 31, 2011, and all workers in the group threatened with total or partial separation from employment on date of certification through two years from the date of certification, are eligible to apply for adjustment assistance under Chapter 2 of Title II of the Trade Act of 1974, as amended.

Signed in Washington, DC, this 21st day of January, 2011.

Del Min Amy Chen,

Certifying Officer, Office of Trade Adjustment Assistance.

[FR Doc. 2011–2249 Filed 2–1–11; 8:45 am]

BILLING CODE 4510–FN–P

DEPARTMENT OF LABOR

Employment and Training Administration

Notice of Determinations Regarding Eligibility to Apply for Worker Adjustment Assistance

In accordance with Section 223 of the Trade Act of 1974, as amended (19 U.S.C. 2273) the Department of Labor herein presents summaries of determinations regarding eligibility to apply for trade adjustment assistance for workers by (TA–W) number issued during the period of *January 17, 2011 through January 21, 2011.*

In order for an affirmative determination to be made for workers of a primary firm and a certification issued regarding eligibility to apply for worker adjustment assistance, each of the group eligibility requirements of Section 222(a) of the Act must be met.

I. Under Section 222(a)(2)(A), the following must be satisfied:

(1) A significant number or proportion of the workers in such workers' firm have become totally or partially separated, or are threatened to become totally or partially separated;

(2) the sales or production, or both, of such firm have decreased absolutely; and

(3) One of the following must be satisfied:

(A) imports of articles or services like or directly competitive with articles produced or services supplied by such firm have increased;

(B) imports of articles like or directly competitive with articles into which one or more component parts produced by such firm are directly incorporated, have increased;

(C) imports of articles directly incorporating one or more component parts produced outside the United States that are like or directly competitive with imports of articles incorporating one or more component parts produced by such firm have increased;

(D) imports of articles like or directly competitive with articles which are produced directly using services supplied by such firm, have increased; and

(4) the increase in imports contributed importantly to such workers' separation or threat of separation and to the decline in the sales or production of such firm; or

II. Section 222(a)(2)(B) all of the following must be satisfied:

(1) A significant number or proportion of the workers in such workers' firm have become totally or partially

separated, or are threatened to become totally or partially separated;

(2) One of the following must be satisfied:

(A) There has been a shift by the workers' firm to a foreign country in the production of articles or supply of services like or directly competitive with those produced/supplied by the workers' firm;

(B) there has been an acquisition from a foreign country by the workers' firm of articles/services that are like or directly competitive with those produced/supplied by the workers' firm; and

(3) the shift/acquisition contributed importantly to the workers' separation or threat of separation.

In order for an affirmative determination to be made for adversely affected workers in public agencies and a certification issued regarding eligibility to apply for worker adjustment assistance, each of the group eligibility requirements of Section 222(b) of the Act must be met.

(1) A significant number or proportion of the workers in the public agency have become totally or partially separated, or are threatened to become totally or partially separated;

(2) the public agency has acquired from a foreign country services like or directly competitive with services which are supplied by such agency; and

(3) the acquisition of services contributed importantly to such workers' separation or threat of separation.

In order for an affirmative determination to be made for adversely affected secondary workers of a firm and a certification issued regarding eligibility to apply for worker adjustment assistance, each of the group eligibility requirements of Section 222(c) of the Act must be met.

(1) A significant number or proportion of the workers in the workers' firm have become totally or partially separated, or are threatened to become totally or partially separated;

(2) the workers' firm is a Supplier or Downstream Producer to a firm that employed a group of workers who received a certification of eligibility under Section 222(a) of the Act, and such supply or production is related to the article or service that was the basis for such certification; and

(3) either—

(A) the workers' firm is a supplier and the component parts it supplied to the firm described in paragraph (2) accounted for at least 20 percent of the production or sales of the workers' firm; or

(B) a loss of business by the workers' firm with the firm described in paragraph (2) contributed importantly to the workers' separation or threat of separation.

In order for an affirmative determination to be made for adversely affected workers in firms identified by the International Trade Commission and a certification issued regarding eligibility to apply for worker adjustment assistance, each of the group eligibility requirements of Section 222(f) of the Act must be met.

(1) The workers' firm is publicly identified by name by the International Trade Commission as a member of a domestic industry in an investigation resulting in—

(A) An affirmative determination of serious injury or threat thereof under section 202(b)(1);

(B) an affirmative determination of market disruption or threat thereof under section 421(b)(1); or

(C) an affirmative final determination of material injury or threat thereof under section 705(b)(1)(A) or 735(b)(1)(A) of the Tariff Act of 1930 (19 U.S.C. 1671d(b)(1)(A) and 1673d(b)(1)(A));

(2) the petition is filed during the 1-year period beginning on the date on which—

(A) a summary of the report submitted to the President by the International Trade Commission under section 202(f)(1) with respect to the affirmative determination described in paragraph (1)(A) is published in the Federal Register under section 202(f)(3); or

(B) notice of an affirmative determination described in subparagraph (1) is published in the Federal Register; and

(3) the workers have become totally or partially separated from the workers' firm within—

(A) the 1-year period described in paragraph (2); or

(B) notwithstanding section 223(b)(1), the 1-year period preceding the 1-year period described in paragraph (2).

Affirmative Determinations for Worker Adjustment Assistance

The following certifications have been issued. The date following the company name and location of each determination references the impact date for all workers of such determination.

The following certifications have been issued. The requirements of Section 222(a)(2)(A) (increased imports) of the Trade Act have been met.

TA–W No.	Subject firm	Location	Impact date
74,161	Mestek, Inc	Wrens, GA	May 28, 2009.
74,162	Designs Des Carolines	Morganton, NC	May 24, 2009.
74,193	Mission Valley Cabinet and Countertech	Poway, CA	June 1, 2009.
74,202	Hubbell Lighting, Inc., HLI Division, Hubbell, Inc	Christiansburg, VA	May 27, 2009.
74,206	CenterPoint Teleservices, LLC, Leased Workers from Robert Half Management Resources, etc.	Eliot, ME	June 4, 2009.
74,389	Domtar Paper Company, Inc., Accountemps, Manpower	Cerritos, CA	July 16, 2009.
74,428	MH Technologies, LLC	Mt. Holly Springs, PA	May 19, 2009.
74,565	Smead Manufacturing Company	McGregor, TX	August 25, 2009.
74,596	International Communication Materials, Inc., Nukote International, Inc.	Connellsville, PA	August 31, 2009.
74,720	Environ Biocomposites Manufacturing, LLC	Mankato, MN	October 11, 2009.
74,741	Seneca Foods Corporation	Buhl, ID	September 10, 2009.
74,760	Eagle Industries, LLC	Bowling Green, KY	October 15, 2009.
74,766	Rocon Manufacturing Corporation	Rochester, NY	October 12, 2009.
74,970	The Wise Company, Inc., A Subsidiary of D. Canale Company, Inc.	Piggott, AR	December 7, 2009.

The following certifications have been issued. The requirements of Section 222(a)(2)(B) (shift in production or services) of the Trade Act have been met.

TA–W number	Subject firm	Location [1]	Impact date
74,188	Siemens IT Solutions and Services, Inc., Client Support Services (CSS) Unit, Native Staffing, etc.	Bellefontaine, OH	May 21, 2009.
74,633	The Estee Lauder Companies Inc., Information Technology Help Desk, ELC Management LLC and Sourcewave, Inc.	Melville, NY	September 15, 2009.
74,633A	Aveda Corporation, A Wholly Owned Subsidiary of the Estee Lauder Companies Inc., IT Help Desk.	Blaine, MN	September 15, 2009.
74,651	Time Insurance Company, dba Assurant Health, Answerport, Inc., etc.	Milwaukee, WI	September 21, 2009.
74,651A	Time Insurance Company, DBA Assurant Health, Manpower	Plymouth, MN	September 21, 2009.
74,654	Plainfield Stamping—Texas, Inc., Plainfield Tool & Engineering, Inc., Select Staffing.	El Paso, TX	September 2, 2009.
74,695	Vico Company, Leased Workers from Roper Personnel Services	Sumter, SC	October 4, 2009.
74,701	Avaya, Inc., Global Sales, Nortel Networks, DiamondWare, etc	Basking Ridge, NJ	October 5, 2009.
74,851	EMC Corporation, Information Infrastructure Products; Unified Storage, Off-Site Workers, etc.	Hopkinton, MA	November 5, 2009.
74,874	Solo Cup Operating Corporation	North Andover, MA	November 8, 2009.
74,875	Pitney Bowes, Global Financial Services Unit, Purchase Power Collections.	Spokane, WA	November 10, 2009.
74,892	Stanley Black and Decker, CDIY Division; Leased Workers from Manpower.	McAllen, TX	November 8, 2009.
74,909	Heritage Valley Health System, Pennsylvanian Medical Transcriptionist, Work from Home.	Moon Township, PA	November 5, 2009.
74,972	CEVA Logistics, U.S., Inc., Accountemps, Randstad Work Solutions, ICX Group.	Jacksonville, FL	December 6, 2009.
75,004	Burroughs Payment Systems, Inc., Including Workers Whose Wages Were Reported Under Unisys Corporation.	Plymouth, MI	December 14, 2009.
75,004A	Leased Workers from Pinnacle, Renhill and Snelling, Working On-Site at Burroughs Payment Systems, Inc.	Plymouth, MI	December 14, 2009.
75,019	Suss Microtec, Inc., Technical Connections, Inc.	Waterbury Center, VT	December 20, 2009.
75,032	PricewaterhouseCoopers LLP, Internal Firm Services	Detroit, MI	December 15, 2009.
75,037	Hartford Compressors, Inc., Dunham—Bush Industries, SDN BHD.	West Hartford, CT	December 21, 2009.
75,064	SOPHOS, Inc.	Dublin, OH	January 3, 2010.
75,068	Dana Holding Corporation, Off Highway Division, Manpower, Inc., Accountemp, Aerotek.	Lugoff, SC	January 3, 2010.
75,074	MAHLE Industries, Inc., MAHLE Engine Components USA, Inc.	Franklin, KY	January 6, 2010.
75,074A	MAHLE Industries, Inc., MAHLE Engine Components USA, Inc., Purchasing Unit.	Muskegon, MI	January 6, 2010.
75,078	NGK Spark Plugs (USA), Inc., NGK Spark Plugs Co., Ltd, Select Staffing, Express Employment.	Irvine, CA	January 10, 2010.
75,084	Valley Towing Products, Express Personnel Services and Accountabilities.	Lodi, CA	January 11, 2010.

The following certifications have been issued. The requirements of Section 222(c) (supplier to a firm whose workers are certified eligible to apply for TAA) of the Trade Act have been met.

TA–W No.	Subject firm	Location [1]	Impact date
74,226	Starn Tool and Manufacturing Company	Meadville, PA	June 7, 2009.
74,825	Mountain City Lumber Company, Roan Sawmill, Cranberry Hardwoods, Inc.	Roan Mountain, TN	October 25, 2009.
74,825A	Mountain City Lumber Company, Sawmill, Cranberry Hardwoods, Inc.	Mountain City, TN	October 25, 2009.
74,825B	Mountain City Lumber Company, Kiln/Millworks, Cranberry Hardwoods, Inc.	Mountain City, TN	October 25, 2009.
74,926	Advance Urethane Technologies, Inc., Sleep Innovation	Dubuque, IA	November 30, 2009.

Negative Determinations for Worker Adjustment Assistance

In the following cases, the investigation revealed that the eligibility criteria for worker adjustment assistance have not been met for the reasons specified.

The investigation revealed that the criterion under paragraph (a)(1), or (b)(1), or (c)(1) (employment decline or threat of separation) of section 222 has not been met.

TA–W No.	Subject firm	Location [1]	Impact date
74,323	Verizon Business Network Services, Inc., Verizon Communications, Inc.	Miami, FL	

The investigation revealed that the criteria under paragraphs (a)(2)(A) (increased imports) and (a)(2)(B) (shift in production or services to a foreign country) of section 222 have not been met.

TA–W No.	Subject firm	Location [1]	Impact date
74,070	California Redwood Company	Eureka, CA	
74,635	Wells Fargo Bank, NA, Formerly Wachovia Corporation, Business Banking Division.	Wilkesboro, NC	
74,856	ACS Education Services, Inc., Financial Services Division	Long Beach, CA	
74,943	Assurant, Inc., Business Enterprise Application Services Division	Woodbury, MN	

Determinations Terminating Investigations of Petitions for Worker Adjustment Assistance

After notice of the petitions was published in the **Federal Register** and on the Department's Web site, as required by Section 221 of the Act (19 U.S.C. 2271), the Department initiated investigations of these petitions.

The following determinations terminating investigations were issued because the petitioner has requested that the petition be withdrawn.

TA–W No.	Subject firm	Location [1]	Impact date
74,769	Goodrich Lighting Systems	Oldsmar, FL	

I hereby certify that the aforementioned determinations were issued during the period of *January 17, 2011 through January 21, 2011.* Copies of these determinations may be requested under the Freedom of Information Act. Requests may be submitted by fax, courier services, or mail to FOIA Disclosure Officer, Office of Trade Adjustment Assistance (ETA), U.S. Department of Labor, 200 Constitution Avenue, NW., Washington, DC 20210 or *tofoiarequest@dol.gov.* These determinations also are available on the Department's Web site at *http://www.doleta.gov/tradeact* under the searchable listing of determinations.

Dated: January 25, 2011.

Elliott S. Kushner,

Certifying Officer, Office of Trade Adjustment Assistance.

[FR Doc. 2011–2246 Filed 2–1–11; 8:45 am]

BILLING CODE 4510–FN–P

DEPARTMENT OF LABOR

Employment and Training Administration

Investigations Regarding Certifications of Eligibility To Apply for Worker Adjustment Assistance

Petitions have been filed with the Secretary of Labor under Section 221(a) of the Trade Act of 1974 ("the Act") and are identified in the Appendix to this notice. Upon receipt of these petitions, the Director of the Division of Trade Adjustment Assistance, Employment and Training Administration, has instituted investigations pursuant to Section 221(a) of the Act.

The purpose of each of the investigations is to determine whether the workers are eligible to apply for adjustment assistance under Title II, Chapter 2, of the Act. The investigations will further relate, as appropriate, to the determination of the date on which total or partial separations began or threatened to begin and the subdivision of the firm involved.

The petitioners or any other persons showing a substantial interest in the subject matter of the investigations may request a public hearing, provided such request is filed in writing with the Director, Division of Trade Adjustment Assistance, at the address shown below, not later than February 14, 2011.

Interested persons are invited to submit written comments regarding the subject matter of the investigations to the Director, Division of Trade Adjustment Assistance, at the address shown below, not later than February 14, 2011.

Copies of these petitions may be requested under the Freedom of Information Act. Requests may be submitted by fax, courier services, or mail, to FOIA Disclosure Officer, Office of Trade Adjustment Assistance (ETA), U.S. Department of Labor, 200 Constitution Avenue, NW., Washington, DC 20210 or to *foiarequest@dol.gov.*

Signed at Washington, DC, this 25th day of January 2011.

Elliott S. Kushner,

Certifying Officer, Office of Trade Adjustment Assistance.

APPENDIX

[TAA Petitions Instituted between 1/3/11 and 1/7/11]

TA–W	Subject firm (petitioners)	Location	Date of institution	Date of petition
75059	Durex Products, Inc. (Workers)	St. Croix Falls, WI	01/03/11	12/28/10
75060	Sitel Operating Corporation (State/One-Stop)	Painted Post, NY	01/03/11	12/31/10
75061	Liberty Homes, Inc. (Workers)	Sheridan, OR	01/03/11	12/30/10

APPENDIX—Continued

[TAA Petitions Instituted between 1/3/11 and 1/7/11]

TA–W	Subject firm (petitioners)	Location	Date of institution	Date of petition
75062	Bucyrus Community Hospital, Inc. (Company)	Bucyrus, OH	01/03/11	12/30/10
75063	NewPage Corporation (Company)	Stevens Point, WI	01/03/11	12/31/10
75064	SOPHOS, Inc. (Workers)	Dublin, OH	01/04/11	01/03/11
75065	Bank of America (State/One-Stop)	Los Angeles, CA	01/04/11	01/03/11
75066	General Wholesale Building Supply (Workers)	New Bern, NC	01/04/11	12/30/10
75067	JLG Industries (Workers)	McConnellsburg, PA	01/04/11	01/03/10
75068	Dana Holding Corporation (Company)	Lugoff, SC	01/04/11	01/03/11
75069	Reliance Globalcom Inc. (Worker)	Denver, CO	01/05/11	12/28/10
75070	EHS—Episcopal Health Services (Workers)	Bethpage, NY	01/06/11	01/05/11
75071	Holophone Division of Acuity Brands Lighting (Workers)	Newark, OH	01/06/11	01/04/11.
75072	National Gypsum Company (Workers)	Charlotte, NC	01/07/11	01/06/11
75073	Thomson Reuters (Workers)	Philadelphia, PA	01/07/11	01/06/11

[FR Doc. 2011–2243 Filed 2–1–11; 8:45 am]

BILLING CODE 4510–FN–P

DEPARTMENT OF LABOR

Employment and Training Administration

Investigations Regarding Certifications of Eligibility To Apply for Worker Adjustment Assistance

Petitions have been filed with the Secretary of Labor under Section 221(a) of the Trade Act of 1974 ("the Act") and are identified in the Appendix to this notice. Upon receipt of these petitions, the Director of the Division of Trade Adjustment Assistance, Employment and Training Administration, has instituted investigations pursuant to Section 221(a) of the Act.

The purpose of each of the investigations is to determine whether the workers are eligible to apply for adjustment assistance under Title II, Chapter 2, of the Act. The investigations will further relate, as appropriate, to the determination of the date on which total or partial separations began or threatened to begin and the subdivision of the firm involved.

The petitioners or any other persons showing a substantial interest in the subject matter of the investigations may request a public hearing, provided such request is filed in writing with the Director, Division of Trade Adjustment Assistance, at the address shown below, not later than February 14, 2011.

Interested persons are invited to submit written comments regarding the subject matter of the investigations to the Director, Division of Trade Adjustment Assistance, at the address shown below, not later than February 14, 2011.

Copies of these petitions may be requested under the Freedom of Information Act. Requests may be submitted by fax, courier services, or mail, to FOIA Disclosure Officer, Office of Trade Adjustment Assistance (ETA), U.S. Department of Labor, 200 Constitution Avenue, NW., Washington, DC 20210 or to *foiarequest@dol.gov.*

Signed at Washington, DC, this 25th day of January 2011.

Elliott S. Kushner,

Certifying Officer, Office of Trade Adjustment Assistance.

APPENDIX

[TAA petitions instituted between 1/17/11 and 1/21/11]

TA–W	Subject firm (petitioners)	Location	Date of institution	Date of petition
75104	Eaton Corporation (Company)	Three Rivers, MI	01/18/11	01/14/11
75105	National Standard/Davis Wire (Company)	Niles, MI	01/18/11	01/14/11
75106	The Factory Company International Inc. (State/One-Stop)	Spokane, WA	01/18/11	01/14/11
75107	Hewlett Packard, Global Business Intelligence (GBI) (State/One-Stop).	Fort Collins, CO	01/18/11	01/07/11
75108	The Fish Harder Companies, LLC (Workers)	Clymer, PA	01/18/11	01/14/11
75109	DATROSE (Company)	Endicott, NY	01/18/11	01/14/11
75110	Propex Operating Company (Company)	Hazlehurst, GA	01/19/11	01/18/11
75111	Affiliated Computer Services (ACS) (Workers)	Schaumburg, IL	01/19/11	01/18/11
75112	Gam Manufacturing Company (Company)	Lancaster, PA	01/19/11	01/17/11
75113	Thomas & Betts Reznor (Union)	Mercer, PA	01/19/11	01/14/11
75114	Allentown Metal Works, Inc. (Union)	Allentown, PA	01/19/11	01/15/11
75115	Accenture (Workers)	Chicago, IL	01/19/11	01/18/11
75116	Cooper Power Systems (Company)	Pewaukee, WI	01/19/11	01/18/11
75117	Acuity Brands Lighting (Company)	Austin, TX	01/19/11	01/18/11
75118	Fairbanks Morse Engine (Union)	Beloit, WI	01/20/11	01/18/11
75119	Acme-McCrary Corporation (Company)	Asheboro, NC	01/20/11	01/19/11
75120	Steelcase Inc. (Company)	Grand Prairie, TX	01/20/11	01/18/11
75121	Maine Industrial Tire LLC (Company)	Wakefield, MA	01/20/11	01/19/11
75122	Imation Corp (Company)	Oakdale, MN	01/20/11	01/18/11
75123	Smith-Haist Dental Laboratory (Workers)	Palm Harbor, FL	01/20/11	01/19/11
75124	Imation Corporation (Company)	Weatherford, OK	01/20/11	01/19/11
75125	WestPoint Home Greenville Distribution Center (Company)	Greenville, AL	01/20/11	01/19/11

APPENDIX—Continued

[TAA petitions instituted between 1/17/11 and 1/21/11]

TA–W	Subject firm (petitioners)	Location	Date of institution	Date of petition
75126	Blue Cross Blue Shield (Company)	Durham, NC	01/21/11	12/20/10

[FR Doc. 2011–2245 Filed 2–1–11; 8:45 am]

BILLING CODE 4510–FN–P

DEPARTMENT OF LABOR

Employment and Training Administration

Investigations Regarding Certifications of Eligibility To Apply for Worker Adjustment Assistance

Petitions have been filed with the Secretary of Labor under Section 221(a) of the Trade Act of 1974 ("the Act") and are identified in the Appendix to this notice. Upon receipt of these petitions, the Director of the Division of Trade Adjustment Assistance, Employment and Training Administration, has instituted investigations pursuant to Section 221(a) of the Act.

The purpose of each of the investigations is to determine whether the workers are eligible to apply for adjustment assistance under Title II, Chapter 2, of the Act. The investigations will further relate, as appropriate, to the determination of the date on which total or partial separations began or threatened to begin and the subdivision of the firm involved.

The petitioners or any other persons showing a substantial interest in the subject matter of the investigations may request a public hearing, provided such request is filed in writing with the Director, Division of Trade Adjustment Assistance, at the address shown below, not later than February 14, 2011.

Interested persons are invited to submit written comments regarding the subject matter of the investigations to the Director, Division of Trade Adjustment Assistance, at the address shown below, not later than February 14, 2011.

Copies of these petitions may be requested under the Freedom of Information Act. Requests may be submitted by fax, courier services, or mail, to FOIA Disclosure Officer, Office of Trade Adjustment Assistance (ETA), U.S. Department of Labor, 200 Constitution Avenue, NW., Washington, DC 20210 or to *foiarequest@dol.gov.*

Signed at Washington, DC this 25th day of January 2011.

Elliott S. Kushner,

Certifying Officer, Office of Trade Adjustment Assistance.

APPENDIX

[TAA petitions instituted between 1/10/11 and 1/14/11]

TA–W	Subject firm (petitioners)	Location	Date of institution	Date of petition
75074	MAHLE Industries, Inc. (Company)	Franklin, KY	01/10/11	01/06/11
75074A	MAHLE Industries, Inc. (Company)	Muskegon, MI	01/10/11	01/06/11
75075	Autodesk, Inc (Workers)	Manchester, NH	01/10/11	01/07/11
75076	Sheet Metal Workers Local 80 (Workers)	Southfield, MI	01/10/11	12/20/10
75077	Dama Jewelry Technology, Inc. (Company)	Johnston, RI	01/10/11	01/07/11
75078	NGK Spark Plugs (USA), Inc (Company)	Irvine, CA	01/11/11	01/10/11
75079	Thomasville Furniture Industries Inc. (Company)	Appomattox, VA	01/11/11	01/07/11
75080	Esselte (State/One-Stop)	Mattoon, IL	01/11/11	01/07/11
75081	Crawford Furniture (Workers)	Jamestown, NY	01/11/11	01/07/11
75082	Simmons Manufacturing Co., LLC (Company)	Neenah, WI	01/11/11	01/07/11
75083	Detroit Axel Plant—Chrysler (Union)	Detroit, MI	01/11/11	12/16/10
75084	Valley Towing Products (Company)	Lodi, CA	01/12/11	01/11/11
75085	Hyde Tools Inc. (Company)	Southbridge, MA	01/12/11	01/11/11
75086	Callaway Golf Company (Company)	Carlsbad, CA	01/12/11	01/10/11
75087	International Business Machines Corp. (State/One-Stop)	Jan Jose, CA	01/12/11	12/22/10
75088	Rieck Mechanical (Company)	Dayton, OH	01/12/11	01/06/11
75089	Startek (State/One-Stop)	Alexandria, LA	01/12/11	01/10/11
75090	Gannett Co., Inc. (Workers)	Wausau, WI	01/12/11	01/05/11
75091	Hotels.com (Workers)	Dallas, TX	01/12/11	01/10/11
75092	Jacobson Hat Co., Inc. (Company)	Scranton, PA	01/13/11	01/07/11
75093	Yakama Forest Products (State/One-Stop)	White Swan, WA	01/13/11	01/12/11
75094	Alstyle Apparel (Company)	Anaheim, CA	01/13/11	01/12/11
75095	InterMetro Industries Corporation (Company)	Wilkes-Barre, PA	01/13/11	01/12/11
75096	Hilton Worldwide (Workers)	Memphis, TN	01/13/11	01/12/11
75097	Fraser Timber Limited (Company)	Ashland, ME	01/13/11	10/22/10
75098	IBM (Company)	Research Triangle Park, NC	01/14/11	01/10/11
75099	Thomson Reuters (State/One-Stop)	Albuquerque, NM	01/14/11	01/13/11
75100	STEC, Inc. (Company)	Santa Ana, CA	01/14/11	01/13/11
75101	Burke Grading and Paving, Inc. (Company)	Drexel, NC	01/14/11	01/13/11
75102	Guilford Mills, Inc. (Workers)	Pine Grove, PA	01/14/11	01/10/11
75103	Sun Mountain Sports, Inc. (Company)	Missoula, MT	01/14/11	01/11/11

[FR Doc. 2011–2244 Filed 2–1–11; 8:45 am]

BILLING CODE 4510–FN–P

DEPARTMENT OF LABOR

Employment and Training Administration

[TA–W–73,091]

The Basic Aluminum Castings Co., Cleveland, OH; Notice of Revised Determination on Reconsideration

By application dated December 3, 2010, The International Union, United Automobile, Aerospace and Agricultural Implement Workers of America, Region 2B, requested administrative reconsideration of the negative determination regarding workers' eligibility to apply for Trade Adjustment Assistance (TAA) applicable to workers and former workers of The Basic Aluminum Castings Co., Cleveland, Ohio (subject firm). The determination was issued on October 14, 2010. The Department's Notice of Determination was published in the **Federal Register** on November 3, 2010 (75 FR 67773). Workers at the subject firm are engaged in employment related to the production of aluminum die castings.

New information revealed that, during the period of investigation, imports of articles like or directly competitive aluminum die castings produced by the subject firm have increased. Specifically, the Department of Labor conducted a survey of the subject firm's major declining customer regarding their purchases of aluminum die castings during the relevant period. The survey revealed increased customer reliance on imported aluminum die castings.

Finally, Section 222(a)(2)(A)(iii) has been met because the increased imports of aluminum die castings by a customer of the subject firm contributed importantly to the worker group separations and sales/production declines at the subject firm.

Conclusion

After careful review of the additional facts obtained during the reconsideration investigation, I determine that workers of The Basic Aluminum Castings Co., Cleveland, Ohio, who are engaged in employment related to the production of aluminum die castings, meet the worker group certification criteria under Section 222(a) of the Act, 19 U.S.C. 2272(a). In accordance with Section 223 of the Act, 19 U.S.C. 2273, I make the following certification:

"All workers of The Basic Aluminum Castings Co., Cleveland, Ohio, who became totally or partially separated from employment on or after December 2, 2008, through two years from the date of this revised certification, and all workers in the group threatened with total or partial separation from employment on date of certification through two years from the date of certification, are eligible to apply for adjustment assistance under Chapter 2 of Title II of the Trade Act of 1974, as amended."

Signed in Washington, DC, this 21st day of January 2011.

Del Min Amy Chen,

Certifying Officer, Office of Trade Adjustment Assistance.

[FR Doc. 2011–2251 Filed 2–1–11; 8:45 am]

BILLING CODE 4510–FN–P

DEPARTMENT OF LABOR

Employment and Training Administration

[TA–W–74,290]

Supermedia LLC, Formerly Known as Idearc Media LLC, Supermedia Information Services LLC, Client Care Group and Publishing Operations Group Including On-Site Leased Workers Of Advantage (TAC), Resprcconn, Tataconssv, Modis, Amdocs, and Database; Middleton, Massachusetts; Notice of Revised Determination on Reconsideration

By application dated October 7, 2010, the petitioner requested administrative reconsideration of the Department's negative determination regarding the eligibility of workers and former workers of SuperMedia LLC, formerly known as Idearc Media LLC, Client Care Group and Publishing Operations Group, Middleton, Massachusetts to apply for Trade Adjustment Assistance (TAA). On October 7, 2010, the Department issued a Notice of Affirmative Determination Regarding Application for Reconsideration applicable to workers of the subject firm. The Notice was published in the **Federal Register** on October 25, 2010 (75 FR 65515). The subject workers are engaged in employment related to the supply of customer service, publishing support services, and publishing operations.

During the reconsideration investigation, the Department received information that revealed that the subject firm had shifted to a foreign country a portion of the supply of services like or directly competitive with the services supplied by the subject workers, and that the shift in services contributed importantly to worker group separations at the subject firm.

Conclusion

After careful review of the additional facts obtained on reconsideration, I determine that workers of the subject firm, who are engaged in employment related to the supply of customer service, publishing support services, and publishing operations, meet the worker group certification criteria under Section 222(a) of the Act, 19 U.S.C. 2272(a). In accordance with Section 223 of the Act, 19 U.S.C. 2273, I make the following certification:

"All workers of SuperMedia LLC, formerly known as Idearc Media LLC, Supermedia Information Services LLC, Client Care Group and Publishing Operations Group, including on-site leased workers from Advantage (TAC), Resprcconn, Tataconssv, Modis, Amdocs, and Database, Middleton, Massachusetts, who became totally or partially separated from employment on or after June 23, 2009, through two years from the date of this revised certification, and all workers in the group threatened with total or partial separation from employment on date of certification through two years from the date of certification, are eligible to apply for adjustment assistance under Chapter 2 of Title II of the Trade Act of 1974, as amended."

Signed in Washington, DC, this 21st day of January, 2011.

Del Min Amy Chen,

Certifying Officer, Office of Trade Adjustment Assistance.

[FR Doc. 2011–2248 Filed 2–1–11; 8:45 am]

BILLING CODE 4510–FN–P

DEPARTMENT OF LABOR

Employment and Training Administration

[TA–W–73,756]

Progressive Furniture, Inc.; a Subsidiary of Sauder Furniture, Claremont, North Carolina; Notice of Revised Determination on Reconsideration

On August 13, 2010, the Department issued an Affirmative Determination Regarding Application for Reconsideration applicable to workers and former workers of Progressive Furniture, Inc., a Subsidiary of Sauder Furniture, Claremont, North Carolina to apply for Trade Adjustment Assistance (TAA). The Department's Notice of Affirmative Determination was published in the **Federal Register** on November 12, 2010 (75 FR 69468). Workers at the subject firm are engaged in employment related to the supply of

decommissioning services for Progressive Furniture.

Workers of Progressive Furniture producing wooden furniture were certified eligible to apply for TAA on the basis of increased company imports of articles like or directly competitive with those manufactured by the worker group at the subject firm.

During the reconsideration investigation, the Department determined that the workers at Progressive Furniture, Inc., a Subsidiary of Sauder Furniture, Claremont, North Carolina, who are engaged in employment related to the supply of decommissioning services, have met the criteria of Section 222(a).

Conclusion

After careful review of the facts provided during the initial investigation, I determine that workers of Progressive Furniture, Inc., Claremont, North Carolina, who are engaged in employment related to the supply of decommissioning services, meet the worker group certification criteria under Section 222(a) of the Act, 19 U.S.C. 2272(a). In accordance with Section 223 of the Act, 19 U.S.C. 2273, I make the following certification:

"All workers of Progressive Furniture, Inc., a Subsidiary of Sauder Furniture, Claremont, North Carolina, who became totally or partially separated from employment on or after March 19, 2009, through two years from the date of this revised certification, and all workers in the group threatened with total or partial separation from employment on date of certification through two years from the date of certification, are eligible to apply for adjustment assistance under Chapter 2 of Title II of the Trade Act of 1974, as amended."

Signed in Washington, DC, this 21st day of January, 2011.

Del Min Amy Chen,

Certifying Officer, Office of Trade Adjustment Assistance.

[FR Doc. 2011–2247 Filed 2–1–11; 8:45 am]

BILLING CODE 4510–FN–P

NATIONAL SCIENCE FOUNDATION

Agency Information Collection Activities: Comment Request

AGENCY: National Science Foundation.

ACTION: Submission for OMB review; comment request.

SUMMARY: The National Science Foundation (NSF) has submitted the following information collection requirement to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995, Public Law 104–13. This is the second notice for public comment; the first was published in the **Federal Register** at 75 FR 68829, and no substantial comments were received. NSF is forwarding the proposed renewal submission to OMB for clearance simultaneously with publication of this second notice. The full submission may be found at: *http://www.reginfo.gov/public/do/PRAMain.* Comments regarding: (a) Whether the collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden, 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 collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology should be addressed to: Office of Information and Regulatory Affairs of OMB, Attention: Desk Officer for National Science Foundation, 725 17th Street, NW., Room 10235, Washington, DC 20503, and to Suzanne H. Plimpton, Reports Clearance Officer, National Science Foundation, 4201 Wilson Boulevard, Suite 295, Arlington, VA 22030, or send e-mail to *splimpto@nsf.gov.* Comments regarding these information collections are best assured of having their full effect if received within 30 days of this notification. Copies of the submission(s) may be obtained by calling (703) 292–7556.

FOR FURTHER INFORMATION CONTACT: Suzanne H. Plimpton at (703) 292–7556 or send e-mail to *splimpto@nsf.gov.* Individuals who use a telecommunications devise for the deaf (TDD) may call the Federal Information Relay Service (FIRS) at 1–800–877–8339 between 8 a.m. and 8 p.m., Eastern time, Monday through Friday.

NSF may not conduct or sponsor a collection of information unless the collection of information displays a currently valid OMB control number and the agency informs potential persons who are to respond to the collection of information that such persons are not required to respond to the collection of information unless it displays a currently valid OMB control number. Under OMB regulations, NSF may continue to conduct or sponsor the collection of information while this submission is pending at OMB.

SUPPLEMENTARY INFORMATION: *Title of Collection:* EHR Generic Clearance.

OMB Approval Number: 3145–0136.

Abstract: The National Science Foundation requests renewal of program accountability and communication data collections (*e.g.,* surveys, face-to-face and telephone interviews, observations, and focus groups) that describe and track the impact of NSF funding that focuses on the Nation's science, technology, engineering, and mathematics (STEM) education and STEM workforce. NSF funds grants, contracts, and cooperative agreements to colleges, universities, and other eligible institutions, and provides graduate research fellowships to individuals in all parts of the United States and internationally.

The Directorate for Education and Human Resources (EHR), a unit within NSF, promotes rigor and vitality within the Nation's STEM education enterprise to further the development of the 21st century's STEM workforce and public scientific literacy. EHR does this through diverse projects and programs that support research, extension, outreach, and hands-on activities that service STEM learning and research at all institutional (*e.g.,* pre-school through postdoctoral) levels in formal and informal settings; and individuals of all ages (birth and beyond). EHR also focuses on broadening participation in STEM learning and careers among United States citizens, permanent residents, and nationals, particularly those individuals traditionally underemployed in the STEM research workforce, including but not limited to women, persons with disabilities, and racial and ethnic minorities.

At the request of OMB an EHR Generic Clearance was established in 1995 to integrate management, monitoring, and evaluation information pertaining to the NSF's Education and Training (E&T) portfolio in response to the Government Performance and Results Acts (GPRA) of 1993. Under this generic survey clearance (OMB 3145–0136), data from the NSF administrative databases are incorporated with findings gathered through initiative-, divisional-, and program-specific data collections. The scope of the EHR Generic Clearance primarily covers descriptive information gathered from education and training projects that are funded by NSF. Most programs subject to EHR Generic data collection are funded by the EHR Directorate, but some are funded in whole or in part by disciplinary directorates or multi-disciplinary or cross-cutting programs. Since 2001 in accordance with OMB's Terms of

Clearance (TOC), NSF primarily uses the data from the EHR Generic Clearance for program planning, management, and audit purposes to respond to queries from the Congress, the public, NSF's external merit reviewers who serve as advisors, including Committees of Visitors (COVs), and the NSF's Office of the Inspector General.

OMB has limited the collection to three categories of descriptive data: (1) Staff and project participants (data that are also necessary to determine individual-level treatment and control groups for future third-party study); (2) project implementation characteristics (also necessary for future use to identify well-matched comparison groups); and (3) project outputs (necessary to measure baseline for pre- and post-NSF-funding-level impacts).

Use of the Information: This information is required for effective administration, communication, program and project monitoring and evaluation, and for measuring attainment of NSF's program, project, and strategic goals, and as identified by the President's Accountable Government Initiative; the GPRA Modernization Act of 2010, and the NSF's Strategic Plan. The Foundation's FY 2006–2011 Strategic Plan describes four strategic outcome goals of Discovery, Learning, Research Infrastructure, and Stewardship. NSF's complete strategic plan may be found at: *http://www.nsf.gov/publications/pub_summ.jsp?ods_key=nsf0648.*

Since the EHR Generic Clearance research is primarily used for accountability purposes, including responding from queries from COVs and other scientific experts, a census rather than sampling design typically is necessary. At the individual project level funding can be adjusted based on individual project's responses to some of the surveys. Some data collected under the EHR Clearance serve as baseline data for separate research and evaluation studies.

In order to conduct program- or portfolio-level evaluations, however, both experimental and quasi-experimental evaluation research studies on STEM education interventions require researchers to identify individual-level and organization- or project-level control and treatment groups or comparison groups. NSF-funded contract or grantee researchers and evaluators in part may identify control, comparison, or treatment groups for NSF's E&T portfolio using some of the descriptive data gathered through OMB 3145–0136 to conduct well-designed, rigorous research and portfolio evaluation studies.

In accordance with the 2001, 2005, and 2008 OMB TOCs, NSF requests separate stand-alone clearance (and separately announces for comment in the **Federal Register**) any program or portfolio research or evaluation. Two examples of third-party evaluations that used EHR OMB 3145–0136 data to inform study design are: OMB No. 3145–0187 (Expiring 8/2011) Evaluation of the NSF's Graduate STEM Fellows in K–12 Education (GK–12) Program and OMB No. 3145–0182 (Expiring 3/2011) Evaluation of the NSF's Integrative Graduate Education and Research Traineeship (IGERT) Program: Follow-up Study of IGERT Graduates, both conducted by Abt Associates.

Respondents: Individuals or households, not-for-profit institutions, business or other for profit, and Federal, State, local or tribal government.

Number of Respondents: 7,470.

Burden of the Public: The total estimate for this collection is 49,556 annual burden hours. This figure is based on the previous 3 years of collecting information under this clearance and anticipated collections. The average annual reporting burden is between 1 and 72 hours per "respondent," depending on whether a respondent is a direct participant who is self-reporting or representing a project and reporting on behalf of many project participants.

Dated: January 28, 2011.

Suzanne H. Plimpton,

Reports Clearance Officer, National Science Foundation.

[FR Doc. 2011–2285 Filed 2–1–11; 8:45 am]

BILLING CODE 7555–01–P

OVERSEAS PRIVATE INVESTMENT CORPORATION

Sunshine Notice; March 10, 2011 Board of Directors Meeting

TIME AND DATE: Thursday, March 10, 2011, 10 a.m. (Open Portion) 10:15 a.m. (Closed Portion).

PLACE: Offices of the Corporation, Twelfth Floor Board Room, 1100 New York Avenue, NW., Washington, DC.

STATUS: Meeting Open to the Public from 10 a.m. to 10:15 a.m. Closed portion will commence at 10:15 a.m. (approx.)

MATTERS TO BE CONSIDERED:

1. President's Report.
2. Approval of September 23, 2010 Minutes (Open Session).
3. Tribute—Sanford L. Gottesman.
4. Confirmations:

Kevin G. Nealer as Member of Board Audit Committee.

Judith D. Pryor as Vice President, Office of External Affairs.

FURTHER MATTERS TO BE CONSIDERED: (Closed to the Public 10:15 a.m.)

1. Reports.
2. Finance Project—Liberia.
3. Finance Project—Georgia.
4. Insurance Project—Ghana.
5. Approval of September 23, 2010 Minutes (Closed Session).
6. Pending Major Projects.

Written summaries of the projects to be presented will be posted on OPIC's Web site on or about February 3, 2011.

CONTACT PERSON FOR INFORMATION: Information on the meeting may be obtained from Connie M. Downs at (202) 336–8438.

Dated: January 28, 2011.

Connie M. Downs,

Corporate Secretary, Overseas Private Investment Corporation.

[FR Doc. 2011–2310 Filed 1–28–11; 4:15 pm]

BILLING CODE 3210–01–P

OVERSEAS PRIVATE INVESTMENT CORPORATION

Sunshine Notice; February 24, 2011 Public Hearing

TIME AND DATE: 2 p.m., Thursday, February 24, 2011.

PLACE: Offices of the Corporation, Twelfth Floor Board Room, 1100 New York Avenue, NW., Washington, DC.

STATUS: Hearing Open to the Public at 2 p.m.

PURPOSE: Public Hearing in conjunction with each meeting of OPIC's Board of Directors, to afford an opportunity for any person to present views regarding the activities of the Corporation.

PROCEDURES: Individuals wishing to address the hearing orally must provide advance notice to OPIC's Corporate Secretary no later than 5 p.m. Thursday, February 17, 2011. The notice must include the individual's name, title, organization, address, and telephone number, and a concise summary of the subject matter to be presented.

Oral presentations may not exceed ten (10) minutes. The time for individual presentations may be reduced proportionately, if necessary, to afford all participants who have submitted a timely request an opportunity to be heard.

Participants wishing to submit a written statement for the record must submit a copy of such statement to OPIC's Corporate Secretary no later than 5 p.m. Thursday, February 17, 2011.

Such statement must be typewritten, double-spaced, and may not exceed twenty-five (25) pages.

Upon receipt of the required notice, OPIC will prepare an agenda, which will be available at the hearing, that identifies speakers, the subject on which each participant will speak, and the time allotted for each presentation.

A written summary of the hearing will be compiled, and such summary will be made available, upon written request to OPIC's Corporate Secretary, at the cost of reproduction.

Written summaries of the projects to be presented at the September 23, 2010 Board meeting will be posted on OPIC's Web site on or about Thursday, August 19, 2010.

CONTACT PERSON FOR INFORMATION: Information on the hearing may be obtained from Connie M. Downs at (202) 336–8438, via facsimile at (202) 218–0136, or via e-mail at *connie.downs@opic.gov*.

Dated: January 28, 2011.

Connie M. Downs,

OPIC Corporate Secretary.

[FR Doc. 2011–2312 Filed 1–28–11; 4:15 pm]

BILLING CODE 3210–01–P

SECURITIES AND EXCHANGE COMMISSION

Submission for OMB Review; Comment Request

Upon Written Request, Copies Available From: Securities and Exchange Commission, Office of Investor Education and Advocacy, Washington, DC 20549–0213.

Extension:

Rule 701; OMB Control No. 3235–0522; SEC File No. 270–306.

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") has submitted to the Office of Management and Budget the request for extension of the previously approved collection of information discussed below.

Rule 701 (17 CFR 230.701) under the Securities Act of 1933 ("Securities Act") (15 U.S.C. 77a *et seq.*) provides an exemption for certain issuers from the registration requirements of the Securities Act for limited offerings and sales of securities issued under compensatory benefit plans or contracts. The purpose of Rule 701 is to ensure that a basic level of information is available to employees and others when substantial amounts of securities are issued in compensatory arrangements. Information provided under Rule 701 is mandatory. Approximately 300 companies annually rely on the Rule 701 exemption and it takes 2 hours per response. We estimate that 25% of the 2 hours per response (0.5 hours) is prepared by the company for a total annual reporting burden of 150 hours (0.5 hours per response × 300 responses).

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.

Background documentation for this information collection may be viewed at the following link, *http://www.reginfo.gov.* Written comments should be directed to the following persons: (i) Desk Officer for the Securities and Exchange Commission, Office of Information and Regulatory Affairs, Office of Management and Budget, Room 10102, New Executive Office Building, Washington, DC 20503 or send an e-mail to: *Shagufta_Ahmed@omb.eop.gov;* Thomas Bayer, Chief Information Officer, Securities and Exchange Commission, C/O Remi Pavlik-Simon, 6432 General Green Way, Alexandria, VA 22312; or send an e-mail to: *PRA_Mailbox@sec.gov.* Comments must be submitted to OMB within 30 days of this notice.

Dated: January 27, 2011.

Elizabeth M. Murphy,

Secretary.

[FR Doc. 2011–2229 Filed 2–1–11; 8:45 am]

BILLING CODE 8011–01–P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–63775; File No. SR–DTC–2011–01]

Self-Regulatory Organizations; The Depository Trust Company; Notice of Filing and Order Granting Accelerated Approval of Proposed Rule Change To Amend the Dividends Service Guide

January 26, 2011.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 ("Act") [1] and Rule 19b–4 thereunder,[2] notice is hereby given that on January 13, 2011, The Depository Trust Company ("DTC") filed with the Securities and Exchange Commission ("Commission") the proposed rule change as described in Items I and II below, which Items have been prepared primarily by DTC.[3] The Commission is publishing this Notice and Order to solicit comments on the proposed rule change from interested persons and to approve the proposed rule change on an accelerated basis.

I. Self-Regulatory Organization's Statement of the Terms of the Substance of the Proposed Rule Change

DTC proposes to amend its Dividends Service Guide ("Guide") to: (1) clarify DTC's policy of payment allocations; (2) begin allocation of funds from agents received with corresponding CUSIP-level identification information at 8:20 a.m.; and (3) make other conforming changes.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, DTC 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 III below. DTC has prepared summaries, set forth in sections (A), (B), and (C) below, of the most significant aspects of these statements.[4]

(A) Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

One of core asset services provided by the DTC is the daily collection and allocation of cash entitlements due on DTC-eligible securities. These entitlements, known as Principal and Income ("P&I") payments, include dividend, interest, periodic principal, redemption, and maturity payments arising from the 3.5 million securities eligible at DTC.

Many paying agents service more than one issue and typically wire to DTC a single "bulk" payment to be allocated to numerous issues or different types of payments for a single issue. Paying agents are required to provide with bulk payments an automated file that provides corresponding Committee on Uniform Security Identification Procedures ("CUSIP") level identification information about the wire payment.[5] CUSIP-level detail

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] The text of the proposed rule change is attached as Exhibit 5 to DTC's filing, which is available at *http://www.dtcc.com/downloads/legal/rule_filings/2011/dtc/2011-01.pdf.*

[4] The Commission has modified the text of the summaries prepared by DTC.

[5] All paying agents are required to sign DTC's Operational Arrangements ("OA") letter agreeing to

Continued

includes the security's CUSIP, the payment amount for the CUSIP, the payable date, and the payment type (*i.e.,* dividend, interest, principal, *etc.*). The automated CUSIP-level detail allows systemic receipt and allocation of the bulk payment.

Funds from paying agents received with CUSIP-level identification information are allocated upon receipt beginning at 9 a.m. ET and continuing until 3 p.m. ET. Payments received without CUSIP-level detail cannot be systematically received and allocated because lack of identifying information included with the payments. In these instances, DTC has to work with the paying agent to obtain CUSIP-level details so that it can manually allocate funds to the appropriate CUSIPs. Currently, funds without corresponding CUSIP-level detail that are received by 3 p.m. ET by DTC are allocated at 3:15 p.m. ET using an algorithmic formula that allocates each agent's unidentified funds.

The majority of payments are sent to DTC over the Fedwire.[6] The "cut-off" time for these allocations is generally at about 3 p.m. ET to permit completion of the settlement process at about 4:30 p.m. ET each day. Since the Fedwire remains open until 6 p.m. ET, significant volumes of expected payments are received between DTC's allocation cut-off at 3 p.m. ET and the Fedwire close at 6 p.m. ET. On peak payment days, the volume of funds received after the allocation cut-off can represent upwards of several billion dollars (on average, about 2–4% of funds due come in after the allocation cut-off time).

Aside from those allocations where DTC has reason to believe that the related payment from the agent or issuer will not be received on the payable date, historically, DTC has allocated nearly all entitlements on their scheduled payable date, including those paid to DTC after established intraday cut-off times or received without the CUSIP level detail. Where DTC had information that payment would not be made on the payable date, DTC are allocated the payments upon receipt and identification.

Proposed Change to the Existing Practice

As a result of an extensive review of current policies and procedures and in consultation with its regulators, DTC has determined that the allocation of entitlements prior to funding or without CUSIP-level detail subjects DTC to potential credit and liquidity risks. For example, one such risk is that of a "double default" where after an allocation is made, the agent/issuer expected to make the payment does not do so, and the participant that received the allocation defaults before DTC can recover it. While this "allocate all" practice provides increased allocations to DTC participants, it does so at the expense of the risks described above.

In order to address these risks, DTC has been working extensively with paying agents to improve their payment timeliness and accuracy in a variety of ways. Paying agents are not provided with reports identifying various defects (for example, late, incomplete, or late and incomplete payment detail) that should allow them to perform root cause analysis and improve their processing and performance. Additionally, DTC has worked with several larger paying agents in their conversion to an automated means of providing CUSIP-level detail. As a result of these improvements, DTC has over the last few years greatly reduced the proportion of funds received late or without appropriate CUSIP level detail (compared to 2009, 2010 allocations relating to late or unidentified payments have decreased 60%—an estimated $50 billion in 2010 compared to $128 billion in 2009).

With risk mitigation at the forefront of market participants and regulators' concerns and given the extensive progress that DTC and paying agents have made in improving agents' payment practices, DTC proposes to discontinue the current "allocate all" practice and to move to a methodology that results in the allocation only of those entitlements paid before the cut-off and identified at a CUSIP-level. As a result of this proposed change in practice, DTC also proposes to discontinue its use of the algorithmic formula to allocate unidentified funds since this calculation will no longer be necessary.

In order to accommodate the anticipated increase in funds not allocated on the payable date due to late or unidentified payments, DTC also proposes to begin allocation of funds received with corresponding CUSIP-level identification information upon receipt, beginning at 8:20 a.m. ET and continuing every 20 minutes until shortly after the 3 p.m. ET cut-off time. This change in time will allow for more customers to receive timely and properly identified payments on the payable date.

DTC believes that the implementation of this policy eliminates the credit risk associated with DTC allocating cash entitlements to participants before such payments are received from the paying agent or issuer.

Implementation Timeframe

DTC proposes to implement the changes set forth in this filing on February 7, 2011. DTC participants, paying agents, and other financial intermediaries were first notified of this intended change through DTCC's publication of a White Paper to the Industry in November 2009.[7] In order to ensure widespread awareness and minimize the service impact to customers, DTC undertook in 2010 a number of initiatives aimed at paying agents in order to prepare them for the implementation of these changes. First, an Industry Task Force was established to ensure collaboration and a voice for key stakeholders and industry constituencies as the policy moved forward.[8] DTC also sponsored educational tools to update paying agents and participants alike about the upcoming changes to the allocation policy.[9] Finally, DTC gave numerous

comply with the provisions of the OA, which set forth the requirements necessary for an issue to become and remain eligible for DTC Services. The OA is available on DTCC's Web site for agents, issuers, and any other interested parties at *http://www.dtcc.com/downloads/legal/rules_proc/eligibility/operational.arrangements.memo.pdf. See also* DTC Important Notice B# 1805–07 (June 29, 2007).

[6] Some payments are sent as Automated Clearing House (ACH) transfers.

[7] The White Paper can be found at *http://www.dtcc.com/downloads/leadership/whitepapers/Payment_Refinement.pdf.*

[8] The Industry Task Force consisted of the following entities: Association of Global Custodians, American Bankers Association, Asset Managers Forum, Bank of America LaSalle, Bank of America Merrill Lynch, Bank of NY Mellon, Bank Depository User Group, Brown Bros. Harriman, Citibank, Computershare, Deutsche Bank, Edward Jones, Government Finance Officers Association, Goldman Sachs, JP Morgan Chase, M&I Bank, Morgan Stanley, NFS (Fidelity Institutional), SIFMA, The Clearing House, U.S. Bank, and Wells Fargo. This Task Force held meetings in February, April, May, June, July, September, November, and December 2010.

[9] Pursuant to the release of the White Paper, DTC customers requested a tool that would help measure the impact of the proposed change at a participant level and identify current allocations occurring in a manner that was not consistent with the proposed methodology. In response to this request and effective January 22, 2010, DTC developed and delivered two weekly reports—"CSH DIV—Imprecise Allocations" (*e.g.,* dividends, interest, pro-rata principal) and "CSH RED—Imprecise Allocations" (*i.e.,* calls, maturities, redemptions) that included all "imprecise" or noncompliant allocations for the given week. The reports were grouped by allocation day and sorted by CUSIP allowing participants to measure the impact of imprecise allocations as well as build a history of noncompliant CUSIPs to assist in driving allocation decisions. DTC then developed and put into place P&I Agent Payment Performance reports which provided agent-specific payment performance data and defects (*e.g.,* late payments, missing detail) to

platform presentations and updates to the following groups: Operations Advisory Committee, ISITC, ABA Corporate Trust Committee, SIFMA DTC Education Conference, SIFMA Operations & Regulatory Committee, SIFMA Asset Managers Forum, and DTC's Asset Services, Settlement and Securities Processing Advisory Boards.

The industry has been advised of the Industry Task Force's and DTC's progress in improving DTC's P&I payment process and the implementation date of the proposed rule changes through the issuance of Important Notices that were published on the DTCC Web site.[10]

(B) Self-Regulatory Organization's Statement on Burden on Competition

DTC does not believe that the proposed rule change would impose any burden on competition.

(C) Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants or Others

Written comments relating to the proposed rule change have not been solicited or received. DTC will notify the Commission of any written comments received by DTC.

III. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's Internet comment form (*http://www.sec.gov/rules/sro.shtml*) or
- Send an e-mail to *rule-comments@sec.gov.* Please include File Number SR–DTC–2011–01 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 submission should refer to File Number SR–DTC–2011–01. 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, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for Web site viewing and printing in the Commission's Public Reference Section, 100 F Street, NE., Washington, DC 20549–1090, on official business days between the hours of 10 a.m. and 3 p.m. Copies of such filings will also be available for inspection and copying at the principal office of DTC and on DTC's Web site at *http://www.dtcc.com/downloads/legal/rule_filings/2011/dtc/2011-01.pdf.* 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–DTC–2011–01 and should be submitted on or before February 23, 2011.

IV. Commission's Findings and Order Granting Accelerated Approval of Proposed Rule Change

For the reasons stated below, the Commission finds that the proposed rule change is consistent with the requirements of the Act and the rules and regulations thereunder applicable to DTC.[11] Specifically, the Commission finds that the proposed rule change is consistent with Section 17A(b)(3)(F) of the Act which requires, among other things, that the rules of a clearing agency be designed to promote the prompt and accurate clearance and settlement of securities transactions, to assure the safeguarding of securities and funds of DTC's participants which are in the custody and control of the clearing agency, and to remove impediments to and perfect the mechanism of a national system for prompt and accurate clearance and settlement of securities transactions.[12]

As described in this filing, DTC's "allocate all" methodology subjects DTC, its participants, and beneficial owners to inherent problems. An in-depth study conducted internally by DTC at the request and recommendation of regulators has resulted in its decision to eliminate the "allocate all" policy. Accordingly, the Commission finds that the rule change is consistent with Section 17A(b)(3)(F) of the Act because it should allow DTC to reduce risks associated with its current P&I payment process, which in turn, should enable DTC to better safeguard the funds and securities which are in DTC's custody and control.

DTC has requested that the Commission find good cause for approving the proposed rule change prior to the thirtieth day after publication of notice of filing thereof in the **Federal Register**. As discussed above, approval of the proposal will allow DTC to immediately cease its current "allocate all" P&I payment policy and implement a policy that reduces risk for DTC, its participants, paying agents, and other financial intermediaries associated with P&I allocations. Furthermore, in anticipation of implementation of these changes, DTC's participants and paying agents have already taken the necessary steps to code their systems for the February 7, 2011, implementation date. Change in this implementation date could cause significant system disruptions at these participants and paying agents. As such, the Commission finds good cause for approving the proposed rule change prior to the thirtieth day after the date of publication of notice filing in the **Federal Register**.

V. Conclusion

It is therefore ordered, pursuant to Section 19(b)(2) of the Act, that the proposed rule change (SR–DTC–2011–01) is approved on an accelerated basis.

For the Commission by the Division of Trading and Markets, pursuant to delegated authority.[13]

Elizabeth M. Murphy,

Secretary.

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BILLING CODE 8011–01–P

agents. DTC identified target agents (*i.e.,* those with late or unidentified payments) and tracked performance. Approximately 4,000 agents were provided targeted feedback on specific process deficiencies (late or unidentified payments) in 2010. DTC also created and maintained a dedicated electronic mailbox for communicating en masse with paying agents. DTC contacted the vast majority of the approximately 7,000 different issuers and agents making entitlement payments to DTC to aid in the awareness of the P&I allocation refinement.

[10] *See* DTCC Important Notice 6132–10 (January 15, 2010); DTC Important Notice #7045–10 (August 2, 2010); DTC Important Notice #7659–10 (November 22, 2010).

[11] In approving this proposal, the Commission has considered its impact on efficiency, competition, and capital formation. 15 U.S.C. 78c(f).

[12] 15 U.S.C. 78q–1(b)(3)(F).

[13] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–63780; File No. SR–Phlx–2011–07]

Self-Regulatory Organizations; NASDAQ OMX PHLX LLC; Notice of Filing and Immediate Effectiveness of Proposed Rule Change Relating to Firm Related Equity Option Cap, Active SQF Port Fees and Other Membership Fees

January 26, 2011.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 ("Act"),[1] and Rule 19b–4 thereunder,[2] notice is hereby given that on January 14, 2011, NASDAQ OMX PHLX LLC ("Phlx" or "Exchange") filed with the Securities and Exchange Commission ("SEC" or "Commission") the proposed rule change as described in Items I, II, and III, below, which Items have been prepared by the Exchange. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Exchange proposes to amend the Exchange's Fee Schedule to: (i) Allow Firms to cap their equity option transaction charges, per month, when such Firms are trading in their own proprietary account; (ii) correct a typographical error related to the Active Specialized Quote Feed ("SQF") Port Fee and also extended the current $40,000 per month cap from March 31, 2011 to November 30, 2011; (iii) clarify the Transfer of Affiliation Fee applies to member organizations; (iv) clarify when an Initiation Fee is assessed; (v) remove a reference to Application Fee in the Fee Schedule; and (vi) remove a note associated with the Options Regulatory Fee which is no longer necessary.

While changes to the Exchange's Fee Schedule pursuant to this proposal are effective upon filing, the Exchange has designated this proposal to be operative on January 17, 2011. The text of the proposed rule change is available on the Exchange's Web site at *http://nasdaqtrader.com/micro.aspx?id=PHLXfilings,* at the principal office of the Exchange, and at the Commission's Public Reference Room.

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the Exchange included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant aspects of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

The purpose of the proposed rule change is to amend the types of equity transaction charges that would count toward the Firm Related Equity Option Cap. The Exchange believes that this amendment would encourage organizations that are not members to become members by further reducing fees. The Exchange is also proposing to extend the timeframe for members to cap their Active SQF Port Fees in order that members will have additional time to transition from SQF 5.0 to SQF 6.0. Finally, the Exchange is proposing to make certain clarifying amendments to the text of the Fee Schedule to more accurately reflect when certain fees would be assessed on members.

Firm Related Equity Option Cap

The Exchange currently caps Firms at $75,000 ("Firm Related Equity Option Cap") for equity options transactions charges, in the aggregate for one billing month per member organization, except for orders of joint back-office ("JBO") participants.[3] The Exchange is proposing to amend the application of the Firm Related Equity Option Cap to state that the $75,000 Firm Related Equity Option Cap would apply to Firm equity option transaction charges, in the aggregate for one billing month per member organization, when such members are trading in their own proprietary account.[4] The Firm Related Equity Option Cap would not apply to orders where a member is acting as agent on behalf of a non-member. The Firm Related Equity Options Cap would apply to trades in which a member acts as agent on behalf of another member, provided those orders are not commingled with orders from a non-member.

Members and member organizations would be required to continue to notify the Exchange, in writing, of all accounts, which under this proposal are not executed for their own proprietary account. The purpose of this provision would be to enable the Exchange to accurately monitor which executions are subject to the Firm Related Equity Option Cap. Furthermore, the Exchange proposes to specify that it would not make adjustments to billing invoices where the member/member organization commingles transactions that are not for their own proprietary account, and thus not subject to the Firm Related Equity Option Cap, with transactions for accounts which are proprietary.[5]

Active SQF Port Fee

The Exchange recently amended the Active SQF Port[6] Fee to establish a tiered schedule of fees.[7] In that rule change, the Exchange placed a $40,000 per month cap ("Cap") on Active SQF Port Fees from January 3, 2011 through March 31, 2011. In that rule change, the Exchange noted that it believed that member organizations will utilize less SQF 6.0 ports than SQF 5.0 ports[8] and that all member organizations should have transitioned to SQF 6.0 by March 31, 2011.

The Exchange now believes that member organizations would require

[3] A JBO participant is a member, member organization or non-member organization that maintains a JBO arrangement with a clearing broker-dealer ("JBO Broker") subject to the requirements of Regulation T Section 220.7 of the Federal Reserve System. *See also* Exchange Rule 703.

[4] The Firm equity options transaction charges are waived for members executing facilitation orders pursuant to Exchange Rule 1064 when such members are trading in their own proprietary account.

[5] In the initial filing, the Exchange stated that "[f]urthermore, the Exchange proposes to specify that it would not make adjustments to billing invoices where the member/member organization commingles transactions that are not for their own proprietary account, and thus not subject to the Firm Related Equity Option Cap, with transactions for accounts which are non-proprietary." The Exchange requested the removal of the letters "non-" before the word "proprietary" because it was incorrect. *See* E-mail from Angela S. Dunn, Assistant General Counsel, Phlx, dated January 26, 2011.

[6] Active SQF ports refer to ports that receive inbound quotes at any time within that month. SQF is an interface that enables specialists, Streaming Quote Traders ("SQTs") and Remote Streaming Quote Traders ("RSQTs") to connect and send quotes into Phlx XL.

[7] *See* Securities Exchange Act Release No. 63619 (December 29, 2010), 76 FR 614 (January 5, 2011) (SR–Phlx–2010–181).

[8] The Exchange released SQF 6.0 on October 11, 2010. The Exchange anticipates that member organizations will utilize both SQF 5.0 and SQF 6.0 for a period of time. *See* Securities Exchange Act Release No. 63034 (October 4, 2010), 75 FR 62441 (October 8, 2010) (SR–Phlx–2010–124).

additional time to properly transition to SQF 6.0 ports and proposes extending the applicability of the Cap until November 30, 2011. On December 1, 2011, there will no longer be a Cap in effect for the Active SQF Port Fee. The purpose of the Cap is to ensure member organizations are not assessed fees in excess of the Active SQF Port Fees.

Additionally, the Exchange proposes to correct a typographical error within the text of the Fee Schedule for the Active SQF Port Fee. When the Exchange filed to create the tiered schedule of fees for the Active SQF Port Fees the Exchange incorrectly noted that there would be a tier for 19–40 Active SQF Ports and another tier that would be for 40 and over. The last tier should be "41 and over" since 40 Active SQF Ports would be assessed fees in the third tier. The Exchange proposes renaming the final tier "41 and over" and assessing that tier for the 41st Active SQF Port and greater than 41 ports.

Transfer of Affiliation

The Exchange is proposing to amend the Transfer of Affiliation Fee which was recently added to the Fee Schedule [9] to clarify that the $350 Transfer of Affiliation Fee would be assessed on a permit holder who applies to transfer affiliation from one member *organization* to another member *organization.* The text currently states from one member to another member, however the transfer would take place between member organizations and the Exchange is proposing to clarify its Fee Schedule to accurately reflect the transfer. The Exchange is also proposing minor corrections to the Transfer of Affiliation Fee text to simplify the text. The Exchange therefore proposes the current text for the Transfer of Affiliation Fee be replaced with the following text, "The Exchange will not assess the Initiation Fee on a permit holder who applies to transfer affiliation from one member organization to another member organization if the permit holder continuously held his or her permit without any lapse in membership." [10]

Initiation Fee

The Exchange is proposing to clarify the rule text of the Initiation Fee, as well as the applicability of that fee.

First, the Exchange proposes to clarify that the Initiation Fee is imposed on a new member upon the issuance of a permit. The current text of the Fee Schedule states that an "Initiation Fee is imposed on a member upon election * * *" This language refers to a former process at the Exchange whereby the former Admissions Committee would review an application for membership and grant an election to membership, which would in turn trigger an Initiation Fee to be assessed upon a member.

The Exchange is proposing to clarify the text of this fee by instead stating that the Initiation Fee would be imposed on "* * * a new member upon the issuance of a permit * * * notwithstanding the fact that the new member may have been a former permit holder." This language would not change the applicability of this fee, but only reflect the current practice of admitting members and the actual trigger for the fee today. Today the Exchange assesses the Initiation Fee on each new member. This would include new members that formerly held a Series A–1 permit. The Exchange does not propose to amend the current applicability of the Initiation Fee, but rather the Exchange desires to merely clarify for members the applicability of the fee.

Application Fee

The Exchange is also seeking to clarify the applicability of the Application Fee with respect to PSX Participants. The Fee Schedule contains a note which states that,

> Applicants that apply for membership solely to participate in the NASDAQ OMX PSX equities market are not assessed a Permit Fee, Application Fee, Initiation Fee, or Account Fee. Should such approved member or member organization subsequently elect to engage in business on Phlx XL II, the Exchange's options platform, the monthly Permit Fee, Application Fee, Initiation Fee and Account Fee will apply.

The Exchange is proposing to instead state:

> Applicants that apply for membership solely to participate in the NASDAQ OMX PSX equities market are not assessed a Permit Fee, Application Fee, Initiation Fee, or Account Fee. Should such approved member or member organization subsequently elect to engage in business on Phlx XL II, the Exchange's options platform, the monthly Permit Fee, Initiation Fee and Account Fee will apply.

Since an Application Fee only applies to new members upon the issuance of a permit, a PSX Participant that subsequently elects to engage in options business would not require a new permit because that member would already possess a Series A–1 permit.[11] Therefore, the Application Fee would never be assessed in that scenario.[12] The Exchange is proposing to correct this oversight by removing that language in the note related to Initiation Fee.

Options Regulatory Fee

The Exchange proposes to remove text in the Fee Schedule related to the Options Regulatory Fee, which is no longer necessary. The Exchange proposes removing the following language in the Fee Schedule, "The Exchange will continue to assess $.0030 until January 3, 2011 at which time the new rate of $.0035 will be assessed." The Exchange has already commenced assessing the new rate, therefore this text is no longer necessary and the Exchange proposes deleting this text.

2. Statutory Basis

The Exchange believes that its proposal to amend its Fee Schedule is consistent with Section 6(b) of the Act [13] in general, and furthers the objectives of Section 6(b)(4) of the Act [14] in particular, in that it is an equitable allocation of reasonable fees and other charges among Exchange members and other persons using its facilities. The Exchange believes that its proposal to amend the Firm Related Equity Option Cap to apply to members trading in their own proprietary account is reasonable because it would allow the Exchange to reduce costs for more member organizations. The Exchange believes that the proposal is equitable because member organizations that are JBOs could be subject to the Firm Related Equity Option Cap, as are other members, as long as the JBO trades were for their own proprietary account. Additionally, the proposed change would encourage JBOs that are not members to seek to become member organizations to further reduce their transaction fees.

The proposed modification to the Firm Related Equity Option Cap is similar to other fees assessed by the Exchange. Specifically, the Firm equity

[9] *See* Securities Exchange Act Release No. 63569 (December 17, 2010), 75 FR 81323 (December 27, 2010) (SR–Phlx–2010–178).

[10] The Exchange is not proposing to amend the $350 fee rate.

[11] The Exchange included language in the initial filing stating that it "was noted above" that Application Fees only apply to new member upon the issuance of a new permit. The Exchange requested the removal of the "as noted above" language because it was incorrect. *See* E-mail from Angela S. Dunn, Assistant General Counsel, Phlx, dated January 26, 2011.

[12] *See* Securities Exchange Act Release No. 61863 (April 7, 2010), 75 FR 20021 (April 16, 2010) (SR–Phlx–2010–54). In this rule change, the Exchange noted "[a]n Exchange member approved to participate in PSX would not be assessed an application fee should it subsequently determine to participate in the Exchange's options market, but would be charged the one-time initiation fee and would thereafter be charged the monthly account fee and permit fee."

[13] 15 U.S.C. 78f(b).

[14] 15 U.S.C. 78f(b)(4).

options transaction charges are waived for members executing facilitation orders [15] pursuant to Exchange Rule 1064 when such members are trading in their own proprietary account.[16] Additionally, dividend, merger and short stock interest strategies are capped at $25,000 per member organization per month when such members are trading in their own proprietary accounts.[17]

The Exchange operates in a highly competitive market in which sophisticated and knowledgeable market participants can readily send orders to buy and sell options to competing venues if they deem fee levels at a particular venue to be excessive. The Exchange believes that the proposed modification to the Firm Related Equity Option Cap is necessary to remain competitive with fees charged by other venues and therefore continues to be reasonable and equitably allocated to those member organizations that opt to direct orders to the Exchange rather than competing venues.

The Exchange believes that its proposal to expand the applicability of the Cap for Active SQF Port Fees is both reasonable and equitable because it would allow members additional time to transition from SQF 5.0 to SQF 6.0.

The Exchange believes that its various proposals to amend the text of the Fee Schedule to clarify the applicability of certain fees, amend typographical errors and remove irrelevant text is both reasonable and equitable because members would benefit from clear guidance in the rule text describing the manner in which the Exchange would assess fees.

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange does not believe that the proposed rule change will impose any burden on competition not necessary or appropriate in furtherance of the purposes of the Act.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

No written comments were either solicited or received.

[15] A facilitation occurs when a floor broker holds an options order for a public customer and a contra-side order for the same option series and, after providing an opportunity for all persons in the trading crowd to participate in the transaction, executes both orders as a facilitation cross. See Exchange Rule 1064.

[16] *See* Securities Exchange Act Release No. 60477 (August 11, 2009), 74 FR 41777 (August 18, 2009) (SR–Phlx–2009–67).

[17] *See* Securities Exchange Act Release Nos. 61115 (December 4, 2009), 74 FR 65571 (December 10, 2009) (SR–Phlx–2009–97) and 63712 (January 12, 2011) (SR–Phlx–2011–01).

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

The foregoing rule change has become effective pursuant to Section 19(b)(3)(A)(ii) of the Act.[18] At any time within 60 days of the filing of the proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act. If the Commission takes such action, the Commission shall institute proceedings to determine whether the proposed rule should be approved or disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's Internet comment form (*http://www.sec.gov/rules/sro.shtml*); or
- Send an e-mail to *rule-comments@sec.gov.* Please include File Number SR–Phlx–2011–07 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–Phlx–2011–07. 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, 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. Copies of the filing also will be available for inspection and copying at the principal office of the Exchange. All comments received will be posted without change; the Commission does not edit personal identifying information from submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR–Phlx–2011–07 and should be submitted on or before February 23, 2011.

[18] 15 U.S.C. 78s(b)(3)(A)(ii).

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[19]

Elizabeth M. Murphy,

Secretary.

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[19] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–63781; File No. SR–Phlx–2011–09]

Self-Regulatory Organizations; NASDAQ OMX PHLX LLC; Notice of Filing and Immediate Effectiveness of Proposed Rule Change Relating to the Order Entry Port Fee

January 26, 2011.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 ("Act"),[1] and Rule 19b–4 thereunder,[2] notice is hereby given that on January 21, 2011, NASDAQ OMX PHLX LLC ("Phlx" or "Exchange") filed with the Securities and Exchange Commission ("SEC" or "Commission") the proposed rule change as described in Items I, II, and III, below, which Items have been prepared by the Exchange. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Exchange proposes to amend the applicability of the Order Entry Port Fee.[3] The text of the proposed rule change is available on the Exchange's Web site at *http://nasdaqtrader.com/micro.aspx?id=PHLXfilings,* at the principal office of the Exchange, and at

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b-4.

[3] The Order Entry Port Fee is a connectivity fee assessed on members in connection with routing orders to the Exchange via an external order entry port. Members access the Exchange's network through order entry ports. A member organization may have more than one order entry port.

the Commission's Public Reference Room.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the Exchange included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant aspects of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

The purpose of the proposed rule change is to amend the applicability of the Order Entry Port Fee. The Exchange currently assesses an Order Entry Port Fee per month per mnemonic [4] of $500. This fee is assessed on members regardless of whether the order entry mnemonic is active [5] during the billing month. The fee is assessed regardless of usage, and solely on the number of order entry ports assigned to each member organization.

The Exchange is proposing to modify the manner in which members are assessed the Order Entry Port Fee as related to complex order.[6] The Exchange proposes to waive the $500 per month per mnemonic Order Entry Port Fee for mnemonics used exclusively for complex orders where one of the components of the complex order is the underlying security.[7]

The Exchange believes that members who transact complex orders may require an increased number of ports due to the member's stock clearance arrangements, which may require additional mnemonics. The Exchange is proposing to limit the fees that would be assessed on members requiring additional ports to transact stock-option orders.[8]

2. Statutory Basis

The Exchange believes that its proposal to amend its Fee Schedule is consistent with Section 6(b) of the Act [9] in general, and furthers the objectives of Section 6(b)(4) of the Act [10] in particular, in that it is an equitable allocation of reasonable fees and other charges among Exchange members and other persons using its facilities. The Exchange believes that the proposal is equitable and reasonable because all members would be able to limit fees related to order entry ports for such complex orders that are stock-option orders, which may require additional mnemonics.

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange does not believe that the proposed rule change will impose any burden on competition not necessary or appropriate in furtherance of the purposes of the Act.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

No written comments were either solicited or received.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

The foregoing rule change has become effective pursuant to Section 19(b)(3)(A)(ii) of the Act.[11] At any time within 60 days of the filing of the proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act. If the Commission takes such action, the Commission shall institute proceedings to determine whether the proposed rule should be approved or disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's Internet comment form (*http://www.sec.gov/rules/sro.shtml*); or
- Send an e-mail to *rule-comments@sec.gov*. Please include File Number SR–Phlx–2011–09 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–Phlx–2011–09. 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, 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. Copies of the filing also will be available for inspection and copying at the principal office of the Exchange. All comments received will be posted without change; the Commission does not edit personal identifying information from submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR–Phlx–

[4] Order entry mnemonics are codes that identify member organization order entry ports.

[5] An order entry mnemonic is considered active if a member organization sends at least one order to the Exchange using that order entry mnemonic during the applicable billing month. *See* Securities Exchange Act Release No. 58728 (October 3, 2008), 73 FR 59695 (October 9, 2008) (SR–Phlx–2008–70).

[6] A complex order is a spread, straddle, combination, ratio or collar order, all of which consist of more than one component, priced like a single order at a net debit or credit based on the prices of the individual components. *See* Exchange Rule 1080, Commentary .08(a)(i).

[7] The Exchange recently filed a proposed rule change to add complex orders where one component is the underlying stock or ETF to the functionality on its electronic trading platform for options, Phlx XL. The Exchange also amended its definition of complex orders in Exchange Rule 1080 as follows: Complex Orders is any order involving the simultaneous purchase and/or sale of two or more different options series in the same underlying security, priced at a net debit or credit based on the relative prices of the individual components, for the same account, for the purpose of executing a particular investment strategy. Furthermore, a Complex Order can also be a stock-option order, which is an order to buy or sell a stated number of units of an underlying stock or ETF coupled with the purchase or sale of options contract(s). The Exchange also proposed to permit complex orders consisting of up to six components. *See* Securities Exchange Act Release No. 63509 (December 9, 2010), 76 FR 2733 (January 14, 2011) (SR–Phlx–2010–157) [sic].

[8] A complex order with one component that is the underlying stock or Exchange Traded Fund Share ("ETF") is also referred to as a stock-option order.

[9] 15 U.S.C. 78f(b).

[10] 15 U.S.C. 78f(b)(4).

[11] 15 U.S.C. 78s(b)(3)(A)(ii).

2011–09 and should be submitted on or before February 23, 2011.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[12]

Elizabeth M. Murphy,

Secretary.

[FR Doc. 2011–2227 Filed 2–1–11; 8:45 am]

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SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–63784; File No. SR–FINRA–2010–052]

Self-Regulatory Organizations; Financial Industry Regulatory Authority, Inc.; Order Approving a Proposed Rule Change Adopting FINRA Rules Regarding Books and Records in the Consolidated FINRA Rulebook

January 27, 2011.

I. Introduction

On October 20, 2010, the Financial Industry Regulatory Authority, Inc. ("FINRA") filed with the Securities and Exchange Commission ("SEC" or "Commission"), pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 ("Exchange Act")[1] and Rule 19b–4 thereunder,[2] a proposed rule change adopting FINRA rules regarding books and records in the consolidated FINRA Rulebook. The proposed rule change was published for comment in the **Federal Register** on November 1, 2010.[3] The Commission received three comments on the proposed rule change.[4] On January 13, 2011, FINRA responded to the comments.[5] This order approves the proposed rule change.

II. Description of Proposed Rule Change

FINRA is proposing to adopt certain paragraphs, as specified below, of NASD Rule 3110 (Books and Records), subject to certain amendments, as FINRA Rules in the consolidated FINRA rulebook and to adopt Incorporated NYSE Rule Interpretations 410/01 (Pre-Time Stamping) and 410/02 (Allocations of Block Orders), subject to certain amendments, as FINRA Rules in the consolidated FINRA rulebook.

The proposed rule change would delete NASD IM–3110 (Customer Account Information) and Incorporated NYSE Rule 410 (Records of Orders). In addition, the proposed rule change would delete Incorporated NYSE Rule 440 (Books and Records), with the exception of Incorporated NYSE Rules 440.10 (Periodic Security Counts, Verifications, Comparisons, etc.) and 440.20 (Identification of Suspense Accounts and Assignment of Responsibility for General Ledger Accounts) and NYSE Rule Interpretation 440.20/01 (Suspense Accounts).

The proposed rule change would renumber NASD Rule 3110(a) (Requirements) as FINRA Rule 4511 (General Requirements), NASD Rule 3110(c) (Customer Account Information) as FINRA Rule 4512 (Customer Account Information), NASD Rules 3110(d) (Record of Written Complaints) and 3110(e) ("Complaint" Defined) as FINRA Rule 4513 (Records of Written Customer Complaints), NASD Rule 3110(f) (Requirements When Using Predispute Arbitration Agreements for Customers Accounts) as FINRA Rule 2268 (Requirements When Using Predispute Arbitration Agreements for Customer Accounts), NASD Rule 3110(g) (Negotiable Instruments Drawn From A Customer's Account) as FINRA Rule 4514 (Authorization Records for Negotiable Instruments Drawn From a Customer's Account), NASD Rule 3110(h) (Order Audit Trail System Record Keeping Requirements) as paragraph (a)(4) of FINRA Rule 7440 (Recording of Order Information) and NASD Rule 3110(j) (Changes in Account Name or Designation) as FINRA Rule 4515 (Approval and Documentation of Changes in Account Name or Designation) in the consolidated FINRA rulebook. The proposed rule change also would renumber NYSE Rule Interpretation 410/01 as FINRA Rule 5340 (Pre-Time Stamping) and NYSE Rule Interpretation 410/02 as FINRA Rule 4515.01 (Allocations of Orders Made by Investment Advisers).

A. Background

1. Purpose

As part of the process of developing a new consolidated rulebook ("Consolidated FINRA Rulebook"),[6] FINRA is proposing to adopt NASD Rules 3110(a), 3110(c), 3110(d) and (e), 3110(f), 3110(g), 3110(h) and 3110(j) as FINRA Rules 4511, 4512, 4513, 2268, 4514, 7440(a)(4) and 4515, respectively, in the Consolidated FINRA Rulebook, with certain changes as described below.[7] FINRA also is proposing to adopt Incorporated NYSE Rule Interpretations 410/01 and 410/02 as FINRA Rules 5340 and 4515.01,[8] respectively, in the Consolidated FINRA Rulebook.[9] FINRA is proposing to delete NASD IM–3110 and NYSE Rules 410 and 440, provided, however, NYSE Rules 440.10 and 440.20 and NYSE Rule Interpretation 440.20/01 are being addressed as part of a separate proposal.[10]

Current NASD Rules and NYSE Rules require members to make and preserve

[12] 17 CFR 200.30–3(a)(12).

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] *See* Securities Exchange Act Release No. 63181 (October 26, 2010), 75 FR 67155 (November 1, 2010).

[4] *See* Letter from Holly H. Smith and Susan S. Krawczyk, Sutherland Asbill & Brennan LLP, for the Committee of Annuity Insurers, to Elizabeth M. Murphy, Secretary, SEC, dated November 22, 2010 ("CAI"); Letter from William A. Jacobson, Associate Clinical Professor of Law and Director, the Cornell Securities Law Clinic, Cornell University Law School, to Elizabeth M. Murphy, Secretary, SEC, dated November 22, 2010 ("Cornell"); and Letter from Melissa MacGregor, Managing Director and Associate General Counsel, the Securities Industry and Financial Markets Association, to Elizabeth M. Murphy, Secretary, SEC, dated November 23, 2010 ("SIFMA"). (*Available at http://www.sec.gov/comments/sr-finra-2010–052/finra2010052.shtml*).

[5] *See* Letter from Afshin Atabaki, FINRA, to Elizabeth M. Murphy, Secretary, SEC, dated January 13, 2011 ("Response to Comments").

[6] The current FINRA rulebook consists of (1) FINRA Rules; (2) NASD Rules; and (3) rules incorporated from NYSE ("Incorporated NYSE Rules") (together, the NASD Rules and Incorporated NYSE Rules are referred to as the "Transitional Rulebook"). While the NASD Rules generally apply to all FINRA members, the Incorporated NYSE Rules apply only to those members of FINRA that are also members of the NYSE ("Dual Members"). The FINRA Rules apply to all FINRA members, unless such rules have a more limited application by their terms. For more information about the rulebook consolidation process, *see Information Notice,* March 12, 2008 (Rulebook Consolidation Process).

[7] NASD Rule 3110(b) (Marking of Customer Order Tickets) requires that members indicate on the order ticket for each transaction in a non-exchange-listed security the name of each dealer contacted and the quotations received to determine the best inter-dealer market as required by NASD Rule 2320(g) (commonly referred to as the "Three Quote Rule"), unless the member can establish and document its reliance on the exclusions to the Three Quote Rule. FINRA is proposing to replace NASD Rule 3110(b) with a more general documentation requirement in the supplementary material to proposed FINRA Rule 5310. *See Regulatory Notice* 08–80 (December 2008) (Proposed FINRA Rule Addressing Best Execution). NASD Rule 3110(i) (Holding of Customer Mail) specifies the circumstances under which members may hold mail for a customer. FINRA is proposing that NASD Rule 3110(i) be rewritten as a standalone rule and relocated to the supervision section of the Consolidated FINRA Rulebook. *See Regulatory Notice* 08–24 (May 2008) (Proposed Consolidated FINRA Rules Governing Supervision and Supervisory Controls).

[8] For convenience, the Incorporated NYSE Rules are referred to as the NYSE Rules.

[9] NYSE Rule Interpretation 410(a)(ii)(5)/01 was deleted as part of a prior rule change. *See* Securities Exchange Act Release No. 61473 (February 2, 2010), 75 FR 6422 (February 9, 2010) (Order Approving File No. SR–FINRA–2009–087).

[10] *See Regulatory Notice* 09–03 (January 2009) (Proposed Consolidated FINRA Rules Governing Financial Responsibility and Operational Requirements).

certain books and records to evidence compliance with federal securities laws and FINRA and SEC rules, as well as to enable FINRA and SEC staffs to conduct effective examinations. Based in large part on the current rules, the proposed rule change would rewrite the FINRA books and records rules with three goals in view:

- To streamline the rules to make them as clear as possible;
- To group the requirements along similar subject matter lines to make finding them a more intuitive process and to provide members with a better understanding of the regulatory scheme; and
- To eliminate those requirements contained in the current rules that have become obsolete or otherwise duplicative.

2. Proposed Amendments

FINRA proposes the following amendments to the books and records rules.

a. General Requirements (Proposed FINRA Rule 4511)

Currently, there are two general recordkeeping rules in effect under NASD Rules and NYSE Rules. NASD Rule 3110(a) requires each member to make and preserve books, accounts, records, memoranda, and correspondence in conformity with all applicable laws, rules, regulations and statements of policy promulgated thereunder, with FINRA's Rules, and as prescribed by Exchange Act Rule 17a–3. NASD Rule 3110(a) further states that the record keeping format, medium, and retention period shall comply with Exchange Act Rule 17a–4. NYSE Rule 440 also sets forth the general obligation of members to make and preserve books and records.[11]

NYSE Rule 410 is a separate NYSE recordkeeping rule for which there is no comparable NASD Rule.[12] NYSE Rule 410, in main part, requires members to make and preserve specific records for every order received (either orally or in writing) and every order entered into the NYSE's Off-Hours Trading Facility.[13] NYSE Rule 410 also permits the NYSE to waive the rule's recordkeeping requirements under exceptional circumstances upon written request.

FINRA Rule 4511 streamlines, and replaces, the language of NASD Rule 3110(a) to clarify that members are obligated to make and preserve books and records as required under the FINRA rules, the Exchange Act and the applicable Exchange Act rules.[14] Additionally, the proposed rule requires members to preserve for a period of at least six years those FINRA books and records for which there is no specified retention period under the FINRA Rules or applicable Exchange Act rules. The proposed rule also clarifies that members are required to preserve the books and records required to be made pursuant to the FINRA Rules in a format and media that complies with Exchange Act Rule 17a–4.

FINRA proposes to delete the general recordkeeping provisions of NYSE Rule 440 because its provisions are substantially similar to FINRA Rule 4511. As noted above, NYSE Rules 440.10 and 440.20 and NYSE Rule Interpretation 440.20/01 are being addressed as part of a separate proposal.[15]

In addition, the proposed rule change would delete NYSE Rules 410(a)(1)–(3) and (b) as the provisions' requirements are largely duplicative of the Exchange Act requirements that are incorporated by reference into FINRA Rule 4511[16] or, in some instances, are directed at orders on an exchange facility. FINRA Rule 7440 (Recording of Order Information) also mandates requirements that are substantially similar to those in Exchange Act Rules 17a–3 and 17a–4 for members that must report order information via FINRA's Order Audit Trail System ("OATS") for over-the-counter ("OTC") and Nasdaq equity securities.[17]

b. Customer Account Information (Proposed FINRA Rule 4512)

NASD Rule 3110(c)(1) requires that members maintain certain information relating to customer accounts, including, among other things, the signature of the registered representative introducing the account and signature of the member, partner, officer or manager who accepts the account. FINRA proposes to simplify this provision by instead requiring members to maintain the name of the associated person, if any, responsible for the account. As discussed in more detail below, the proposed rule change would require that where a member designates multiple individuals as being responsible for an account, the member maintain each of their names and a record indicating the scope of their responsibilities with respect to the account. The proposed rule change also would clarify that members maintain the signature of the partner, officer or manager denoting that the account has been accepted in accordance with the member's policies and procedures for acceptance of accounts.

NASD Rule 3110(c)(3) requires that for discretionary accounts, in addition to the requirements set forth in NASD Rules 3110(c)(1) and (2), members must: Obtain the signature of each person authorized to exercise discretion in the account; record the date such discretion is granted; and, in connection with exempted securities (other than municipals), record the age or approximate age of the customer. FINRA proposes to simplify and clarify NASD Rule 3110(c)(3) in the following ways:

- Consistent with the Exchange Act requirements,[18] the rule would be amended to require members to maintain a record of the dated signature of each named, natural person authorized to exercise discretion in the account;
- The proposed rule change would delete the requirement to record the date discretion was granted[19] and the requirement to record the age or

[11] In addition, NYSE Rules 440.10 and 440.20 and NYSE Rule Interpretation 440.20/01 set forth financial and operational recordkeeping requirements for which there are no equivalent NASD Rules.

[12] Previously, NYSE Rule 410 applied only to orders transmitted or carried to the NYSE Trading Floor ("Floor"), but was amended in 2004 to apply to all orders sent to any marketplace, not just those carried or transmitted to the Floor. *See NYSE Information Memo* 04–38 (July 26, 2004) (Amendments to NYSE Rules 342, 401, 408 and 410 Relating to Supervision and Internal Controls).

[13] The "Off-Hours Trading Facility" is the NYSE facility that permits members to effect securities transactions on the NYSE pursuant to the NYSE Rule 900 Series. *See* NYSE Rule 900(e)(v).

[14] As proposed in *Regulatory Notice* 08–25 (discussed in Item 5 of this filing), FINRA Rule 4511 would have required members to make and preserve books and records as required under FINRA rules, Section 17(a) of the Exchange Act and the applicable associated Exchange Act rules; however, FINRA has modified proposed FINRA Rule 4511 to eliminate the specific reference to Section 17(a) of the Act given that certain Exchange Act recordkeeping requirements are located outside of Section 17(a).

[15] *See supra* note 10.

[16] *See generally* 17 CFR 240. 17a–3(a)(6)–(a)(8).

[17] The FINRA Rule 7400 Series (Order Audit Trail System) requires members to capture, record, and report via OATS specific data elements related to the handling or execution of orders in OTC and Nasdaq equity securities, including recording all times of these events in hours, minutes, and seconds, and to synchronize their business clocks. FINRA is proposing to extend the recording and reporting requirements in the OATS rules to include all NMS stocks. *See* Securities Exchange Act Release No. 62739 (August 18, 2010), 75 FR 52380 (August 25, 2010) (Notice of Filing of SR–FINRA–2010–044).

[18] *See* 17 CFR 240.17a–3(a)(17)(ii).

[19] Pursuant to NASD Rule 2510 (Discretionary Accounts), members would still be required to obtain the customer's prior written authorization. As part of the proposed changes to NASD Rule 2510, FINRA is proposing to require members to obtain the customer's dated prior written authorization. *See Regulatory Notice* 09–63 (November 2009) (Proposed Consolidated FINRA Rule Governing Discretionary Accounts and Transactions).

approximate age of the customer in connection with exempted securities;[20]

• The rule would be amended to provide that its requirements do not apply to investment discretion granted by a customer as to the price at which or the time to execute an order given by the customer for the purchase or sale of a definite dollar amount or quantity of a specified security; and

• The proposed rule change would clarify that nothing in the rule shall be construed as allowing members to maintain discretionary accounts or exercise discretion in such accounts except to the extent permitted under the federal securities laws.

In addition, as discussed in more detail below, the proposed rule change would require that members obtain a "manual" dated signature of each named, natural person authorized to exercise discretion in the account.

NASD Rule 3110(c)(4) sets forth the definition of "institutional account" for purposes of NASD Rule 3110 as well as for NASD Rules 2310 (Recommendations to Customers (Suitability)) and 2510. FINRA proposes to amend this definition of "institutional account" to delete the cross-references to NASD Rules 2310 and 2510 because these rules already include cross-references to this definition.

FINRA also proposes to amend NASD Rule 3110(c) to provide that with respect to accounts opened pursuant to prior NASD Rules (*e.g.,* the January 1991 cut-off specified in NASD Rule 3110(c)), members will be permitted to continue maintaining the information required by those prior NASD Rules until such time as they update the account information in the course of their routine and customary business or as required by other applicable laws or rules.

In addition, the proposed rule change would add supplementary material to:

• Clarify that required customer account records are subject to a six-year retention period;

• Remind members that they may be subject to additional recordkeeping requirements under the Exchange Act (*e.g.,* Exchange Act Rule 17a–3(a)(17));

• Remind members of their obligation to comply with the requirements of FINRA Rule 2070 (Transactions Involving FINRA Employees);[21] and

• Provide general explanations of the terms "maintain" and "preserve" for purposes of Rule 4512 only.

The proposed rule change would renumber NASD Rule 3110(c) as FINRA Rule 4512. The remaining provisions of NASD Rule 3110(c) would be incorporated into FINRA Rule 4512 without material change.

NASD IM–3110 includes cross-references to the requirements of certain other rules that may apply to customer accounts (such as Exchange Act Rules 15g–1 through 15g–9), and it includes a historical reference relating to accounts opened prior to January 1991. FINRA proposes to delete NASD IM–3110 because certain provisions are redundant and others are outdated.

c. Records of Written Customer Complaints (Proposed FINRA Rule 4513)

NASD Rule 3110(d) addresses a member's obligation to preserve records of written customer complaints at each office of supervisory jurisdiction ("OSJ"). NASD Rule 3110(e) defines the term "complaint." Because the definition of "complaint" in NASD Rule 3110(e) relates directly to the requirements of NASD Rule 3110(d), FINRA proposes to merge the two provisions into one rule for simplification. The proposed rule change would renumber NASD Rules 3110(d) and (e) as FINRA Rule 4513.

The proposed rule change also would clarify that the obligation to keep customer complaint records in each OSJ applies only to complaints that relate to that office, including complaints that relate to activities supervised from that office and would provide that members may maintain the required records at the OSJ or make them promptly available at such office upon FINRA's request.

Currently, members are required to preserve customer complaint records for a period of at least three years.[22] To take into account FINRA's four-year routine examination cycle for certain members, the proposed rule change would require that members preserve the customer complaint records for a period of at least four years.

d. *Requirements When Using Predispute Arbitration Agreements for Customer Accounts (Proposed FINRA Rule 2268)*

To ensure that customers are advised about what they are agreeing to when they sign predispute arbitration agreements, NASD Rule 3110(f) requires, among other things, that such agreements contain certain highlighted disclosures. FINRA proposes to incorporate the requirements of the rule with minor changes into the Consolidated FINRA Rulebook. Specifically, FINRA proposes to update the disclosure language to reflect amendments to FINRA Rule 12904 requiring arbitrators to provide an explained decision to the parties in eligible cases[23] if there is a joint request by all parties at least 20 days before the first scheduled hearing date.[24]

The proposed rule change would renumber NASD Rule 3110(f) as FINRA Rule 2268 and would move it to the disclosure section of the Consolidated FINRA Rulebook as a standalone rule.

e. Authorization Records for Negotiable Instruments Drawn From a Customer's Account (Proposed FINRA Rule 4514)

NASD Rule 3110(g) provides that members shall not obtain from a customer or submit for payment a check, draft or other form of negotiable paper drawn on the customer's checking, savings, share or similar account, without that person's express written authorization, which may include the customer's signature on the negotiable instrument. The rule requires members to maintain the required written authorization (other than a copy of a negotiable instrument signed by the customer) for a period of three years. FINRA proposes to amend this provision to clarify that where the required authorization is separate from the negotiable instrument, members must preserve the authorization for a period of three years following the date it expires. The proposed rule change would renumber NASD Rule 3110(g) as FINRA Rule 4514.

f. OATS Recordkeeping Requirements (Proposed FINRA Rule 7440(a)(4))

NASD Rule 3110(h) sets forth the OATS recordkeeping requirements for members that are "Reporting Members," as defined in the OATS rules, for orders received or executed at their trading departments. FINRA proposes to relocate this recordkeeping provision without material change into the OATS rules. The proposed rule change would renumber NASD Rule 3110(h) as paragraph (a)(4) of FINRA Rule 7440.

[20] This would be a conforming revision. The requirement that for discretionary accounts generally members must record the age or approximate age of the customer was eliminated effective in 1991. *See Notice to Members* 90–52 (August 1990) (SEC Approval of Amendments to Article III, Sections 2 and 21 (c) of the Rules of Fair Practice Re: Customer Account Information).

[21] FINRA Rule 2070 plays a vital role in helping FINRA monitor whether employees are abiding by trading restrictions imposed by the FINRA Code of Conduct.

[22] *See* 17 CFR 240.17a–3(a)(18); 17 CFR 240.17a–4(b)(4).

[23] Pursuant to FINRA Rule 12904(g)(6), the requirement does not apply to simplified cases decided without a hearing under FINRA Rule 12800 or to default cases conducted under FINRA Rule 12801.

[24] *See* Securities Exchange Act Release No. 59358 (February 4, 2009), 74 FR 6928 (February 11, 2009) (Order Approving File No. SR–FINRA–2008–051).

g. Approval and Documentation of Changes in Account Name or Designation (Proposed FINRA Rule 4515)

NASD Rule 3110(j) requires that, before a customer order is executed, the account name or designation must be placed upon the memorandum for each transaction.[25] The rule also addresses the approval and documentation procedures for changes in such account name or designation.

As discussed in more detail below, FINRA proposes to amend this provision to clarify that with respect to any change in account name or designation that takes place prior to execution of the trade, the essential facts the principal relied on in approving such change must be documented in writing prior to execution. The proposed rule change would renumber NASD Rule 3110(j) as FINRA Rule 4515. NYSE Rules 410 and 410.10 also include provisions regarding approval and documentation of changes in account name or designation. FINRA proposes to delete the corresponding provisions in NYSE Rules 410 and 410.10 because these provisions are substantially similar to FINRA Rule 4515. As stated earlier, FINRA also proposes to delete the recordkeeping provisions of NYSE Rule 410.

NYSE Rule Interpretation 410/02 outlines an exception to the order entry requirements of NYSE Rule 410 by permitting a member to accept block orders and allowing investment advisers to make allocations on such orders to customers (*i.e.,* allocations among sub-accounts), provided that the member obtains specific account designations or customer names for the order records by the end of the business day. The proposed rule change would transfer NYSE Rule Interpretation 410/02 as FINRA Rule 4515.01, with certain changes as described below.

FINRA proposes to amend the provision so that the exception applies not only to block orders, but to all orders submitted by an investment adviser on behalf of multiple customers. Additionally, members have indicated that in some cases they are unable to obtain the required information by the end of the business day on which the order is executed. Therefore, as a clerical accommodation to members, FINRA proposes to amend the provision and give members until noon of the next business day following the trading session to obtain the required information. The proposal also clarifies that the exception only applies where there is more than one customer for any particular order. Further, the current exception only applies to investment advisers that are either registered under the Investment Advisers Act or subject to state regulation pursuant to Section 203A of the Investment Advisers Act. To cover all investment advisers, FINRA proposes to expand the category of investment advisers subject to the exception to also include investment advisers that qualify for an exception from the Investment Advisers Act's registration requirements pursuant to Section 203(b) of the Investment Advisers Act. FINRA also proposes to clarify that the exception does not apply to accounts handled by registered representatives who otherwise exercise discretionary authority over accounts pursuant to NASD Rule 2510.

Moreover, FINRA proposes to explicitly state that nothing in the rule or supplementary material may be construed as allowing a member knowingly to facilitate the allocation of orders from investment advisers in a manner other than in compliance with both (i) the investment adviser's intent at the time of trade execution to allocate shares on a percentage basis to the participating accounts and (ii) the investment adviser's fiduciary duty with respect to allocations for such participating accounts, including but not limited to allocations based on the performance of a transaction between the time of execution and the time of allocation.

h. Pre-Time Stamping (Proposed FINRA Rule 5340)

NYSE Rule Interpretation 410/01 notes that pre-time stamping of order tickets in connection with block positioning is contrary to NYSE Rule 410. The proposed rule change would adopt this NYSE Rule Interpretation as FINRA Rule 5340 without material change, except for replacing the reference to NYSE Rule 410 with FINRA Rule 4511. FINRA believes that retaining this requirement is appropriate as it expressly prohibits violative conduct for which there are no direct NASD rule equivalents. FINRA Rule 5340 would be new to legacy NASD-only members.

FINRA will announce the implementation date of the proposed rule change in a *Regulatory Notice* to be published no later than 90 days following Commission approval. The implementation date will be no later than 240 days following publication of the *Regulatory Notice* announcing Commission approval.

III. Summary of Comment Letters and FINRA's Response

The proposed rule change was published for comment in the **Federal Register** on November 1, 2010, and the comment period closed on November 22, 2010. The Commission received three comment letters in response to the proposing release: The CAI Letter, the Cornell letter, and the SIFMA letter.[26]

A. Requirements When Using Predispute Arbitration Agreements for Customer Accounts (Proposed FINRA Rule 2268)

One commenter requested that FINRA confirm that the proposed disclosure language applies to predispute arbitration agreements entered into after the effective date of FINRA Rule 2268.[27] In its Response to Comments, FINRA confirmed that the requirement will apply prospectively to predispute arbitration agreements entered into on or after the effective date of FINRA Rule 2268.

B. General Requirements (Proposed Rule 4511)

FINRA noted in its filing with the Commission that its proposed rule would require members to preserve for a period of at least six years those FINRA books and records for which there is no other specified retention period under the FINRA rules or applicable Exchange Act rules. One commenter noted that this requirement is too vague.[28] Another commenter requested that the proposed rule provide a start date for the six-year retention period.[29] In its Response to Comments, FINRA noted that this six-year retention period is a default retention period for FINRA rules that require members to preserve certain books and records but do not specify a retention period, and where there is no retention period specified under Exchange Act rules.

C. Customer Accounts Information (Proposed FINRA Rule 4512)

One commenter requests that FINRA provide guidance regarding the use of "electronic" signatures to satisfy any FINRA signature requirements relating to a member's book and records.[30] In its Response to Comments, FINRA found this comment to be outside of the scope of the proposed rule change and directed the commenter to review the various Commission and self-regulatory

[25] *See also* 17 CFR 240.17a–3(a)(6).

[26] *See supra,* note 4.

[27] CAI.

[28] SIFMA.

[29] CAI.

[30] SIFMA.

organization guidance available. This same commenter also requested clarification on the scope of FINRA Rule 4512(a)(3).[31] In its Response to Comments, FINRA clarified that the provision applies to all discretionary accounts. FINRA further stated that it would address the requirements applicable to other types of accounts in which a person is authorized by a customer to act on the customer's behalf in the context of the proposed changes to NASD Rule 2510 (Discretionary Accounts).[32]

One commenter inquired about the customer age component of Rule 4512(a)(1)(B).[33] Under proposed FINRA Rule 4512(a)(1)(B) members are required to maintain certain information about their customers, including, "whether the customer is of legal age." One commenter suggests that members should instead collect and retain a customer's date of birth.[34] In its Response to Comments, FINRA disagreed and specified that its rule requires members to maintain information establishing that the customer is of legal age to engage in transactions with the member.

FINRA Rule 4512(a)(1)(C) requires members to maintain the name of the associated person, if any, responsible for the account. One commenter requested that the register representative signature requirement currently used in NASD Rule 3110(c)(1)(C) be retained in the new consolidated FINRA rulebook.[35] In its Response to Comments, FINRA reaffirmed that it believes it is "sufficient for a member to maintain the name of the associated person (if any) responsible for the account together with the signature of the partner, officer, or manager denoting that the account has been accepted in accordance with the member's policies and procedures for acceptance of accounts." Regarding this same rule section, one commenter asked for clarification that commission sharing on a customer account or sharing responsibility does not necessarily determine whether an individual is engaged in activities whereby the individual becomes "responsible" for the account.[36] In its Response to Comments, FINRA clarified that for purposes of this rule, responsibility is determined on the scope of the individual's activities with respect to the account.

Finally, with respect to FINRA Rule 4512, one commenter believes that the requirement to update account information for accounts that were opened prior to FINRA Rule 4512 is burdensome.[37] In its Response to Comments, FINRA disagreed, noting that this new requirement promotes greater consistency and uniformity with regards to account record information.

D. Records of Written Customer Complaints (Proposed FINRA Rule 4513)

Two commenters requested that FINRA maintain its current three-year retention period for customer complaint records, rather than the proposed four-year retention period.[38] One commenter further explained that, "[e]xtending the retention period to four (4) years for customer complaint records increases compliance costs for all member firms without regard to the inspection cycles for the majority of firms, and overlooks the fact that all firms, regardless of inspection cycle, report customer complaints directly to FINRA." In its Response to Comments, FINRA noted that its four-year retention period better accommodates its four-year routine examination cycle for certain members. One commenter also suggested that the phrase "written customer complaints" in the proposed rule was not sufficiently clear and recommended that the definition of a "customer complaint" expressly include only a "written grievance."[39] In its Response to Comments, FINRA stated that it believes that the scope of the proposed rule and the definition of "customer complaint" are both appropriate and sufficiently clear.[40]

E. Allocations of Orders Made by Investment Advisers (Proposed FINRA Rule 4515.01)

One commenter was concerned with the scope of Rule 4515.01 and asked whether this provision required the broker-dealers to make a legal determination regarding an adviser's fiduciary duty. In its Response to Comments, FINRA noted that, in this case, "the 'knowingly facilitate' standard means the broker-dealer may not act recklessly or with knowledge in facilitating an investment adviser's breach of its fiduciary duty to clients, and compliance with that standard turns on the facts and circumstances."

F. Other Comment

Finally, one commenter requested that FINRA specifically state that the proposed rule requirements, "apply only to records generated after the effective date of the proposal."[41] In its Response to Comments, FINRA responded to the request by specifying that the requirements, "will apply prospectively on or after the effective date of the proposed rule change."

IV. Discussion and Commission Findings

The Commission has carefully considered the proposed rule change, the comments received, and FINRA's Response to Comments and finds that the proposed rule change is consistent with the requirements of the Exchange Act, and the rules and regulations thereunder that are applicable to a national securities association.[42] In particular, the Commission finds that the proposal is consistent with Section 15A(b)(6) of the Act,[43] which requires, among other things, that the rules of a national securities association be designed to prevent fraudulent and manipulative acts and practices, to promote just and equitable principles of trade, remove impediments to and perfect the mechanism of a free and open market and a national market system, and, in general, protect investors and the public interest.

Proposed FINRA Rule 4511 would streamline and replace the language of current NASD Rule 3110(a), as well as eliminate NYSE Rule 410 and subparagraphs (a)(1)–(3) and (b) of NYSE Rule 440.[44] Further, in cases where there is no specified retention period under FINRA rules or applicable Exchange Act rules, the proposed rule would require members to preserve such records for a period of six years. The Commission notes that one commenter stated that the six-year default retention period was too vague,[45] and another commenter requested clarification regarding the start date for the default six-year retention period.[46] FINRA adequately responded to these concerns in its Response to Comments. The Commission believes this proposed change would be beneficial insofar as it would consolidate in one rule the obligations of FINRA members to make

[31] SIFMA.

[32] *See Regulatory Notice* 09–63 (November 2009) (Proposed Consolidated FINRA Rule Governing Discretionary Accounts and Transactions).

[33] SIFMA.

[34] SIFMA.

[35] Cornell.

[36] CAI.

[37] CAI.

[38] CAI and SIFMA.

[39] SIFMA.

[40] Response to Comments.

[41] SIFMA.

[42] In approving this proposed rule change, the Commission notes that it has considered the proposed rule's impact on efficiency, competition, and capital formation. 15 U.S.C. 78c(f).

[43] 15 U.S.C. 78*o*–3(b)(6).

[44] *See supra* Part II.A.2.a.

[45] SIFMA.

[46] CAI.

and preserve certain books and records. In so doing, the proposed rule would clarify the obligations of FINRA members and promote compliance by virtue of such greater clarity.

Proposed FINRA Rule 4512 would, among other things, simplify the customer account information requirements in NASD Rule 3110(c)(1) and simplify and clarify certain requirements set forth in NASD Rule 3110(c)(3) with respect to discretionary accounts. As noted above, proposed FINRA Rule 4512 would also provide that with respect to accounts opened prior to January 1991, members will be permitted to continue maintaining the information required by the prior NASD rules in effect at that time until such time as the member updates the account information in the course of their routine and customary business or as otherwise required by law or rules.[47] The proposed rule would also eliminate certain redundant cross-references.

FINRA received a number of comments on this aspect of the proposed rule change,[48] and the Commission believes that FINRA has adequately responded to such comments in its Response to Comment.[49] Further, the Commission believes that the proposed changes in FINRA Rule 4512 would update, clarify, and streamline existing rule requirements regarding customer account information. The Commission believes that such changes will be helpful to FINRA members, as well as assist FINRA in fulfilling its responsibilities as an SRO under the Act.

As noted above, proposed FINRA Rule 4513 would merge existing requirements in NASD Rules 3110(d) and 3110(e), clarify that the obligation to keep customer complaint records in each OSJ applies only to complaints that relate to that office and provide that members may maintain the required records at the OSJ or make them promptly available at such office upon FINRA's request.[50] Finally, the proposed rule change would require that members preserve customer complaints be preserved for at least four years to take into account FINRA's four-year routine examination cycle.

Two commenters recommended maintaining the current three-year retention period for customer complaint records,[51] and one of these commenters suggested the use of the term "written customer complaints" in the proposed rule is not sufficiently clear.[52] The Commission believes that FINRA adequately responded to these concerns in its Response to Comments. The Commission also believes that the changes relating to the definition of the term "complaint" in NASD Rules 3110(d) and 3110(e), and the elucidation regarding the obligation to keep customer complaint records, are helpful changes that will clarify FINRA's rulebook and promote compliance by FINRA members. Similarly, preserving customer complaint records for four years will promote FINRA's ability to supervise its members for compliance with the federal securities laws and FINRA's rules.

As noted above, FINRA is also proposing to incorporate NASD Rule 3110(f), relating to predispute arbitration agreements, into the Consolidated FINRA Rulebook as FINRA Rule 2268, with some additional changes to reflect amendments to FINRA Rule 12904.[53] One commenter requested that FINRA confirm that the proposed disclosure language will only apply to predispute arbitration agreements entered into after the effective date of FINRA Rule 2268.[54] In its Response to Comments, FINRA provided such confirmation.[55] Consistent with other changes FINRA is proposing, the Commission believes FINRA Rule 2268 will update and clarify the FINRA rulebook and that such changes will promote greater compliance by FINRA members and assist FINRA in discharging its duties as an SRO.

FINRA also proposes to relocate the OATS recordkeeping requirement for members that are "Reporting Members" (as defined in the OATS rules) from NASD Rule 3110(h) to paragraph (a)(4) of FINRA Rule 7440.[56] The Commission believes that this aspect of the proposed rule change is reasonable given that it is logical to include an OATS recordkeeping requirement in the OATS rules.

FINRA also proposes to amend NASD Rule 3110(j) to clarify that with respect to any change in account name or designation that takes place prior to execution of the trade, the essential facts the principal relied upon in approaching such change must be documented in writing prior to execution.[57] This modified provision would be designated as FINRA Rule 4515. FINRA also is proposing to delete corresponding provisions in NYSE Rules 410 and 410.10, because these provisions are largely duplicative of proposed FINRA Rule 4515. FINRA would transfer NYSE Rule Interpretation 410/02 as FINRA Rule 4515.01, with certain modifications as described above in more detail.[58]

The Commission believes that the changes in proposed FINRA Rule 4515 relating to clarifying the change in account name or designation prior to trade execution are consistent with the protection of investors because the proposed rule provides that any such changes will be documented in writing, an important safeguard. Further, as stated previously with respect to other changes eliminating duplicative or overlapping provisions, the elimination of NYSE Rules 410 and 410.10 should provide a clearer, more streamlined, and simplified rulebook that will promote greater compliance by FINRA members and help FINRA discharge its responsibilities as an SRO.[59] The Commission also notes that with respect to the rule change adopting NYSE Rule Interpretation 410/02 as FINRA Rule 4515.01, FINRA has explicitly stated that nothing in the rule or supplementary material may be construed as allowing a member knowingly to facilitate the allocation of orders from investment advisers in a manner other than in compliance with both (i) the investment adviser's intent at the time of the trade execution to allocate shares on a percentage basis to the participating accounts; and (ii) the investment adviser's fiduciary duty with respect to allocations for such participating accounts, including but not limited to allocations based on the performance of a transaction between the time of execution and the time of allocation.

NYSE Rule Interpretation 410/01 notes that pre-time stamping of order tickets in connection with block positioning is contrary to NYSE Rule 410. FINRA proposes incorporating NYSE Rule Interpretation 410/01 as FINRA Rule 5340 without substantive changes. FINRA has stated, and the Commission agrees, that retaining this requirement is appropriate because it expressly prohibits violative conduct for which there are no direct NASD rule equivalents.[60]

[47] *See supra* Part II.A.2.b.

[48] SIFMA, CAI, Cornell.

[49] Response to Comments.

[50] *See supra* Part II.A.2.c.

[51] SIFMA and CAI.

[52] SIFMA.

[53] *See supra* Part II.A.2.d.

[54] CAI.

[55] Response to Comments.

[56] *See supra* Part II.A.2.f.

[57] *See supra* Part II.A.2.g.

[58] *Id.*

[59] *See supra* Part II.A.2.g.

[60] *See supra* Part II.A.2.h.

It is therefore ordered, pursuant to Section 19(b)(2) of the Act,[61] that the proposed rule change (SR–FINRA–2010–052) be, and hereby is, approved.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[62]

Elizabeth M. Murphy,

Secretary.

[FR Doc. 2011–2292 Filed 2–1–11; 8:45 am]

BILLING CODE 8011–01–P

[61] 15 U.S.C. 78(b)(2).

[62] 17 CFR 200.30–3(a)(12).

SMALL BUSINESS ADMINISTRATION

[Disaster Declaration #12454 and #12455]

Missouri Disaster #MO–00046

AGENCY: U.S. Small Business Administration.

ACTION: Notice.

SUMMARY: This is a notice of an Administrative declaration of a disaster for the State of Missouri.

Dated 01/28/2011.

Incident: Severe Storms, High Winds, Hail, and Tornadoes.

Incident Period: 12/30/2010 through 12/31/2010.

Effective Date: 01/28/2011.

Physical Loan Application Deadline Date: 03/29/2011.

Economic Injury (EIDL) Loan Application Deadline Date: 10/28/2011.

ADDRESSES: Submit completed loan applications to: U.S. Small Business Administration, Processing and Disbursement Center, 14925 Kingsport Road, Fort Worth, TX 76155.

FOR FURTHER INFORMATION CONTACT: A. Escobar, Office of Disaster Assistance, U.S. Small Business Administration, 409 3rd Street, SW., Suite 6050, Washington, DC 20416.

SUPPLEMENTARY INFORMATION: Notice is hereby given that as a result of the Administrator's disaster declaration, applications for disaster loans may be filed at the address listed above or other locally announced locations.

The following areas have been determined to be adversely affected by the disaster:

Primary Counties: Franklin.

Contiguous Counties:

Missouri: Crawford, Gasconade, Jefferson, Saint Charles, Saint Louis, Warren, Washington.

The Interest Rates are:

	Percent
For Physical Damage:	
Homeowners With Credit Available Elsewhere	4.500
Homeowners Without Credit Available Elsewhere	2.250
Businesses With Credit Available Elsewhere	6.000
Businesses Without Credit Available Elsewhere	4.000
Non-Profit Organizations With Credit Available Elsewhere	3.250
Non-Profit Organizations Without Credit Available Elsewhere	3.000
For Economic Injury:	
Businesses & Small Agricultural Cooperatives Without Credit Available Elsewhere	4.000
Non-Profit Organizations Without Credit Available Elsewhere	3.000

The number assigned to this disaster for physical damage is 12454 B and for economic injury is 12455 0.

The State which received an EIDL Declaration # is Missouri.

(Catalog of Federal Domestic Assistance Numbers 59002 and 59008)

Dated: January 28, 2011.

Karen G. Mills,

Administrator.

[FR Doc. 2011–2277 Filed 2–1–11; 8:45 am]

BILLING CODE 8025–01–P

SMALL BUSINESS ADMINISTRATION

[Disaster Declaration #12456 and #12457]

California Disaster #CA–00164

AGENCY: U.S. Small Business Administration.

ACTION: Notice.

SUMMARY: This is a Notice of the Presidential declaration of a major disaster for Public Assistance Only for the State of California (FEMA–1952–DR), dated 01/26/2011.

Incident: Severe Winter Storms, Flooding, and Debris and Mud Flows

Incident Period: 12/17/2010 through 01/04/2011.

EFFECTIVE DATE: 01/26/2011.

Physical Loan Application Deadline Date: 03/28/2011.

Economic Injury (EIDL) Loan Application Deadline Date: 10/26/2011.

ADDRESSES: Submit completed loan applications to: U.S. Small Business Administration, Processing and Disbursement Center, 14925 Kingsport Road, Fort Worth, TX 76155.

FOR FURTHER INFORMATION CONTACT: A. Escobar, Office of Disaster Assistance, U.S. Small Business Administration, 409 3rd Street, SW., Suite 6050, Washington, DC 20416

SUPPLEMENTARY INFORMATION: Notice is hereby given that as a result of the President's major disaster declaration on 01/26/2011, Private Non-Profit organizations that provide essential services of governmental nature may file disaster loan applications at the address listed above or other locally announced locations.

The following areas have been determined to be adversely affected by the disaster:

Primary Counties: Inyo, Kern, Kings, Orange, Riverside, San Bernardino, San Diego, San Luis Obispo, Santa Barbara, Tulare.

The Interest Rates are:

	Percent
For Physical Damage:	
Non-Profit Organizations With Credit Available Elsewhere	3.250
Non-Profit Organizations Without Credit Available Elsewhere	3.000
For Economic Injury:	
Non-Profit Organizations Without Credit Available Elsewhere	3.000

The number assigned to this disaster for physical damage is 12456B and for economic injury is 12457B

(Catalog of Federal Domestic Assistance Numbers 59002 and 59008)

James E. Rivera,

Associate Administrator for Disaster Assistance.

[FR Doc. 2011–2280 Filed 2–1–11; 8:45 am]

BILLING CODE 8025–01–P

DEPARTMENT OF THE TREASURY

Submission for OMB Review; Comment Request

January 24, 2011.

The Department of the Treasury will submit the following public information collection requirement(s) 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. Copies of the submission(s) may be obtained by calling the Treasury Bureau Clearance Officer listed. Comments regarding this information collection should be addressed to the OMB reviewer listed and to the Treasury Department Clearance Officer, Department of the Treasury, Room 11000, 1750 Pennsylvania Avenue, NW., Washington, DC 20220.

Dates: Written comments should be received on or before March 4, 2011 to be assured of consideration.

Alcohol and Tobacco Tax and Trade Bureau (TTB)

OMB Number: 1513–0001.

Type of Review: Extension without change of a currently approved collection.

Title: Tax Information Authorization.

Form: TTB F 5000.19.

Abstract: TTB F 5000.19 is required by TTB to be filed when a respondent's representative, not having a power of attorney, wishes to obtain confidential information regarding the respondent. After proper completion of the form, information can be released to the representative. TTB uses this form to properly identify the representative and his/her authority to obtain confidential information.

Respondents: Individuals and Households.

Estimated Total Burden Hours: 50 hour.

OMB Number: 1513–0003.

Type of Review: Extension without change of a currently approved collection.

Title: Referral of Information.

Form: TTB F 5000.21.

Abstract: When we discover potential violations of Federal, State, or local, we use TTB F 5000.21 to make referrals to Federal, State, or local agencies to determine if they plan to take action, and to internally refer potential violations of TTB administered statutes. We also use TTB F 5000.21 to evaluate effectiveness of these referrals.

Respondents: Federal Government.

Estimated Total Burden Hours: 500 hour.

Clearance Officer: Gerald Isenberg, Alcohol and Tobacco Tax and Trade Bureau, Room 200 East, 1310 G Street, NW, Washington, DC 20005; (202) 453–2097.

OMB Reviewer: Shagufta Ahmed, Office of Management and Budget, New Executive Office Building, Room 10235, Washington, DC 20503; (202) 395–7873.

Celina M. Elphage,

Treasury PRA Clearance Officer.

[FR Doc. 2011–1915 Filed 1–27–11; 8:45 am]

BILLING CODE 4810–31–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 1 individual and 12 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 1 individual and 12 entities identified in this notice pursuant to section 805(b) of the Kingpin Act is effective on January 26, 2011.

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 January 26, 2011, the Director of OFAC designated 1 individual and 12 entities whose property and interests in property are blocked pursuant to section 805(b) of the Foreign Narcotics Kingpin Designation Act.

The list of additional designees is as follows:

1. KHARROUBI, Ali Mohamed (a.k.a. KHAROUBI, Ali; a.k.a. "KAROBY, Ali"), c/o SOLMAR, Lebanon; c/o ELLISSA HOLDING, Lebanon; c/o ELLISSA GROUP SA, Benin; c/o AGROPHEN, Benin; c/o ELLISSA SHIPPING, Benin; c/o YAMEN BENIN SARL, Benin; c/o ELLISSA PARC COTONOU, Benin; c/o ELLISSA MEGASTORE,Benin; c/o SOCIETE ELLISSA GROUP CONGO, Congo, Republic of the; c/o ELLISSA EXCHANGE COMPANY, Lebanon; DOB 8 Jul 1970; citizen Lebanon; nationality Lebanon; Passport RL0603911 (Lebanon) (INDIVIDUAL) [SDNTK]

2. ELLISSA HOLDING (a.k.a. ELLISSA SAL (HOLDING)), Atrium Building, Weygand Street, Central District, Beirut, Lebanon (ENTITY) [SDNTK]

3. SOLMAR, Atrium Building, Weygand Street, Central District, Beirut, Lebanon (ENTITY) [SDNTK]

4. ELLISSA GROUP SA (a.k.a. "ELESSA GROUP"), 01 BP 6269, Cotonou, Atlantique, Benin; C.R. No. 03–B–1620 (ENTITY) [SDNTK]

5. AGROPHEN (a.k.a. AGRO–PHEN), 01 BP 6269, Cotonou, Benin (ENTITY) [SDNTK]

6. ELLISSA SHIPPING, 01 BP 6269, Cotonou, Benin (ENTITY) [SDNTK]

7. YAMEN BENIN SARL, 01 BP 6269, Cotonou, Benin (ENTITY) [SDNTK]

8. ELLISSA PARC COTONOU, 01 BP 6269, Cotonou, Benin (ENTITY) [SDNTK]

9. ELLISSA MEGASTORE (a.k.a. ELLISSA MEGA STORE), Quartier SCOA GBETO, Carre 148, Cotonou, Benin; 01 BP 6269, Cotonou, Benin (ENTITY) [SDNTK]

10. ALMACEN JUNIOR, Carrera 13 No. 11–24, Maicao, Colombia; Matricula Mercantil No. 00002911 (Colombia) (ENTITY) [SDNTK]

11. ALMACEN JUNIOR NO. 2, Calle 10 No. 12–46, Maicao, Colombia; Matricula Mercantil No. 00008712 (Colombia) (ENTITY) [SDNTK]

12. COMERCIAL PLANETA, Carrera 12 No. 12–13, Maicao, Colombia; Matricula Mercantil No. 00072179 (Colombia) (ENTITY) [SDNTK]

13. SOCIETE ELLISSA GROUP CONGO (a.k.a. ELLISSA GROUP SA

CONGO; a.k.a. ELLISSA PARC CONGO; a.k.a. ELLISSA GROUP CONGO), Avenir Lassy Zephyr, Immeuble Socotra, Pointe Noire, Congo, Republic of the; C.R. No. 07B233 (ENTITY) [SDNTK]

Dated: January 26, 2011.

Adam J. Szubin,

Director, Office of Foreign Assets Control.

[FR Doc. 2011–2179 Filed 2–1–11; 8:45 am]

BILLING CODE 4810–AL–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 9 individuals and 8 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 9 individuals and 8 entities identified in this notice pursuant to section 805(b) of the Kingpin Act is effective on January 26, 2011.

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 January 26, 2011, the Director of OFAC designated 9 individuals and 8 entities whose property and interests in property are blocked pursuant to section 805(b) of the Foreign Narcotics Kingpin Designation Act.

The list of additional designees is as follows:

1. JOUMAA, Ayman Saied (a.k.a. JOMAA KHARFAN, Aiman Said; a.k.a. JOMAA, Aymen; a.k.a. JOMAA, Aymen Saeid; a.k.a. JOUMAA, Aiman; a.k.a. JOUMAA, Eiman; a.k.a. JOUMHA, Aymen), Lebanon; Maicao, Colombia; Medellin, Colombia; DOB 21 Jun 1964; alt. DOB 15 Jun 1976; POB Al Karouan, Lebanon; alt. POB Barranquilla, Colombia; citizen Lebanon; alt. citizen Colombia; nationality Lebanon; alt. nationality Colombia; Cedula No. 84075050 (Colombia); Passport RL 0235074 (Lebanon); alt. Passport P013331 (Colombia) (individual) [SDNTK]

2. JOUMAA, Akram Saied (a.k.a. JOMAA YOUSSEF, Akram Said), Lebanon; DOB 07 Jun 1956; POB Al Karouan, Lebanon; nationality Lebanon; Passport 11869936 (Venezuela); RUC # 3–NT–1–6255 (Panama) (individual) [SDNTK]

3. JOUMAA, Anwar Saied (a.k.a. JOMAA, Anmar; a.k.a. JOMAA, Anwar Said), Lebanon; POB Al Karouan, Lebanon; nationality Lebanon; Cedula No. 84072009 (Colombia); Passport 392065 (Panama) (individual) [SDNTK]

4. JOUMAA, Mohamad Said (a.k.a. JOMAA, Mohamed Said), Lebanon; DOB 06 Apr 1977; POB Lala, Lebanon; Cedula No. 84076630 (Colombia) (individual) [SDNTK]

5. YOUSSEF, Ismael Mohammed (a.k.a. YOUSSEF ABDALLAH, Ismael; a.k.a. YOUSSEF, Ismail Mohammad), Lebanon; DOB 12 Sep 1979; POB Santa Marta, Colombia; alt. POB Lebanon; citizen Colombia; nationality Colombia; alt. nationality Lebanon; Cedula No. 17900973 (Colombia); Passport AF038564 (Colombia); alt. Passport AK037837 (Colombia) (individual) [SDNTK]

6. YOUSSEF, Ziad Mohamad, Lebanon; DOB 22 Sep 1976; POB West Bekaa, Baaloul, Lebanon; citizen Lebanon; nationality Lebanon (individual) [SDNTK]

7. AYASH, Hassan (a.k.a. AYACHE, Mahmoud Hassan), Beirut, Lebanon; DOB 1943; POB Miziara, Lebanon; nationality Lebanon (individual) [SDNTK]

8. AYACHE, Hassan Mahmoud (a.k.a. AYACH, Hassan; a.k.a. AYACHE, Hassan Mohamad; a.k.a. AYASH, Hassan; a.k.a. AYASH, Hassan Muhammad; a.k.a. AYASH, Hassane), Beirut, Lebanon; DOB 01 May 1963; POB Beirut, Lebanon; citizen Lebanon; nationality Lebanon; Passport RL0361632 (Lebanon) (individual) [SDNTK]

9. KHAROUBI, Jamal Mohamad, Lebanon; DOB 01 Nov 1976; POB Saida, Lebanon; citizen Lebanon; Passport RL0068313 (Lebanon) (individual) [SDNTK]

10. JOUMAA MONEY LAUNDERING ORGANIZATION/DRUG TRAFFICKING ORGANIZATION (a.k.a. "JOUMAA MLO/DTO"); Beirut, Lebanon; Maicao, Colombia; (ENTITY) [SDNTK]

11. HASSAN AYASH EXCHANGE COMPANY (a.k.a. HASSAN AYAS PARTNER EXCHANGE CO; a.k.a. AYASH XCHANGE CO.; a.k.a. AYASH EXCHANGE COMPANY SARL; a.k.a. MAKDESSI SAYRAFI COMPANY; a.k.a. HASSANE AYASH EXCHANGE CO. SARL; a.k.a. HASSAN AYACH EXCHANGE); Madame Curie St., Hamra St., Beirut, Lebanon; (ENTITY) [SDNTK]

12. ELLISSA EXCHANGE COMPANY (a.k.a. ELESSA EXCHANGE; a.k.a. ELISSA EXCHANGE); Sarafand, Lebanon; (ENTITY) [SDNTK]

13. PHENICIA SHIPPING OFFSHORE SARL, Beirut, Lebanon; (ENTITY) [SDNTK]

14. NEW LINE EXCHANGE TRUST CO., 2901 Omar and Khaled Richani Building, Beirut, Lebanon; 2901 Icaria, Ras Beirut, Lebanon; (ENTITY) [SDNTK]

15. CAESAR'S PARK HOTEL (a.k.a. CEASAR'S PARK HOTEL; a.k.a.

CEASERS PARK HOTEL); Madame Curie St., Beirut, Lebanon; (ENTITY) [SDNTK]

16. GOLDI ELECTRONICS S.A., Colon, Panama; RUC # 1476422–1–642962 (Panama); (ENTITY) [SDNTK]

17. ZONA LIBRE INTERNATIONAL MARKET S.A., Colon, Panama; RUC # 66161–20–363386 (Panama); (ENTITY) [SDNTK]

Dated: January 26, 2011.

Adam J. Szubin,

Director, Office of Foreign Assets Control.

[FR Doc. 2011–2181 Filed 2–1–11; 8:45 am]

BILLING CODE 4810–AL–P

FEDERAL REGISTER

Vol. 76 Wednesday,
No. 22 February 2, 2011

Part II

Department of Health and Human Services

Centers for Medicare & Medicaid Services

42 CFR Parts 405, 424, 447 et al.

Office of Inspector General

42 CFR Part 1007
Medicare, Medicaid, and Children's Health Insurance Programs; Additional Screening Requirements, Application Fees, Temporary Enrollment Moratoria, Payment Suspensions and Compliance Plans for Providers and Suppliers; Final Rule

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Parts 405, 424, 447, 455, 457, and 498

Office of Inspector General

42 CFR Part 1007

[CMS–6028–FC]

RIN 0938–AQ20

Medicare, Medicaid, and Children's Health Insurance Programs; Additional Screening Requirements, Application Fees, Temporary Enrollment Moratoria, Payment Suspensions and Compliance Plans for Providers and Suppliers

AGENCY: Centers for Medicare & Medicaid Services (CMS); Office of Inspector General (OIG), HHS.

ACTION: Final rule with comment period.

SUMMARY: This final rule with comment period will implement provisions of the ACA that establish: Procedures under which screening is conducted for providers of medical or other services and suppliers in the Medicare program, providers in the Medicaid program, and providers in the Children's Health Insurance Program (CHIP); an application fee imposed on institutional providers and suppliers; temporary moratoria that may be imposed if necessary to prevent or combat fraud, waste, and abuse under the Medicare and Medicaid programs, and CHIP; guidance for States regarding termination of providers from Medicaid and CHIP if terminated by Medicare or another Medicaid State plan or CHIP; guidance regarding the termination of providers and suppliers from Medicare if terminated by a Medicaid State agency; and requirements for suspension of payments pending credible allegations of fraud in the Medicare and Medicaid programs. This final rule with comment period also discusses our earlier solicitation of comments regarding provisions of the ACA that require providers of medical or other items or services or suppliers within a particular industry sector or category to establish compliance programs.

We have identified specific provisions surrounding our implementation of fingerprinting for certain providers and suppliers for which we may make changes if warranted by the public comments received. We expect to publish our response to those comments, including any possible changes to the rule made as a result of them, as soon as possible following the end of the comment period. Furthermore, we clarify that we are finalizing the adoption of fingerprinting pursuant to the terms and conditions set forth herein.

DATES: *Effective date:* These regulations are effective on March 25, 2011. *Comment date:* We will consider public comments only on the Fingerprinting Requirements, contained in §§ 424.518 and 455.434 and discussed in section II.A.5. of the preamble of this document, if we receive them at one of the addresses provided below, no later than 5 p.m. on April 4, 2011.

ADDRESSES: In commenting, please refer to file code CMS–6028–FC. Because of staff and resource limitations, we cannot accept comments by facsimile (FAX) transmission.

You may submit comments in one of four ways (please choose only one of the ways listed):

1. *Electronically.* You may submit electronic comments on this regulation to *http://www.regulations.gov.* Follow the instructions for "submitting a comment."

2. *By regular mail.* You may mail written comments to the following address ONLY: Centers for Medicare & Medicaid Services, Department of Health and Human Services, *Attention:* CMS–6028–FC, P.O. Box 8013, Baltimore, MD 21244–8013.

Please allow sufficient time for mailed comments to be received before the close of the comment period.

3. *By express or overnight mail.* You may send written comments to the following address ONLY: Centers for Medicare & Medicaid Services, Department of Health and Human Services, *Attention:* CMS–6028–FC, Mail Stop C4–26–05, 7500 Security Boulevard, Baltimore, MD 21244–1850.

4. *By hand or courier.* If you prefer, you may deliver (by hand or courier) your written comments before the close of the comment period to either of the following addresses: a. For delivery in Washington, DC—Centers for Medicare & Medicaid Services, Department of Health and Human Services, Room 445–G, Hubert H. Humphrey Building, 200 Independence Avenue, SW., Washington, DC 20201.

(Because access to the interior of the Hubert H. Humphrey Building is not readily available to persons without Federal government identification, commenters are encouraged to leave their comments in the CMS drop slots located in the main lobby of the building. A stamp-in clock is available for persons wishing to retain a proof of filing by stamping in and retaining an extra copy of the comments being filed.)

b. For delivery in Baltimore, MD—Centers for Medicare & Medicaid Services, Department of Health and Human Services, 7500 Security Boulevard, Baltimore, MD 21244–1850.

If you intend to deliver your comments to the Baltimore address, please call telephone number (410) 786–9994 in advance to schedule your arrival with one of our staff members.

Comments mailed to the addresses indicated as appropriate for hand or courier delivery may be delayed and received after the comment period.

FOR FURTHER INFORMATION CONTACT: Frank Whelan (410) 786–1302 for Medicare enrollment issues. Claudia Simonson (312) 353–2115 for Medicaid and CHIP enrollment issues. Lori Bellan (410) 786–2048 for Medicaid payment suspension issues and Medicaid termination issues. Joseph Strazzire (410) 786–2775 for Medicare payment suspension issues. Laura Minassian-Kiefel (410) 786–4641 for compliance program issues.

SUPPLEMENTARY INFORMATION: Due to the many organizations and terms to which we refer by acronym in this final rule with comment period, we are listing these acronyms and their corresponding terms in alphabetical order below. In addition, we are providing a table of contents which follows the list of acronyms to assist readers in referencing sections contained in this preamble.

Acronyms

ABC American Board for Certification in Orthotics and Prosthetics
A/B MAC Part A or Part B Medicare Administrative Contractor
ACA "Affordable Care Act"
APD Advance planning document
ASC Ambulatory surgical center
BBA Balanced Budget Act of 1997 (Pub. L. 105–33)
BIPA Medicare Medicaid, and SCHIP Benefits Improvement Protection Act of 2000 (Pub. L. 106–544)
CAH Critical access hospital
CAP Competitive acquisition program
CBA Competitive bidding area
CFR Code of Federal Regulations
CHIP Children's Health Insurance Program
CJIS Criminal Justice Information Services
CLIA Clinical laboratory improvement amendments
CMHC Community mental health centers
CMS Centers for Medicare & Medicaid Services
CON Certificate of Need
CoP Condition of participation
CORF Comprehensive outpatient rehabilitation facility
CPI–U Consumer price index for all urban consumers
DAB Department Appeal Board

DEA Drug Enforcement Agency
DHUD Department of Housing and Urban Development
DME Durable medical equipment
DMEPOS Durable medical equipment prosthetics, orthotics, and supplies
DOB Dates of birth
DOJ Department of Justice
EIN Employer Identification Number
EMTALA Emergency Medical Treatment and Active Labor Act
VIN Vehicle Identifier Number
ESRD End-stage renal disease
EPLS General Service Administration's Excluded Parties List System
FBI Federal Bureau of Investigation
FFP Federal Financial Participation
FFS Medicare fee-for-service program
FQHC Federally qualified health center
GAO Government Accountability Office
HHAs Home health agencies
HHS [Department of] Health and Human Services
HIO Health insuring organization
IAFIS Integrated Automated Fingerprint Identification System
ICF/MR Intermediate care facilities for persons with mental retardation
IDTF Independent diagnostic testing facility
IHCIA Indian Health Care Improvement Act
IHS Indian Health Service
IHSS In-home supportive services
IPF Inpatient psychiatric facility
IRF Inpatient rehabilitation facility
ISDEAA Indian Self-Determination and Education Assistance Act
LEIE List of Excluded Individuals/Entities
MCEs Managed care entities
MFCU Medicaid fraud control unit
MAO Medicare Advantage organizations
MMA Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (Pub. L. 108–173)
NASDAQ National Association of Securities Dealers Automated Quotation System
NF Nursing facility
NPI National Provider Identifier
NPPES National Plan and Provider Enumeration System
NSC National Supplier Clearinghouse
NTIS National Technical Information Service
NPDB National Practitioner Data Bank
NYSE New York Stock Exchange
OIG Office of Inspector General
OMB Office of Management and Budget
OPO Organ procurement organization
PAHP Prepaid ambulatory health plan
PECOS Provider Enrollment, Chain, and Ownership System
PIHP Prepaid inpatient health plan
PSC Program Safeguard Contractors
PTAN Provider transaction account number
RFA Regulatory Flexibility Act
RHC Rural health clinic
RNHCI Religious nonmedical health care institution
SEC Securities and Exchange Commission
SMP Senior Medicare Patrol
SNFs Skilled nursing facilities
SPIA State Program Integrity Assessment
SSA Social Security Administration
SSA DMF Social Security Administration Death Master File
SSN Social Security Number
TTAG Tribal Technical Advisory Group
WAN [FBI CJIS Division's] Wide Area Network
ZPIC Zone Program Integrity Contractors

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I. Background

The Medicare program (title XVIII of the Social Security Act (the Act)) is the primary payer of health care for 47 million enrolled beneficiaries. Under section 1802 of the Act, a beneficiary may obtain health services from an individual or an organization qualified to participate in the Medicare program. Qualifications to participate are specified in statute and in regulations (*see,* for example, sections 1814, 1815, 1819, 1833, 1834, 1842, 1861, 1866, and 1891 of the Act; and 42 CFR Chapter IV, subchapter G, which concerns standards and certification requirements).

Providers and suppliers furnishing services must comply with the Medicare requirements stipulated in the Act and in our regulations. These requirements are meant to ensure compliance with applicable statutes, as well as to promote the furnishing of high quality care. As Medicare program expenditures have grown, we have increased our efforts to ensure that only qualified individuals and organizations are allowed to enroll or maintain their Medicare billing privileges.

The Medicaid program (title XIX of the Act) is a joint Federal and State health care program for eligible low-income individuals providing coverage to more than 51 million people. States have considerable flexibility in how they administer their Medicaid programs within a broad Federal framework and programs vary from State to State.

The Children's Health Insurance Program (CHIP) (title XXI of the Act) is a joint Federal and State health care program that provides health care coverage to more than 7.7 million otherwise uninsured children.

Historically, States, in operating Medicaid and CHIP, have permitted the enrollment of providers who meet the State requirements for program enrollment.

The Patient Protection and Affordable Care Act (Pub. L. 111–148), as amended by the Health Care and Education Reconciliation Act of 2010 (Pub. L. 111–152) (collectively known as the Affordable Care Act or ACA) makes a number of changes to the Medicare and Medicaid programs and CHIP that enhance the provider and supplier enrollment process to improve the integrity of the programs to reduce fraud, waste, and abuse in the programs.

The following is an overview of some of the statutory authority relevant to enrollment in Medicare, Medicaid, and CHIP:

- Sections 1102 and 1871 of the Act provide general authority for the Secretary of Health and Human Services (the Secretary) to prescribe regulations for the efficient administration of the Medicare program. Section 1102 of the Act also provides general authority for the Secretary to prescribe regulations for the efficient administration of the Medicaid program and CHIP.
- Section 4313 of the Balanced Budget Act of 1997 (BBA) (Pub. L. 105–33) amended sections 1124(a)(1) and 1124A of the Act to require disclosure of both the Employer Identification Number (EIN) and Social Security Number (SSN) of each provider or supplier, each person with ownership or control interest in the provider or supplier, any subcontractor in which the provider or supplier directly or indirectly has a 5 percent or more ownership interest, and any managing employees including directors and officers of corporations and non-profit organizations and charities. The "Report to Congress on Steps Taken to Assure Confidentiality of Social Security Account Numbers as required by the Balanced Budget Act" was signed by the Secretary and sent to the Congress on January 26, 1999. This report outlines the provisions of a mandatory collection of SSNs and EINs effective on or after April 26, 1999.
- Section 936(a)(2) of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) (Pub. L. 108–173) amended the Act to require the Secretary to establish a process for the enrollment of providers of services and suppliers. We are authorized to collect information on the Medicare enrollment application (that is, the CMS–855, (Office of Management and Budget (OMB) approval number 0938–0685)) to ensure that correct payments are made to providers and suppliers under the Medicare program as established by title XVIII of the Act.
- Section 1902(a)(27) of the Act provides general authority for the Secretary to require provider agreements under the Medicaid State Plans with every person or institution providing services under the State plan. Under these agreements, the Secretary may require information regarding any payments claimed by such person or institution for providing services under the State plan.
- Section 2107(e) of the Act, which provides that certain title XIX and title XI provisions apply to States under title XXI, including 1902(a)(4)(C) of the Act, relating to conflict of interest standards.
- Section 1903(i)(2) of the Act relating to limitations on payment.
- Section 1124 of the Act relating to disclosure of ownership and related information.
- Sections 6401, 6402, 6501, and 10603 of the ACA and 1304 of the Health Care and Education Reconciliation Act (Pub. L. 111–152) amended the Act by establishing: (1) Procedures under which screening is conducted for providers of medical or other services and suppliers in the Medicare program, providers in the Medicaid program, and providers in the CHIP; (2) an application fee to be imposed on providers and suppliers; (3) temporary moratoria that the Secretary may impose if necessary to prevent or combat fraud, waste, and abuse under the Medicare and Medicaid programs and CHIP; (4) requirements that State Medicaid agencies must terminate any provider that is terminated by Medicare or another State plan; (5) requirements for suspensions of payments pending credible allegations of fraud in both the Medicare and Medicaid programs.

II. Proposed Provisions and Responses to Public Comments

We received approximately 300 timely pieces of correspondence containing multiple comments on the Additional Screening Requirements, Application Fees, Temporary Enrollment Moratoria, Payment Suspensions and Compliance Plans for Providers and Suppliers proposed rule published September 23, 2010 (75 FR 58204). We note that we received some comments that were outside the scope of the proposed rule. These comments are not addressed in this final rule with comment period. Summaries of the public comments that are within the scope of the proposals and our responses to those comments are set forth in the various sections of this final rule with comment period under the appropriate headings.

A. Provider Screening Under Medicare, Medicaid, and CHIP

1. Statutory Changes

Section 6401(a) of the ACA, as amended by section 10603 of the ACA, amends section 1866(j) of the Act to add a new paragraph, paragraph "(2) Provider Screening." Section 1866(j)(2)(A) of the Act requires the Secretary, in consultation with the Department of Health of Human Services' Office of the Inspector General (HHS OIG), to establish procedures under which screening is conducted with respect to providers of medical or other items or services and suppliers under Medicare, Medicaid, and CHIP. Section 1866(j)(2)(B) of the Act requires the Secretary to determine the level of screening to be conducted according to the risk of fraud, waste, and abuse with respect to the category of provider of medical or other items or services or supplier. The provision states that the screening shall include a licensure check, which may include such checks across State lines; and the screening may, as the Secretary determines appropriate based on the risk of fraud, waste, and abuse, include a criminal background check; fingerprinting; unscheduled or unannounced site visits, including pre-enrollment site visits; database checks, including such checks across State lines; and such other screening as the Secretary determines appropriate. Section 1866(j)(2)(C) of the Act requires the Secretary to impose a fee on each institutional provider of medical or other items or services or supplier that would be used by the Secretary for program integrity efforts including to cover the cost of screening and to carry out the provisions of sections 1866(j) and 1128J of the Act. We discussed the fee in section II.B. of the proposed rule.

Section 6401(b) of the ACA amends section 1902 of the Act to add new paragraph (a)(77) and (ii), which requires States to comply with the process for screening providers and suppliers as established by the Secretary under 1866(j)(2) of the Act.[1] Note that section 6401(b) of the ACA erroneously added a duplicate section 1902(ii) to the Act. Therefore, in the Medicare and Medicaid Extenders Act of 2010 (Pub. L. 111–309), the Congress enacted a technical correction to redesignate the section 1902(ii) of the Act added by section 6401(b) of ACA as section 1902(kk) of the Act. In this regulation, we therefore reference section 1902(kk) of the Act when referring to the provisions added by section 6401(b) of the ACA.

We noted in the proposed rule that the statute uses the terms "providers of medical or other items or services," "institutional providers," and "suppliers." The Medicare program enrolls a variety of providers and suppliers, some of which are referred to as "providers of services," "institutional providers," "certified providers," "certified suppliers," and "suppliers." In Medicare, the term "providers of services" under section 1861(u) of the Act means health care entities that furnish services primarily payable under Part A of Medicare, such as hospitals, home health agencies (including home health agencies providing services under Part B), hospices, and skilled nursing facilities. The term "suppliers" defined in section 1861(d) of the Act refers to health care entities that furnish services primarily payable under Part B of Medicare, such as independent diagnostic testing facilities (IDTFs), durable medical equipment prosthetics, orthotics, and supplies (DMEPOS) suppliers, and eligible professionals, which refers to health care suppliers who are individuals, that is, physicians and the other professionals listed in section 1848(k)(3)(B) of the Act. For Medicaid and CHIP, we use the terms "providers" or "Medicaid providers" or "CHIP providers" when referring to all Medicaid or CHIP health care providers, including individual practitioners, institutional providers, and providers of medical equipment or goods related to care. The term "supplier" has no meaning in the Medicaid program or CHIP.

The new screening procedures implemented pursuant to new section 1866(j)(2) of the Act are applicable to newly enrolling providers and suppliers, including eligible professionals, beginning on March 25, 2011. These new procedures are applicable to currently enrolled Medicare, Medicaid, and CHIP providers, suppliers, and eligible professionals beginning on March 23, 2012. These new screening procedures implemented pursuant to new section 1866(j)(2) of the Act are applicable beginning on March 25, 2011 for those providers and suppliers currently enrolled in Medicare, Medicaid, and CHIP who revalidate their enrollment information. Within Medicare, the March 25, 2011 implementation date will impact those current providers and suppliers whose 5-year revalidation cycle (or 3-year revalidation cycle for DMEPOS suppliers) results in revalidation occurring on or after March 25, 2011 and before March 23, 2012.

The requirements for revalidation are discussed in § 424.515. It is important to note that revalidation—for purposes of both provider enrollment in general and this final rule with comment period—does not include routine changes of information as described in § 424.516(d) and (e), such as address changes or changes in phone number.

2. Summary of Existing Screening Measures

Before we outline the new measures we are finalizing under the ACA, it may be helpful to provide a summary of some of the screening measures already being utilized in Medicare, Medicaid, and CHIP. Pursuant to other authority, but with the notable exception of background checks and fingerprinting, Medicare, generally through private contractors, already employs a number of the screening practices described in section 1866(j)(2)(B) of the Act to determine if a provider or supplier is in compliance with Federal and State requirements to enroll or to maintain enrollment in the Medicare program.

We also believe it important to note that nothing in this rule is intended to abridge our established screening authority under existing statutes and regulations or to diminish the screening that providers and suppliers currently undergo. To the contrary; the provisions specified in this final rule with comment period are intended to enhance our existing authority. This rule's provisions, in other words, set "floors"—not ceilings—on enrollment requirements for each screening level.

a. Licensure Requirements—Medicare and Medicaid

Over the past several years, we have taken a number of steps to strengthen our ability to deny or revoke Medicare billing privileges when providers or suppliers do not have or do not maintain the applicable State licensure requirements for their provider or supplier type or profession. We established reporting responsibilities for all providers, suppliers, and eligible professionals in earlier regulations at § 424.516(b) through (e). To ensure that only qualified providers and suppliers remain in the Medicare fee-for-service (FFS) program, we require that Medicare

[1] We believe that the reference to section 1886(j)(2) of the Act in section 6401(b)(1) of the ACA is a scrivener's error. We believe the Congress intended to refer to section 1866(j)(2) of the Act, which, as amended by section 6401(a) of the ACA, requires the Secretary to establish a process for screening providers and suppliers. Because the drafting error is apparent, and a literal reading of the reference to section 1886(j)(2) of the Act would produce absurd results, we interpret the cross-reference to section 1886(j)(2) in the new section 1902(kk) of the Act as if the reference were to section 1866(j)(2).

contractors review State licensing board data on a monthly basis to determine if providers and suppliers remain in compliance with State licensure requirements. Medicare billing privileges would be revoked for those providers and suppliers who do not report a final adverse action (for example, license revocation or suspension, felony conviction) within the applicable reporting period, as required in § 424.516(b) through (e). Medicare suppliers of DMEPOS and IDTFs are already subject to similar provisions in § 424.57(c) and § 410.33(g), respectively. DMEPOS suppliers are also subject to additional requirements including accreditation and surety bonding, pursuant to § 424.57(c)(22) through (26) and § 424.57(d).

Medicare Advantage organizations (MAOs) are required to verify licensure of providers and suppliers, including physicians and other health care professionals, in accordance with § 422.204.

For Medicaid and CHIP, most States do some checking of in-State provider licenses, but the extent of scrutiny varies. For example, in some States, the existence of the license may be verified, but little attention might be given to any restrictions on the license.

b. Site Visits—Medicare

Pursuant to § 424.517, Medicare conducts the following site visits and takes the following actions, generally through private contractors under CMS direction:

- The National Supplier Clearinghouse (NSC) Medicare Administrative Contractor (the Medicare contractor that processes enrollment applications for suppliers of DMEPOS) conducts pre-enrollment site visits to DMEPOS suppliers that are not associated with a chain supplier of DMEPOS (a chain supplier of DMEPOS is a supplier with 25 or more distinct practice locations.)
- The NSC also conducts unannounced post-enrollment site visits to DMEPOS suppliers for which CMS or the NSC believes there is a likelihood of fraudulent or abusive activities to ensure those DMEPOS suppliers remain in compliance with the supplier standards found at § 424.57(c). CMS at times exercises its right to—
- Have the NSC conduct ad hoc pre- and post-enrollment site visits to any DMEPOS supplier;
- Have Medicare contractors conduct pre-enrollment site visits to all IDTFs; and
- Conduct ad hoc pre-and post enrollment site visits to any prospective Medicare provider and supplier or any enrolled Medicare provider or supplier.

In addition, under 42 CFR parts 488 and 489, a State survey agency or an approved national accreditation organization with deeming authority conducts pre-enrollment surveys for certified providers and suppliers to determine whether they meet the applicable Federal conditions and requirements for their provider or supplier type before they can participate in the Medicare program.

We note that the site visits discussed here and elsewhere within this preamble and the final regulations are separate and apart from the site visits that are conducted pursuant to the Clinical Laboratory Improvement Amendments (CLIA). We will work with our State survey agency partners in coordinating these site visits so as to avoid duplication and burden on providers.

c. Database Checks—Medicare

Under existing regulation, Medicare contractors employ database checks of eligible professionals, owners, authorized officials, delegated officials, managing employees, medical directors, and supervising physicians (at IDTFs and laboratories) as part of the Medicare provider and supplier enrollment process. These include database checks with the Social Security Administration (SSA) (to verify an individual's SSN), the National Plan and Provider Enumeration System (NPPES) to verify the National Provider Identifier (NPI) of an eligible professional, and State licensing board checks to determine if an eligible professional is appropriately licensed to furnish medical services within a given State. These checks also include checking a provider or supplier against the HHS OIG's List of Excluded Individuals/Entities (LEIE) and the General Service Administration's Excluded Parties List System (EPLS). All of the database checks have been used to assess the eligibility and qualifications of providers and suppliers to enroll in the Medicare program, to confirm the identity of an eligible professional to ensure that he or she may be considered for enrollment in the Medicare program.

Also, on a monthly basis, CMS' Medicare contractors systematically compare enrolled providers, suppliers, and eligible professionals against the information in the Medicare Exclusions Database. The Medicare Exclusions Database identifies providers, suppliers, and eligible professionals who have been excluded from the Medicare and Medicaid programs by the HHS OIG. When a match is found, the HHS OIG exclusion information is systematically noted in the Medicare enrollment record of the provider, supplier, or eligible professional. In the Medicare program, we deny or revoke the billing privileges of providers, suppliers, and eligible professionals who have been excluded by the HHS OIG. If the HHS OIG lifts the exclusion, the provider, supplier or eligible professional must reapply for enrollment in the Medicare program. In addition, Medicare contractors also review State licensure Web sites on a monthly basis to ensure that eligible professionals continue to meet State licensing requirements.

In addition, since January 2009, we have compared date of death information obtained from the Social Security Administration Death Master File (SSA DMF) with the information maintained in the National Plan and Provider Enumeration System (NPPES), the system that assigns an NPI to individuals and organizations. Based on this comparison and the subsequent verification, we have deactivated the NPIs of more than 11,500 individuals who were previously assigned a type 1 (individual) NPI. We automatically transfer this information from NPPES to the Provider Enrollment, Chain, and Ownership System (PECOS), CMS' national Medicare enrollment repository to deactivate a deceased individual's Medicare billing privileges. In addition, Medicare contractors are required to review and act upon monthly files that contain a list of non-practitioner individuals enrolled in the Medicare program who have been reported to the SSA as deceased. These individuals include: Owners, authorized officials, and delegated officials.

MAOs, as required by § 422.204, generally use database checks to verify licensure and licensure sanctions and limitations with State licensing boards and the Federation of State Medical Boards, DEA certificates with the National Technical Information Service (NTIS), history of adverse professional review actions and malpractice from the National Practitioner Data Bank (NPDB), accreditation status of institutional providers and suppliers with national accrediting boards, such as The Joint Commission (TJC), and search for HHS OIG exclusions using the HHS OIG Web site *http://oig.hhs.gov/fraud/exclusions/exclusions_list.asp.*

d. Criminal Background Checks—Medicare

Section 6401(a) of the ACA amended Section 1866(j) of the Act authorized the Secretary to perform criminal background checks. As described in § 424.530(a) and § 424.535(a), CMS or its

designated Medicare contractor may deny or revoke the Medicare billing privileges of the owner of a provider or supplier, a physician or non-physician practitioner, and terminate any corresponding provider or supplier agreement for a number of reasons, including an exclusion from the Medicare, Medicaid, and any other Federal health care program, a felony within the preceding 10 years that is considered detrimental to the Medicare program, and/or submission of false or misleading information on the Medicare enrollment application. While we require our Medicare contractors to verify data submitted on, and as part of, the Medicare provider/supplier enrollment application, our contractors are not able to verify information that may have been purposefully omitted or changed in a manner to obfuscate any previous criminal activity. A 2005 report issued by the National Task Force on the Criminal Backgrounding of America, sponsored by the Bureau of Justice Statistics and the U.S. Department of Justice, defined a Criminal History Record Check as a check that returns records from official criminal repositories (meaning State repositories and the Federal Bureau of Investigations (FBI) Interstate Identification Index that links Federal and State criminal record systems), and the FBI uses the same terminology. For purposes of responding to comments in this document we use the term criminal history record check to mean criminal background checks when referring to such fingerprint-based checks. Criminal History Record Checks have not been historically used in the FFS Medicare enrollment screening process.

e. Medicare MAO Requirements

As mentioned earlier in this section, MAOs already employ a number of screening procedures in accordance with regulations and CMS manual instructions. Specifically, under § 422.204(b)(3) in the case of providers meeting the definition of "provider of services" in section 1861(u) of the Act, basic benefits may only be provided through providers if they have a provider agreement with us permitting them to furnish services under original Medicare. With respect to other entities like suppliers, § 422.204(b)(3) requires that they "meet the applicable requirements of title XVIII and Part A of title XI of the Act." Given these requirements we considered to what extent MAOs would be required to apply the identical screening requirements we proposed for the original Medicare program or whether substantively similar alternative approaches adopted by MAOs would be acceptable. Accordingly, we solicited public comments on whether or to what extent MAOs should be required to implement the same enhanced screening requirements for providers, suppliers and physicians that we proposed for the original Medicare program.

f. Fingerprinting—Medicare

Previous to this final rule with comment period fingerprinting and fingerprint-based criminal history record information from the FBI was not used in the Medicare enrollment screening process.

g. Screening—Medicaid and CHIP

States vary in the degree to which they employ screening methods such as unscheduled and unannounced site visits and database checks, including such checks across State lines, criminal background checks, and fingerprinting. However, at least a few States utilize each of those methods.

States also varied in what they require their managed care entities (MCEs) [2] to do in terms of screening network-level providers that are not also enrolled in the Medicaid program as FFS providers. We considered to what extent States must require their MCEs to apply the identical screening requirements we proposed for the States or whether substantively similar alternative approaches adopted by MCEs are acceptable. Accordingly, we solicited public comments on whether or to what extent MCEs should be required to implement the same enhanced screening requirements for Medicaid and CHIP providers that we proposed for State Medicaid and CHIP programs.

We again stress that the provider enrollment verification tools that we are currently using—including, but not limited to, those described previously—will not in any way be diminished as a result of this final rule with comment period. In other words, the validation techniques in this rule do not supplant those that are presently in use.

[2] For purposes of this preamble and the final regulations, "managed care entity" and "MCE" will have the meaning Medicaid managed care organization (MCO), primary care case manager (PCCM), prepaid inpatient health plan (PIHP), prepaid ambulatory health plan (PAHP), and health insuring organization (HIO). This definition differs from the meaning in section 1932(a)(1)(B) of the Social Security Act, which limits MCEs to Medicaid MCOs and PCCMs. We are using a more inclusive definition for the regulation so that all those entities in States' managed care programs will provide disclosure information.

3. General Screening of Providers—Medicare

a. Proposed Screening Requirements

Section 1866(j)(2)(B) of the Act requires the Secretary to determine the level of screening applicable to providers and suppliers according to the risk of fraud, waste, and abuse the Secretary determines is posed by particular provider and supplier categories.

In considering how to establish consistent screening standards, we proposed to designate provider and supplier categories that are subject to certain screening procedures based on CMS' assessment of fraud, waste and abuse risk of the provider or supplier category, taking into consideration a variety of factors. These factors include our own experience with claims data used to identify fraudulent billing practices as well as the expertise developed by our contractors charged with investigating and identifying instances of Medicare fraud across a broad spectrum of providers. In addition, CMS has relied on insights gained from numerous studies conducted by the HHS–OIG, GAO, and other sources. We have designated categories of providers or suppliers (for example, "newly enrolling DME suppliers" or "currently enrolled home health agencies") that are subject to screening procedures based on our assessment of the level of screening based on the risk presented by the category of provider. There are three levels of screening and associated risk: "limited," "moderate" and "high," and each provider/supplier category is assigned to one of these three screening levels. The categories described below and associated risk levels assigned are designed to identify those categories of providers and suppliers that pose a risk of fraud, waste, and abuse.

The screening procedures applicable to each screening level are set by us and are included in this final rule with comment period. Under this approach, the relevant Medicare contractor (for example, fiscal intermediary, regional home health intermediary, carriers, Part A or Part B Medicare Administrative Contractor (A/B MAC), or the NSC Administrative Contractor) would utilize the screening tools mandated by us for the screening level assigned to a particular provider or supplier category.

We solicited comments on the proposed assignment of specific provider and supplier types to the proposed risk screening levels, including what criteria should be considered in making such assignments, whether such assignments should be

released publicly, whether they should be subject to agency review and updated according to an established schedule (that is, annually, bi-annually), and the extent to which they should be updated according to evolving risks. We also solicited comments on any additional database checks that we should consider as a type of screening.

Based on the level of screening assigned, we proposed that the Medicare contractors would establish and conduct the following categorical screenings.

TABLE 1—PROPOSED SCREENING LEVELS AND PROCEDURES FOR MEDICARE PHYSICIANS, NON-PHYSICIAN PRACTITIONERS, PROVIDERS, AND SUPPLIERS

Type of screening required	Limited	Moderate	High
Verification of any provider/supplier-specific requirements established by Medicare	X	X	X
Conduct license verifications, (may include licensure checks across States)	X	X	X
Database Checks (to verify Social Security Number (SSN), the National Provider Identifier (NPI), the National Practitioner Data Bank (NPDB) licensure, an OIG exclusion; taxpayer identification number; tax delinquency; death of individual practitioner, owner, authorized official, delegated official, or supervising physician)	X	X	X
Unscheduled or Unannounced Site Visits		X	X
Criminal Background Check			X
Fingerprinting			X

As described previously, we already require Medicare contractors to ensure that every provider or supplier meets any applicable Federal regulations or State requirements, including applicable licensure requirements [3] for the provider or supplier type prior to making an enrollment determination. In addition, we also require that Medicare contractors conduct monthly reviews of State licensing board actions to determine if an individual practitioner, such as a physician or non-physician practitioner continues to meet State licensing requirements. In the case of organizational entities, we also require our Medicare contractors to conduct monthly or periodic checks to determine if an organizational entity continues to meet the Federal and State requirements for its provider or supplier type. Such verifications help ensure that a prospective provider or supplier is eligible to participate in the Medicare program or that an existing provider or supplier is eligible to maintain its Medicare billing privileges.

Previous to this final rule with comment period, in the Medicare program, DMEPOS suppliers were required to re-enroll every 3 years, and other providers were required to revalidate their enrollment every 5 years. The terms revalidation and re-enrollment were often used interchangeably, but are actually specific to these provider types. To eliminate any confusion about which term applies to which provider or supplier, we proposed language at § 424.57(e) to change all references from re-enroll or re-enrollment to revalidate or revalidation. In addition, the ACA requires that no provider or supplier shall be allowed to enroll in Medicare or revalidate its enrollment in Medicare after March 23, 2013 without being screened pursuant to the authorities covered by this final rule with comment period. To assist us in assuring that the statutory effective date is met, we proposed at § 424.515 to permit us to require that a provider or supplier revalidate its enrollment at any time. After the revalidation, the current cycle for revalidation (3 years for DMEPOS, and 5 years for all other providers) would apply.

(1) Limited

Based on our own analysis of historical trends and our own experience with provider screening and enrollment we proposed that, as a category, the following providers and suppliers pose a limited risk to the Medicare program: Physician or non-physician practitioners and medical groups or clinics; providers or suppliers that are publicly traded on the NYSE or NASDAQ; ambulatory surgical centers (ASCs); end-stage renal disease (ERSD) facilities; Federally qualified health centers (FQHCs); histocompatibility laboratories; hospitals, including critical access hospitals (CAHs); Indian Health Service (IHS) facilities; mammography screening centers; organ procurement organizations (OPOs); mass immunization roster billers, portable x-ray suppliers; religious nonmedical health care institutions (RNHCIs); rural health clinics (RHCs); radiation therapy centers; skilled nursing facilities (SNFs), and public or government-owned ambulance services suppliers.

In § 424.518(a), we proposed that the following screening tools will apply to providers and suppliers in categories designated as limited risk: (1) Verification that a provider or supplier meets any applicable Federal regulations, or State requirements for the provider or supplier type prior to making an enrollment determination; (2) verification that a provider or supplier meets applicable licensure requirements; and (3) database checks on a pre- and post-enrollment basis to ensure that providers and suppliers continue to meet the enrollment criteria for their provider/supplier type.

To assist readers in understanding the type of providers and suppliers that we proposed to include in the limited risk screening level, we are providing the following table.

TABLE 2—PROPOSED MEDICARE PROVIDERS AND SUPPLIERS DESIGNATED AS A "LIMITED" CATEGORICAL RISK FOR SCREENING PURPOSES

Provider/supplier category
Physician or non-physician practitioners and medical groups or clinics.
Providers or suppliers that are publicly traded on the NYSE or NASDAQ.

[3] We note that under section 408 of the reauthorized Indian Health Care Improvement Act, "[a]ny requirement for participation as a provider of health care services under a Federal health care program that an entity be licensed or recognized under the State or local law where the entity is located to furnish health care services shall be deemed to have been met in the case of an entity operated by the [Indian Health] Service, an Indian tribe, tribal organization, or urban Indian organization if the entity meets all the applicable standards for such licensure or recognition, regardless of whether the entity obtains a license or other documentation under such State or local law." 25 U.S.C. 1647a.

TABLE 2—PROPOSED MEDICARE PROVIDERS AND SUPPLIERS DESIGNATED AS A "LIMITED" CATEGORICAL RISK FOR SCREENING PURPOSES—Continued

Provider/supplier category
Ambulatory surgical centers, end-stage renal disease facilities, Federally qualified health centers, histocompatibility laboratories, hospitals, including critical access hospitals, Indian Health Service facilities, mammography screening centers, organ procurement organizations, mass immunization roster billers, portable x-ray supplier, religious non-medical health care institutions, rural health clinics, radiation therapy centers, skilled nursing facilities, and public or government-owned or -affiliated ambulance service suppliers.

(2) Moderate

Based on our experience, we proposed that community mental health centers (CMHCs); comprehensive outpatient rehabilitation facilities (CORFs); hospice organizations; independent diagnostic testing facilities (IDTFs); independent clinical laboratories; and non-public, non-government owned or affiliated ambulance services suppliers pose a moderate risk to the Medicare program. However, we provided that any such provider or supplier that is publicly traded on the NYSE or NASDAQ would be considered limited risk. Furthermore, we proposed that currently enrolled (revalidating) home health agencies would be considered "moderate" risk, except any such provider that is publicly traded on the NYSE or NASDAQ would be considered limited risk. Finally, we proposed that currently enrolled (re-validating) suppliers of DMEPOS pose a moderate risk, except that any such supplier that is publicly traded on the NYSE or NASDAQ would be considered "limited" risk. We provide our rationale for these categories in this section below.

For those provider and supplier categories in the "moderate" screening level, we proposed that Medicare contractors would conduct unannounced pre- and/or post-enrollment site visits in addition to those screening tools applicable to the limited level of screening. Based on the success of pre-and/or post enrollment site visits conducted by the NSC during the enrollment process for suppliers of DMEPOS and a similar process established by carriers and A/B MACs during the enrollment of IDTFs, we believe that unscheduled and unannounced pre-and post-enrollment site visits help ensure that suppliers are operational and meet applicable supplier standards or performance standards. In addition, we believe that unscheduled and unannounced pre-and post-enrollment site visits are an essential tool in determining whether a provider or supplier is in compliance with its reporting responsibilities, including the requirement in § 424.516 to notify the Medicare contractor of any change of practice location.

Moreover, § 424.530(a)(5) and § 424.535(a)(5) give us the authority to deny or revoke Medicare billing privileges for providers and suppliers if the provider or supplier is not operational or the provider does not maintain the established provider or supplier performance standards. And while we do not believe that unscheduled or unannounced site visits are necessary for all providers and suppliers, we do believe that a number of businesses, like the ones mentioned below, pose an increased risk to the Medicare program, due at least in part to the lack of individual professional licensure.

In addition, as discussed below, we have found that certain types of providers and suppliers that easily enter a line or business without clinical or business experience—for example, by leasing minimal office space and equipment—present a higher risk of possible fraud to our programs. As such, we believe that because these types of providers pose an increased risk of fraud they should be subject to substantial scrutiny before being permitted to enroll and bill Medicare, Medicaid, or CHIP. This type of pre-enrollment scrutiny will help us move away from the "pay and chase" approach.

Most of the provider and supplier categories in the moderate screening level are generally highly dependent on Medicare, Medicaid, or CHIP to pay their salaries and other operating expenses and are subject to less additional government or professional oversight than the providers and suppliers in the limited risk screening level. Accordingly, we believe it is appropriate and necessary to conduct unscheduled and unannounced pre-enrollment site visits to ensure that these prospective providers and suppliers meet our enrollment requirements prior to enrolling in the Medicare program. Moreover, we believe that post-enrollment site visits are also important to ensure that the enrolled provider or supplier remains a viable health care provider or supplier in the Medicare program.

Accordingly, we proposed in § 424.518(b) that in addition to the categorical screening tools used with respect to limited risk providers and suppliers, Medicare contractors would conduct unannounced and unscheduled site visits prior to enrolling the providers and suppliers assigned to the moderate risk screening level, as set forth earlier in this Section.

In the proposed rule, we set forth our rationale for the assessment of risk ascribed to the providers and suppliers assigned to the "moderate" level of screening. First, we noted that HHS OIG and GAO have issued studies indicating that several of the provider and supplier types cited previously pose an elevated risk of fraud, waste and abuse to the Medicare and Medicare programs and CHIP. In an October 2007 report titled, "Growth in Advanced Imaging Paid under the Medicare Physician Fee Schedule" (OEI–01–06–00260), the HHS OIG recommended that CMS consider conducting site visits to monitor IDTFs' compliance with Medicare requirements." In addition, in an April 2007 report titled, "Medicare Hospices: Certification and Centers for Medicare & Medicaid Services Oversight" (OEI–06–05–00260), the HHS OIG recommended that CMS seek legislation to establish additional enforcement remedies for poor hospice performance. In response to this recommendation, CMS stated that it was considering whether to pursue new enforcement remedies for poor hospice performance. While the Medicare enrollment process is not designed to verify the conditions of participation, we do believe that more frequent onsite visits may help identify those hospice organizations that are no longer operational at the practice location identified on the Medicare enrollment application.

In a January 2006 report titled, "Medicare Payments for Ambulance Transports" (OEI–05–02–000590), the HHS OIG found that "25 percent of ambulance transports did not meet Medicare's program requirements, resulting in an estimated $402 million in improper payments."

In an August 2004 report titled, "Comprehensive Outpatient Rehabilitation Facilities: High Medicare Payments in Florida Raise Program Integrity Concerns" (GAO–04–709), the GAO concluded that, "[s]izeable disparities between Medicare therapy payments per patient to Florida CORFs and other facility-based outpatient therapy providers in 2002—with no clear indication of differences in patient needs—raise questions about the appropriateness of CORF billing practices. After finding high rates of medically unnecessary therapy services to CORFs, CMS's claims administration

contractor for Florida took steps to ensure appropriate claim payments for a small, targeted group of CORF patients. Despite its limited success, billing irregularities continued among some CORFs and many CORFs continued to receive relatively high payments the following year. This suggests that the contractor's efforts were too limited in scope to be effective with all CORF providers."

In addition to GAO and HHS OIG studies and reports, a number of Zone Program Integrity Contractors (ZPIC) and Program Safeguard Contractors (PSC) used by CMS in helping to fight fraud in Medicare, have taken a number of administrative actions including payment suspensions and increased medical review, for the provider and supplier types shown previously. For example, the Zone 7 ZPIC contractor in South Florida has conducted onsite reviews at 62 CORFs since January 2010 and recommended revocation for 51 CORFs, or 82 percent of the CORFS in the area. The same contractor has conducted an onsite reviews at 38 CMHCs located in Dade, Broward, and Palm Beach County since January 2010, and recommended that 30 CMHCs be revoked for noncompliance (79 percent of the CMHCs in the area). In each instance where the ZPIC requested a revocation, the CMHC was also placed on prepay review. We have also conducted an analysis of IDTF licensure requirements and have found several circumstances that indicate irregularity and potential risk of fraud. Although independent clinical laboratories are subject to survey against CLIA requirements, there are nonetheless a number of potentials for fraud, not the least of which is the sheer volume of service and associated billing generated by these entities.

We believe that there is ample evidence to support the use of post-enrollment site visits as a reliable and effective tool to ensure that a current supplier of DMEPOS remains operational and continues to meet the supplier standards found in § 424.57(c). In a March 2007 report titled, "Medical Equipment Suppliers Compliance with Medicare Enrollment Requirements" (OEI–04–05–00380), the HHS OIG concluded that, "By helping to ensure the legitimacy of DMEPOS suppliers, out-of-cycle site visits may help to prevent fraud, waste, and abuse in the Medicare program. CMS may want to consider the findings of our study as they determine how and to what extent out-of-cycle site visits of DMEPOS suppliers will occur." Today, the NSC MAC utilizes post-enrollment site visits as the primary screening to determine ongoing compliance with the enrollment criteria set forth in § 424.57(c). Therefore, we have included currently enrolled DMEPOS suppliers in the "moderate" category.

We also noted that, in addition to the new screening measures proposed in the proposed rule under the existing regulation at § 424.517, a Medicare contractor may conduct an unannounced or unscheduled site visit at any time for any provider or supplier type prior to enrolling a prospective provider or supplier or for any existing provider or supplier enrolled in the Medicare program. While the primary purpose of an unannounced and unscheduled site visit is to ensure that a provider or supplier is operational at the practice location found on the Medicare enrollment application, a Medicare contractor may also verify established supplier standards or performance standards other than conditions of participation (CoP) subject to survey and certification by the State Survey agency, where applicable, to ensure that the supplier remains in compliance with program requirements.

To assist readers in understanding the type of providers and suppliers that we proposed to be in the "moderate" risk screening level, we are providing the following table.

TABLE 3—PROPOSED MEDICARE PROVIDERS AND SUPPLIERS DESIGNATED AS A "MODERATE" CATEGORICAL RISK FOR SCREENING PURPOSES

Provider/supplier category
Community mental health centers; comprehensive outpatient rehabilitation facilities; hospice organizations; independent diagnostic testing facilities; independent clinical laboratories; and non-public, non-government owned or affiliated ambulance services suppliers. (Except that any such provider or supplier that is publicly traded on the NYSE or NASDAQ is considered "limited" risk.)
Currently enrolled (revalidating) home health agencies. (Except that any such provider that is publicly traded on the NYSE or NASDAQ is considered "limited" risk.)
Currently enrolled (re-validating) suppliers of DMEPOS. (Except that any such supplier that is publicly traded on the NYSE or NASDAQ is considered "limited" risk.)

(3) High

For those provider and supplier categories assigned the "high" level of screening, we proposed that, in addition to the screening tools applicable to the limited and moderate level of screening, Medicare contractors would use the following screening tools in the enrollment process: (1) Criminal background check; and (2) submission of fingerprints using the FD–258 standard fingerprint card. (The FD–258 fingerprint card is recognized nationally and can be found at local, county or State law enforcement agencies where, for a fee, agencies will supply the card and take the fingerprints.) We proposed that these tools would be applied to owners, authorized or delegated officials or managing employees of any provider or supplier assigned to the "high" level of screening. We believe that criminal background checks will assist us in determining if such individuals submitted a complete and truthful Medicare enrollment application and whether an individual is eligible to enroll in the Medicare program or maintain Medicare billing privileges. We believe that this position is supported by testimony of the GAO before the subcommittees for Health and Oversight and Ways and Means within the House of Representatives on June 15, 2010, stating in part that "[c]hecking the background of providers at the time they apply to become Medicare providers is a crucial step to reduce the risk of enrolling providers intent on defrauding or abusing the program. In particular, we have recommended stricter scrutiny of enrollment processes for two types of providers whose services and items CMS has identified as especially vulnerable to improper payments—home health agencies (HHAs) and suppliers of durable medical equipment, prosthetics, orthotics, and supplies (DMEPOS)."

In § 424.518(c)(1), we proposed that, unless they are publicly traded on the NYSE or NASDAQ, newly enrolling HHAs and suppliers of DMEPOS would be assigned to the high risk screening level. Based on our experience and on work conducted by the HHS OIG and the GAO, and because we do not have the monitoring experience with newly enrolling DMEPOS suppliers or HHAs that we have with those currently enrolled, we assigned these providers and suppliers to the "high" risk screening level. We are especially concerned about newly enrolling HHAs and suppliers of DMEPOS because of the high number of HHAs and suppliers of DMEPOS already enrolled in the Medicare program and program vulnerabilities that these entities pose to the Medicare program. Below is a list of HHS OIG and GAO reports identifying home health agencies and suppliers of DMEPOS as posing an elevated risk to the Medicare program.

- In a December 2009 report titled, "Aberrant Medicare Home Health Outlier Payment Patterns in Miami-Dade County and Other Geographic

Areas in 2008" (OEI–04–08–00570), the HHS OIG recommended that CMS continue with efforts to strengthen enrollment standards for home health providers to prevent illegitimate HHAs from obtaining billing privileges.

• In a February 2009 report titled, "Medicare: Improvements Needed to Address Improper Payments in Home Health" (GAO–09–185), the GAO concluded that the Medicare enrollment process does not routinely include verification of the criminal history of applicants, and without this information individuals and businesses that misrepresent their criminal histories or have a history of relevant convictions, such as for fraud, could be allowed to enter the Medicare program. In addition, the GAO recommended that CMS assess the feasibility of verifying the criminal history of all key officials named on the Medicare enrollment application.

• In a February 2008 report titled, "Los Angeles County Suppliers' Compliance with Medicare Standards: Results from Unannounced Visits" (OEI–09–07–00550) and in a March 2007 report titled, "South Florida Suppliers' Compliance with Medicare Standards: Results from Unannounced Visits (OEI–03–07–00150), the HHS OIG recommended that CMS strengthen the Medicare DMEPOS supplier enrollment process and ensure that suppliers meet Medicare supplier standards. The HHS OIG provided several options to implement this recommendation including: (1) Conducting more unannounced site visits to suppliers; (2) performing more rigorous background checks on applicants; (3) assessing the fraud risk of suppliers; and (4) targeting, monitoring, and enforcement of high risk suppliers.

• In a September 2005 report titled, "Medicare: More Effective Screening and Stronger Enrollment Standards Needed for Medical Equipment Suppliers" (GAO–05–656), the GAO concluded that,

> CMS is responsible for assuring that Medicare beneficiaries have access to the equipment, supplies, and services they need, and at the same time, for protecting the program from abusive billing and fraud. The supplier standards and NSC's gate keeping activities were intended to provide assurance that potential suppliers are qualified and would comply with Medicare rules. However, there is overwhelming evidence—in the form of criminal convictions, revocations, and recoveries—that the enrollment processes and the standards are not strong enough to thoroughly protect the program from fraudulent entities. We believe that CMS must focus on strengthening the standards and overseeing the supplier enrollment process. It needs to better focus on ways to scrutinize suppliers to ensure that they are responsible businesses, analogous to Federal standards for evaluating potential contractors.

We recognize that there may also be circumstances where a particular provider or supplier or group of providers and suppliers may pose a higher risk of fraud, waste, and abuse than the screening level assignment for their category assessed. Therefore, in § 424.518(c)(3), we proposed specific criteria that we would use to adjust the classification of a provider or supplier into a higher risk screening level than would generally apply to the entire category of provider or supplier, in order to address specific program vulnerabilities. We solicited comments on specific additional circumstances that might justify shifting a provider or supplier into a higher screening level than would generally apply to its category. We also solicited comments on the criteria that we could use to shift the screening level back down.

In § 424.518(c)(3)(i), we proposed to adjust a provider or supplier from the limited or "moderate" risk screening level to the "high" risk screening level when we have evidence from or concerning a physician or non-physician practitioner that another individual is using his or her identity within the Medicare program. In § 424.518(c)(3)(ii) and (iii), which in this final rule with comment period has been redesignated § 424.518(c)(3)(i) and (ii), we proposed to adjust a provider or supplier from the "limited" or "moderate" level of screening to the "high" screening level when: The provider or supplier has been placed on a previous payment suspension within the previous ten years; or the provider or supplier has been excluded by the HHS OIG or had its Medicare billing privileges revoked by a Medicare contractor within the previous 10 years and is attempting to establish additional Medicare billing privileges for a new practice location or by enrolling as a new provider or supplier. In addition, we believe that providers that have been terminated or otherwise precluded from billing Medicaid should be adjusted from the "limited" or "moderate" screening level to the "high" screening level. We believe that such providers or suppliers pose an elevated level of risk to the Medicare program.

In § 424.518(c)(3)(iv), redesignated in this final rule with comment period as § 424.518(c)(3)(iii), we proposed to adjust providers or suppliers from the "limited" or "moderate" level of screening to the "high" level of screening for 6 months after we lift a temporary moratorium (*see* section II.C. of this final rule with comment period) applicable to such providers or suppliers. This would include providers and suppliers revalidating their enrollment if the moratorium is applicable to the provider or supplier type. We solicited comments on criteria that would justify reassignment of providers or suppliers from the "limited" or "moderate" screening level to the "high" screening level. We also solicited comments on criteria appropriate to the reassignment from "high" to "moderate" screening levels or "limited" screening levels. We also solicited comment on the applicability of geographical circumstances as a possible criterion for adjusting providers or suppliers from one screening level to another. We also solicited comment on whether non-practitioner owned facilities and suppliers should be subject to a higher level of screening than their practitioner-owned counterparts or, whether there is an appropriate corresponding trigger for non-practitioner owned facilities and suppliers. We solicited comment on whether providers and suppliers should be subject to higher levels of screening when the provider specialty does not match clinic type on an enrollment application. We solicited comment on what objective conditions might support a broad set of circumstances or factors that would allow us to determine that provider screening levels by risk should be based on "other conditions or factors that CMS determines are necessary to combat fraud, waste, and abuse."

We solicited public comment on the appropriateness of using criminal background checks in the provider enrollment screening process, including the instances when such background checks might be appropriate, the process of notifying a provider, supplier or individual that a criminal background check is to be performed, and the frequency of such checks.

We solicited comment on the use of fingerprinting as a screening measure in our programs. We recognized that requesting, collecting, analyzing, and checking fingerprints from providers and suppliers are complex and sensitive undertakings that place certain burdens on affected individuals. There are privacy concerns and operational concerns about how to assure individual privacy, how to check fingerprints against appropriate law enforcement fingerprint databases, and how to store the results of the query of the data bases and also how to handle the subsequent analysis of the results. As a result, we solicited comments on how CMS or its contractor should maintain and store fingerprints, what security processes

and measures are needed to protect the privacy of individuals, and any other issues related to the use of fingerprints in the enrollment screening process. We were interested in comments on possible circumstances in which fingerprinting would be potentially useful in provider screening or other fraud prevention efforts. Our proposed screening approach contemplated requesting fingerprints from providers and suppliers designated as presenting a "high" risk of fraud. We solicited comment on this requirement, the circumstances under which it is appropriate, limitations on its use and any alternatives to the proposed approach regarding fingerprints. Our proposed approach allowed denial of billing privileges to newly enrolled providers and suppliers and revocation of billing privileges for revalidating providers and suppliers if owners or officials of providers or suppliers refused to submit fingerprints when requested to do so. We solicited comments on this proposal including its appropriateness and utility as a fraud prevention tool. In addition, we also solicited comment on the applicability and appropriateness of using, in addition to or in lieu of fingerprinting, other enhanced identification techniques and secure forms of identification including but not limited to other biological or biometric techniques, passports, United States Military identification, or Real ID drivers licenses. As technology and secure identification techniques change, the tools we use may change to reflect improvements or shifts in technology or in risk identification. We solicited comment on the appropriate uses of these techniques.

We noted that any physician or non-physician practitioner or organizational provider or supplier that is denied enrollment into the Medicare program or whose Medicare billing privileges are revoked is afforded due process rights under § 405.874.

To assist readers in understanding the type of providers and suppliers that we proposed to include in the "high" risk screening level, we are providing the following table.

TABLE 4—PROPOSED MEDICARE PROVIDERS AND SUPPLIERS DESIGNATED AS A "HIGH" CATEGORICAL RISK FOR SCREENING PURPOSES

Provider/supplier category
Prospective (newly enrolling) home health agencies and suppliers of DMEPOS. (Except that any such provider or supplier that is publicly traded on the NYSE or NASDAQ is considered "limited" risk.)

The new screening procedures implemented pursuant to new section 1866(j)(2) of the Act will be applicable to newly enrolling categories providers and suppliers beginning on March 25, 2011. These new screening procedures will also be applicable beginning on March 25, 2011 for those providers and suppliers currently enrolled in Medicare, Medicaid, and CHIP who revalidate their enrollment information. For Medicare, this will impact those providers and suppliers whose revalidation cycle results in revalidation occurring between March 25, 2011 and March 23, 2012. Finally, these new procedures will be applicable to currently enrolled Medicare, Medicaid, and CHIP providers and suppliers beginning on March 23, 2012, in accordance with section 1866(j)(2)(ii) of the Act. As such, some providers and suppliers may be required to revalidate their enrollment outside of their regular revalidation cycle. However, the additional screening procedures for categories and individuals in the high level of screening, namely, as discussed below, fingerprint-based criminal history record checks, will be implemented 60 days following the publication of subregulatory guidance.

b. Analysis of and Responses to Public Comment on Medicare Screening Categories

Below is a summary of the comments we received regarding the screening categories and the validation activities contained within each category.

Comment: Several commenters expressed concern that we differentiated between publicly traded and non-publicly traded entities. Many commenters stated that CMS did not specify how publicly traded companies were any less of a fraud risk than companies that are not publicly traded. Several commenters suggested this distinction was arbitrary and without merit. One commenter stated that being publicly traded does not offer immunity from risk, and that having one set of standards for all providers will make it easier for governments, providers and consumers to identify and address fraud and abuse. One trade association argued that it preferred an approach that would elevate its members into a higher risk screening level than to distinguish among its members based upon whether a particular entity was publicly traded. Another commenter suggested that CMS withdraw its proposal; and requested that if CMS decides to implement it, it should provide the data analysis it used in creating this policy choice and explain why large privately held companies are a greater risk than publicly traded companies.

Response: We agree with the arguments the commenters made regarding distinguishing among screening levels based on a provider or supplier's publicly traded status, and thus we have eliminated the distinction between publicly traded and non-publicly traded companies for purposes of the screening levels. While it has been our general experience that publicly traded companies have not posed the elevated risk of fraud, waste or abuse as non-publicly traded companies, we do not believe the risk differential between publicly traded and non-publicly traded entities is such as to warrant the automatic assignment of the former into a lesser screening level.

Comment: Similar to the distinction between publicly traded versus non-publicly traded, several comments suggested that the distinction between government-owned or affiliated versus non-government owned or affiliated ambulance service suppliers was not based on any evidence. One commenter stated that CMS furnished little or no supporting data for the position that publicly owned companies pose less of a risk. Another commenter contended that this distinction presented challenges that would make it difficult for states to operationalize. Another commenter believes that the distinction is arbitrary, and noted that private ambulance companies are, like public companies, held to the same strict standards, such as the need for them and their personnel to be State-licensed. The commenter added that there is no evidence to support the assertion that private ambulance services pose a greater risk of fraud, waste or abuse than public companies, and that the OIG report referred to in the proposed rule entitled "Medicare Payments for Ambulance Transports" (OEI–05–02–000590) did not single out private ambulance services as posing such a risk. Another commenter was concerned that assigning private ambulance companies to a higher screening level could put them at a competitive disadvantage vis-à-vis their public counterparts.

Response: We disagree that this distinction would be difficult to operationalize. The enrollment process generally captures information on the supplier's ownership; this enables contractors and States to distinguish between government-owned and non-government owned entities. However, we do agree with the arguments made regarding the use of public ownership as a criterion for making a distinction in the level of screening as determined by the risk of fraud, waste or abuse posed to the programs, and we have eliminated the distinction between government-owned and non-government owned ambulance companies for purposes of the screening level assignments. The available evidence does not suggest that the risk differential between government-owned and non-government owned ambulance companies is such as to warrant the automatic placement of the former into a lower screening level. Moreover, we note that the ACA requires levels of screening according to the risk of fraud, waste and abuse posed by categories of providers and suppliers. The approach taken in this final rule with comment period whereby we assign specific categories of providers and suppliers to screening levels determined by a categorical assessment of the risk of fraud, waste or abuse to the programs—rather than assessing individual's risk—is consistent with the requirements of the statute. While we believe that a more nuanced and precise approach for classifying specific categories of providers and suppliers into screening levels, for example using a scoring algorithm to create categories, could also be consistent with the statute under certain circumstances and were we able to provide an adequate rationale for the classification, we do not yet have experience with such an approach, and are therefore finalizing an approach based on classifications by entire provider and supplier types. We may consider additional classifications in future rulemaking.

Comment: A commenter supported CMS's designation of provider fraud and abuse risk into three levels for Medicare, Medicaid, and CHIP providers, and stated that CMS appropriately assigned hospitals (including critical access hospitals) to the limited level.

Response: We appreciate this commenter's support.

Comment: A commenter expressed support for CMS's proposal to move a provider type from one screening level to another only if it has been found by CMS to pose more or less of a fraud and abuse risk. However, the commenter suggested, that CMS: (1) Review a provider class over pre-prescribed time periods (for example, 24 months), and (2) allow sufficient time for the provider community to offer comment prior to changing a provider's screening level.

Response: Our proposal to reassign providers or suppliers or provider or supplier types to another level of screening was based on changes in circumstances that contribute to the risk of fraud. We believe that to restrict ourselves to reassigning providers and suppliers only at specific, pre-defined time intervals would not provide us with the flexibility we need to quickly address emerging program integrity risks. If a situation arose where there was an immediate risk of fraud that required the imposition of enhanced screening procedures, we must be able to deal with it rapidly, rather than wait until a particular prescribed time interval arrives. We will periodically reexamine screening level classifications for provider and supplier categories. Should a change in a particular provider or supplier type's assignment be warranted and should it necessitate a change in existing regulatory language, we will publish notice of the change in the **Federal Register**.

Comment: A commenter expressed support for CMS' inclusion of physicians, non-physician practitioners, and medical groups or clinics in the limited screening level. The commenter stated that these suppliers submit the CMS–855I to enroll in Medicare and are subject to all of the penalties listed in Section 14 of CMS–855I regarding falsifying information.

Response: We appreciate the commenter's support.

Comment: A commenter requested that CMS consider moving CMHCs and CORFs from the "moderate" screening level to the "limited" screening level. With respect to CORFs, the commenter stated that CMS' studies regarding program integrity concerns have been limited to the State of Florida, and contended that it is arbitrary to extrapolate that experience to the rest of the country.

Response: We disagree with the commenter's assessment of the risk of fraud associated with CMHCs and CORFs. These risks extend beyond any single region of the country. As a result we have decided to keep these provider types assigned to the moderate level of screening. We believe that the assignment of CMHCs and CORFs into the moderate screening level was appropriate based on the information we presented in the proposed rule.

Comment: A commenter expressed support for background checks and fingerprinting, but requested that they be limited to only providers and suppliers assigned to the high risk level because of the potential administrative burden.

Response: The final rule with comment period is clear that fingerprint-based criminal background checks are only applicable to providers and suppliers assigned to the high screening level.

Comment: A commenter stated that CMS, in listing various provider types and the levels of risk into which they were assigned, did not provide the documentation on which it based its conclusions, therefore violating the Administrative Procedure Act. The commenter recommended that CMS furnish the following information by provider/supplier type to justify its conclusions and to inform the public as to why certain providers are a limited risk to the Medicare program: (1) Number of Medicare revocations; (2) number of Medicare deactivations; (3) Medicare payment suspensions; (4) Medicare civil monetary penalties; (5) OIG mandatory exclusions; (6) OIG permissive exclusions; (7) indictments; and (8) felony convictions.

Response: We based our risk assessments on a variety of factors, including some of those listed by the commenter, as well as others. However, because our conclusions were not based on any one factor nor any specific combination of factors, but rather on CMS's aggregate experience with each provider and supplier type, providing the data requested by the commenter would not serve to clarify the determinations of risk.

Comment: Several commenters stated that CMS did not describe how it will screen providers and suppliers with a designated "other" category, or which types of providers and suppliers fall within this category and how many there are. One commenter stated that providers and suppliers in the "Other" category should be assigned to the high risk level.

Response: The "other" category is largely reserved for future situations in which a statute is enacted that authorizes a particular provider or supplier type to bill the Medicare program; it is designed as a placeholder of sorts pending the revision of the CMS–855 application to accommodate the new provider or supplier type. Since we cannot predict which new provider or supplier types may be able to bill Medicare in the future, we are unable to assign them to a particular screening level in this final rule with comment period.

Comment: Several commenters stated that CMS did not explain which risk level outpatient physical therapy/occupational therapy (PT/OT), speech pathology, and rehabilitation agencies would fall into.

Response: We received a number of comments on this issue. We will assign occupational therapists, speech language pathology, and rehabilitation agencies to the "limited" level of risk because we do not have evidence of program integrity risk that suggest that these entities should be assigned to the moderate or high levels of screening. However, we will assign physical therapists (including physical therapy groups) to the moderate screening level. We believe this classification is supported, in part, by a recent OIG report entitled "Questionable Billing for Medicare Outpatient Therapy Services" (December 2010) (*http://oig.hhs.gov/oei/reports/oei-04-09-00540.pdf*), which found, among other things, that Miami-Dade County had three times, and nineteen other counties had at least twice, the national level on five of six questionable billing characteristics. Law enforcement has also identified fraudulent billing schemes involving physical therapy.

Comment: One commenter stated that CMS did not describe how it would screen new providers or suppliers types permitted to enroll in Medicare. Since CMS excluded these providers and suppliers from its discussion, the commenter recommended that these entities be considered a high risk.

Response: Since we cannot predict which new provider or supplier types may be able to bill Medicare in the future, we are unable to assign them to a particular screening level in this final rule with comment period. When such entities emerge, we will make an appropriate determination based on the data sources we have already described in this final rule with comment period, as to what screening level assignment is most appropriate for such new entities. As previously discussed, we will publish notice of these new provider category assignments in the **Federal Register** prior to making final any such assignment.

Comment: One commenter recommended that non-physician owned medical facilities and groups be considered a higher risk than physician-owned medical facilities.

Response: In the proposed rule, we solicited comments on whether non-practitioner owned facilities and suppliers should be subject to a higher level of screening than practitioner-owned facilities and suppliers. We received several comments suggesting that the former category should be subject to higher screening than the latter. We are declining to adopt this suggestion in this final rule with comment period, however. As previously stated, the ACA requires levels of screening according to the risk of fraud, waste and abuse posed by categories of providers and suppliers. The approach taken in this final rule with comment period whereby we assign specific categories of providers and suppliers to risk levels that determine screening requirements—rather than determining individual risk—is consistent with the statute.

Comment: Several commenters stated that extending the enhanced screening requirements to MAOs will prove duplicative and unnecessarily increase costs for providers. Identifying those providers participating in multiple health programs and coordinating their screening and monitoring could, the commenters contended, avoid unnecessary administrative burden for all involved. Otherwise, by extending the screening requirements to MAOs, providers will be forced to undergo the same screening process multiple times, for each MAO with whom they contract. One commenter stated that it would be more efficient for CMS and the States to perform the screenings and make that data available to the MAO plans through a centralized process. Another commenter recommended that fingerprinting and background checks be restricted to State and Federal law enforcement agencies, adding that there is no legitimate purpose for MA or Medicare managed care plans to collect and maintain this information.

Another commenter opposed applying the proposed requirements to MAOs and other managed care organizations (MCOs) for several reasons. First, there are already appropriate screening tools for MAOs for their providers and suppliers pursuant to § 422.204(b)(3). Second, MAOs have other requirements, as established in § 422.204, to access certain data bases to verify licensure, licensure sanctions and other limitations. Third, traditional Medicare has a greater population to serve and a wider network of providers and suppliers to process and screen than individual MA plan networks. Therefore, the processes should stem from those with oversight and administration of traditional Medicare, with a trickledown effect and benefit for MAOs. Fourth, if a limited, moderate or high risk provider has an enrollment verification letter from Medicare issued after March 25, 2011, the provider has been appropriately credentialed and needs no further credentials for a MAO. Fifth, Medicare's enrollment application captures certain elements that are not currently captured by some insurers' enrollment applications, such as delegated representative, authorized representative, and owners. This information would be difficult to capture and verify, and the workload would increase substantially on the part of MCOs to credential numerous individuals who may not have a significant role within the providers/supplier entity.

Response: Because there are a large number of other regulatory provisions that form the framework for oversight of managed care plans, and we do not want to duplicate these requirements by imposing additional screening and enrollment criteria on these organizations, we have decided not to apply the provisions of this final rule with comment period to managed care plans and organizations.

Comment: A commenter stated that MCOs design their anti-fraud initiatives based on the risks they encounter, which may be unique and different from the risks faced by FFS programs. Consequently, CMS should give MCOs the flexibility to decide whether to adopt any of the proposed new screening requirements and, if so, how to do so; CMS should not extend the screening requirements to MCOs. The commenter stated that MCOs should be allowed to: (1) Assign providers and suppliers to a level that is higher or lower than the level assigned by Medicare FFS or the State FFS Medicaid programs, and (2) deem a provider as having satisfied its screening requirements if the provider is enrolled in Medicare FFS and/or a Medicaid FFS program, and has gone through their screening procedures.

Response: As explained previously, we are concerned that the application of the screening provisions to MCOs would duplicate existing oversight and regulatory authority. We therefore have decided not to apply the provisions of this final rule with comment period to managed care plans and organizations. This will, as the commenter suggests, allow MCOs to develop provider screening requirements that are unique to their circumstances, including (1) assign providers and suppliers to a level that is higher or lower than that assigned by Medicare or the State Medicaid program, and (2) deem a provider as having satisfied their screening requirements if the provider is enrolled in Medicare and/or a State Medicaid program.

Comment: A commenter stated that applying consistent risk management

practices throughout an organization fosters a culture of program integrity. As such, the commenter recommended that MAOs be required to implement the same enhanced screening processes that CMS is considering for the original Medicare program.

Response: As mentioned earlier, we have decided not to apply the provisions of this final rule with comment period to managed care plans and organizations.

Comment: A commenter recommended that CMS explain what type of screening process will be used for Medicare Advantage, managed care organizations or health maintenance organizations.

Response: As previously stated, there are a large number of other regulatory provisions that form the framework for oversight of managed care plans. We do not want to duplicate these requirements by imposing additional screening and enrollment criteria on these organizations. We therefore have decided not to apply the provisions of this final rule with comment period to managed care plans and organizations.

Comment: A commenter recommended that CMS establish screening criteria for slide preparation facilities and competitive acquisition program/Part B vendors.

Response: We will not be establishing screening criteria or prescribing screening levels for slide preparation facilities in this final rule with comment period. Slide preparation facilities do not enroll in Medicare at this time; thus, we do not believe it is appropriate to assign a level of screening to such entities. As for competitive acquisition program/Part B vendors, these will be assigned to the limited screening level. It has not been our experience that this supplier type poses an elevated risk of fraud, waste or abuse to the Medicare program.

In addition, we are adding portable x-ray suppliers to the moderate screening level. In support of this classification, we note that the OIG has analyzed Medicare claims data to identify suppliers with questionable billing patterns. The unusual claims patterns that were found raise concerns about the integrity of payments to certain portable x-ray suppliers. Based on this, and combined with the fact that there are low barriers to entry for this type of supplier, portable x-ray suppliers will be placed in the moderate screening level.

Comment: A commenter recommended that CMS establish higher levels of screening when: (1) A provider or supplier changes ownership on a frequent basis; (2) a physician or non-physician practitioner is enrolled in different States; (3) a physician has a large number of reassignments or when reassignments cross States; (4) a physician is engaging or billing in a reciprocal billing or locum tenens billing arrangement; (5) owners have businesses in different States; and (6) when owners establish banking relationships in different States from where their practice is located.

Response: In the proposed rule, we sought comment on what factors should permit us to elevate an individual provider or supplier to a higher level of screening. We appreciate the commenter's suggestion. While we are not adopting these recommendations at this time, such suggestions may form the basis of future rulemaking. We would first like to evaluate how the factors we will finalize as part of this rule will work prior to adopting new factors such as the ones the commenter has identified.

Comment: One commenter recommended that CMS assign to the higher screening level any owner or physician who had an final adverse action within the previous 10 years; has an unrepaid overpayment with Medicare, Medicaid or CHIP; has a Medicare or Medicaid payment suspension; exclusion or debarment; a felony conviction; unpaid taxes; or a Medicare revocation. Another commenter stated that in Table 1, CMS appears not to consider previous payment suspensions, overpayments, OIG exclusions, or Medicare revocations in establishing higher risk levels. The commenter recommended that CMS explain why such actions are not an indicator of higher program risk and the need for enhanced screening.

Response: As in the proposed rule, we state in § 424.518(c) of the final rule with comment period that a provider or supplier will be moved from the "limited" or "moderate" category to the "high" level if it has been excluded by the OIG, or has had its Medicare billing privileges revoked in the previous ten years. We have added in the final rule with comment that a provider or supplier that has been subject to any final adverse action as defined at § 424.502 would also be moved to the high level of screening. With regard to these commenters' other proposals, we are generally supportive of them, and may examine the possibility of future rulemaking to include some of them as factors that may elevate a provider or supplier to a higher level of risk. As previously mentioned, however, we would first like to evaluate how the factors we will finalize as part of this rule will work prior to adopting new factors.

Comment: A commenter recommended that CMS propose a definition for the term "tax delinquency," as it is used in Table 1 of the proposed rule, and clarify whether the term refers to Federal, State and/or local taxes.

Response: We have removed tax delinquency from the list of database checks in this final rule with comment period. Though we do have new authorities to obtain tax information as part of ACA and other recently enacted statutes, we are not prepared to operationalize this provision at this time.

Comment: A commenter stated that CMS' categorical risk approach did not address the individual risk associated with certain owners and individual practitioners. The commenter recommended that CMS issue a new proposed rule to establish specific risk factors would increase/decrease a provider or supplier's screening level.

Response: The ACA requires levels of screening according to the risk of fraud, waste and abuse posed by categories of providers and suppliers. The approach taken in the final rule with comment period whereby we assign specific categories of providers and suppliers to screening levels determined by risk of fraud, waste and abuse is consistent with the requirements of the statute. Furthermore, we believe the approach taken in this final rule with comment period is objective and allows us to avoid subjective assessments of a provider's or supplier's risk to the programs.

Comment: A commenter supported the use of background checks to ensure the identity and integrity of owners and senior managers of home health and hospice agencies. While supporting the maintenance of the confidentiality of this information, the commenter believes it should be used to: (1) Target agencies for special oversight, (2) alert owners of patterns of criminal behavior on the part of their managers, and (3) disqualify owners or managers that have criminal histories.

Response: We intend to use this tool in a way that safeguards personal information and also helps prevent fraud, waste and abuse. The criminal history record will verify whether a provider, supplier, or an individual with a 5 percent or greater direct or indirect ownership interest in such provider or supplier has been convicted of certain types of felonies that could result in the denial or revocation of billing privileges under § 424.530 or § 424.535, respectively. We believe that

criminal history record checks will confirm the accuracy of information submitted in enrollment applications, and the discovery of false or misleading information could result in denial or revocation of billing privileges under § 424.530 or § 424.535. Providers or suppliers who have been denied on these bases are afforded all applicable appeals rights.

While in some instances, such a denial may result in alerting a provider or supplier of an individual's criminal history, this is not the purpose or intention of this enrollment screening tool. Rather we will use this authority for the purpose of verifying eligibility for Medicare enrollment. We will disseminate guidance and instructions to providers, suppliers and our enrollment contractors shortly after the publication of this final rule with comment period regarding the implementation of the criminal history record check requirement.

Comment: A commenter opposed the proposal to move those who have previously been placed on a payment suspension or subject to a denial or revocation in the past year, into a higher screening level. The commenter stated that a payment suspension may be imposed upon a mere or false suspicion of wrongdoing, and that the denial or revocation could have been based on an innocent mistake.

Response: We agree with this commenter with respect to the denial of billing privileges. Many denials occur simply because the provider does not meet the requirements to enroll as a particular provider type or other clerical errors. We have therefore removed the denial of billing privileges as a basis for moving a provider or supplier into a higher risk screening level. We have retained revocations of Medicare billing privileges as such a basis because we believe that such a provider poses a heightened risk of fraud, waste or abuse to the Medicare Trust Fund.

Payment suspension is used as a fraud fighting tool only in instances where facts available point to possible fraud, waste, or abuse. Consequently, because of the risk to the program posed by individuals and entities upon which a payment suspension has been imposed, we believe we are justified in placing them in the high risk screening level.

Comment: One commenter suggested that in lieu of fingerprinting, each owner or physician should submit: (1) A U.S. Passport or a Foreign Passport with their enrollment application, and/or (2) copies of their Federal Tax Returns.

Response: We agree with the commenter that there may be alternatives to fingerprint-based criminal history record checks to verify identity; however information on U.S. or foreign passports and Federal Tax Returns, such as name, date of birth and Social Security number are duplicative of information that is captured in the Medicare enrollment application. Information that would be obtained from a U.S. or foreign passport or Federal Tax Returns could only be used to process a name-based criminal history record check, and the FBI does not process name-based requests for non-criminal justice purposes. The submission of fingerprints is the only way to obtain a criminal history record check from the FBI.

Additionally, the National Task Force on the Criminal Backgrounding of America concluded that fingerprint-based criminal history record checks are more accurate than name-based checks because "names tend to be unreliable because: people lie about their names; obtain names from false documents; change their names; people have the same name; people misspell names; people use different versions of their names * * * people use aliases * * *" The suppliers assigned to the high screening level have been so assigned because, in CMS, and its law enforcement partners' experience, such supplier types have, as a category, not undergone sufficient scrutiny in the enrollment process. Some may have gained entry in the past through falsification of an enrollment application that may have passed a name based check. As a result, the extra level of screening provided by the submission of fingerprints for the purposes of an FBI database check has the potential to deny enrollment to individuals whose sole intent is to defraud the Medicare program. We believe fingerprint-based criminal history record checks will be an effective tool to prevent fraud, waste, and abuse in Federal health care programs by independently verifying information provided on applications of potential providers and suppliers in the high screening level.

If, after a sufficient period of evaluation, we conclude that fingerprint-based FBI criminal history record checks do not fulfill our program integrity objective of identifying applicants who pose a heightened risk of fraud, waste, and abuse prior to enrollment or we determine that supplementary actions are needed, we may pursue additional rulemaking that seeks to adopt alternative or additional safeguards consistent with authorities given to the Secretary in the ACA.

Comment: A commenter stated the screening process described by CMS does little to ensure that a provider or supplier is submitting legitimate claims for eligible individuals, since there is no linkage between the enrollment process and claim submission process. The commenter contended that it did not appear that CMS considered the alternative approach of linking its proposed screening requirements to section 1866(j)(3) of the Act. The commenter recommended that CMS establish a link between the screening process and the payment process by establishing payment caps and prepayment claims review as described in section 1866(j)(3) of the Act.

Response: The commenter references new section 1866(j)(3) of the Act, which addresses a provisional period of enhanced oversight for new providers or suppliers of services. We believe that the payment caps and prepayment claims processes should supplement, but not be used in lieu of, the procedures outlined in this proposed rule. Payment caps and prepayment claims processes will be addressed in separate vehicles. Clearly, the provisions of section 1866(j)(3) of the Act are an important complement to the pre-enrollment screening provisions in this rule. We intend to use both to fight fraud. However, this provision is not part of this final rule with comment period. In fact, the ACA authorizes the Secretary to implement the provisions of section 1866(j)(3) of the Act through instruction or otherwise.

Comment: A commenter contended that with respect to the limited risk screening requirements, the language in proposed § 424.518(a)(2)(i) may be overly broad. The commenter believes the intent of this provision is for the contractor to verify that the provider or supplier meets only the applicable regulations or requirements that qualify it for the appropriate provider or supplier type. However, the commenter stated that, as written, § 424.518(a)(2)(i) could be construed to require the Medicare contractor to verify the provider or supplier's compliance with virtually every Federal regulation and State requirement that applies to the provider or supplier type. This, the commenter argued, could subject limited categorical risk providers and suppliers to an overly broad, burdensome, and time-consuming verification process.

Response: As explained in the proposed rule, the verification process for limited risk providers and suppliers will be that which is currently used for most providers and suppliers. The verification will be limited to enrollment requirements, and will not examine compliance with all other State

and Federal regulations unless the other State and Federal regulations have an impact on whether the provider or supplier meets the requirements for enrolling or revalidating enrollment in Medicare. The table that describes the types of screening to be performed for each of the three screening levels explains clearly the kinds of verification processes that CMS contractors will be using to verify a provider's or supplier's eligibility to enroll or remain enrolled in Medicare.

Comment: One commenter requested that CMS explain why it did not consider compliance plans in establishing its screening criteria.

Response: We solicited comments regarding the use of compliance plans in combating fraud, waste, and abuse. Because there are a several complex policy and implementation issues we are pursuing separate additional rulemaking in this area.

Comment: One commenter stated that CMS did not include a discussion of low quality of care when it established its screening criteria.

Response: Quality of care is the subject of several other CMS regulations. Accordingly, we did not include quality consideration in our development of levels of categorical screening. We believe that the factors we included in the proposed rule for establishing the screening criteria support our classifications.

Comment: A commenter recommended that CMS increase the level of screening for any provider using a billing agent or clearinghouse convicted of health care fraud. The commenter also recommended that, similar to the provisions found in section 6503 of the ACA, CMS establish enrollment standards for clearinghouses and billing agents for Medicare. CMS, the commenter stated, mentioned in the proposed rule that "based on our data analysis including analysis of historical trends and CMS' own experience with provider screening and enrollment we believe the following providers and suppliers pose a limited risk." The commenter also recommended that CMS furnish the data analysis used to assign each provider type in the limited screening levels and the moderate screening levels.

Response: As for the commenter's recommendation regarding billing agents and clearinghouses, the commenter references section 6503 of ACA, which calls for billing agents and clearinghouses to register under Medicaid. The implementation of 6503 of the ACA, is not part of this rule; however, we will be addressing that provision in the future. We do not propose to screen billing agents and/or clearinghouses as part of this rule because such entities do not enroll in Medicare as providers or suppliers.

With respect to the data analysis we used, we furnished information in the proposed rule regarding our reasons for assigning certain provider and supplier types to limited, moderate or high level of screening. We relied on our experience to identify categories of providers with a higher incidence of fraud as well as our familiarity with types of fraudulent schemes that are currently prevalent in Medicare. In addition, we used the expertise of our contractors charged with identifying and investigating instances of fraudulent billing practices in making our decisions regarding the appropriate risk assessment of various providers. In some instances, we also relied on the data analysis and expertise of the OIG, GAO, and other sources to develop screening levels designed to increase scrutiny for specific categories of providers and suppliers as the risk posed to the Medicare and Medicaid programs increases.

Comment: A commenter asked whether CMS, in grouping all hospital types—including specialty hospitals, physician-owned hospitals, short-term hospitals, and acute hospitals—into one risk level, is stating that all hospitals have the same risk. If so, the commenter requested that CMS provide data to support this assertion and to explain why it believes that all hospitals pose the same risk

Response: Our assignment of hospitals to the limited screening level should not be construed as meaning that every type of hospital poses the same exact degree of risk. We did, however, base our assignment on the premise that all hospital provider types have certain features in common that make them less likely to be a program integrity concern on the whole. For example, such entities have significant start up costs and capital and infrastructure costs. In addition, such entities are subject to significant government oversight, at both the State and Federal levels. Finally, such entities often are subject to oversight from other accrediting bodies through deeming authority. These features are, in general, less apparent with other provider and supplier types. We note that these are not the only features we considered when evaluating hospitals and that these features, by themselves, are not sufficient to cause us to place a provider or supplier type in the limited screening category.

Comment: A commenter stated that in Table 1, CMS appears not to consider previous payment suspensions, overpayments, OIG exclusions, or Medicare revocations in establishing higher risk levels. The commenter recommended that CMS explain why such actions are not an indicator of higher program risk and the need for enhanced screening.

Response: As mentioned previously, we state in this final rule with comment period that a provider or supplier will be placed into the high screening level if the provider or supplier (or an individual who maintains a 5 percent or greater direct or indirect ownership interest in such provider or supplier) has had a final adverse action—as that term is defined in § 424.502—imposed against it within the previous 10 years.

Comment: A commenter stated that because of the wide variation in DMEPOS items and services and differing levels of behavior, CMS should subdivide the general category of DMEPOS suppliers and assign appropriate screening levels to each product category, rather than to DMEPOS suppliers as a whole.

Response: We think the commenter's suggestion might lead to an overly complex system of provider screening and related oversight tools. Accordingly, we have decided not to create such a distinction based on such sub-categories. At this time, we are not determining the risk of fraud, waste, and abuse by product category.

Comment: Several commenters requested CMS to change the proposed rule to state that both publicly traded entities and their wholly-owned subsidiaries are afforded "limited categorical risk" status.

Response: As stated previously, publicly traded status is not being included as a criterion for assigning provider or supplier categories to screening levels. The approach taken in this final rule with comment period whereby we assign specific categories of providers and suppliers to screening levels determined by the categorical risk of fraud—rather than determining individual risk—is consistent with the requirements of the ACA.

Comment: One commenter supported CMS's proposal to place new HHAs into the high screening level. The commenter stated that much of the fraud and abuse that has been detected in the home health benefit is associated with new providers, particularly in areas not subject to certificate of need (CON) or other State controls on provider development.

Response: We appreciate this commenter's support.

Comment: One commenter recommended that the proposed rules for assigning screening levels for

existing home health and hospice providers be modified so as to more accurately focus enforcement efforts on certain existing providers within a particular category. More specifically, the commenter stated that CMS can use its ample data resources to more precisely differentiate between agencies with proven histories of good performance and those that are either untested or have demonstrated irregular patterns of performance. The commenter recommended that any nonprofit home health or hospice agency that was certified in Medicare or Medicaid before October 1, 2000, and has not been identified as having program integrity problems, be placed in the limited risk screening level. The commenter added that CMS should also create a scoring algorithm that would identify those HHAs and hospices at moderate risk based on criteria such as: (1) Years of program participation; (2) ownership type; (3) number of medical review requests; (4) pattern of selectively serving highly profitable cases; (5) frequent changes in ownership; (6) geographic location; (7) relationship to other stable (for example, hospital) or less stable provider types (DMEPOS); and (8) current accreditation status.

Response: We did not base our development of levels of screening on provider-specific risk assessments. As described previously, the statutory requirements set forth in ACA guided our approach in assigning categories of providers and suppliers to screening levels appropriate to the risk of fraud, rather than pre-screening individuals prior to the assignment of a screening level. Adopting the type of scoring algorithm suggested by the commenter would automatically provide for individual breakdowns of each HHA's or hospice's risk, which we believe would be inconsistent with the statute and constitute a pre-screening step in the enrollment process. We do not rule out the possibility of using scoring algorithms in the future for other program integrity functions or for provider and supplier enrollment, but we decline to adopt this suggestion for enrollment screening purposes at this time. For the reasons stated previously, we believe that the moderate risk screening level is appropriate for currently enrolled HHAs and hospices.

Comment: A commenter did not believe that site visits were necessary to ensure that ambulance providers and suppliers were in compliance with applicable program requirements. The commenter expressed concern that the time associated with conducting pre-enrollment site visits could slow down the enrollment process. The commenter added that ambulance services are already subject to site inspections by the State licensing agency (as well as other State and Federal requirements), and that the existing procedures are sufficient to ensure that ambulance providers and suppliers are operating in compliance with program requirements. Another commenter stated that in this proposed rule, CMS states that it only conducts a limited number of unscheduled or unannounced site visits for certain provider types. If this is based on a policy decision, the commenter requested that CMS explain why it now believes that unscheduled or unannounced site visits will reduce fraud, waste, and abuse. The commenter also requested a cost/benefit analysis for its previous onsite efforts to show the effectiveness of this new strategy. If a fiscal constraint, the commenter requested that CMS explain: (1) Why it is spending $9 million on grants to Senior Medicare Patrol (SMP) and millions in advertising to promote "Stop Medicare Fraud" in lieu of conducting unscheduled and unannounced site visits, and (2) where the additional funds will come from to conduct thousands of unannounced site visits.

Response: We have been conducting site visits of one kind or another for years, and have found such visits to be an extremely effective tool in fighting fraud. We plan to conduct site visits pursuant to the authorities provided in the ACA and as outlined in this final rule with comment period. We have received many valuable tips and other information from SMP volunteers across the country. We believe that site visits are appropriate for ambulance companies, especially considering that we have uncovered several instances where an enrolling ambulance company—contrary to the information it furnished on the CMS–855B—had no base of operations. Regarding the commenters concern about the Senior Medicare Patrol initiative, we believe the SMP program is outside the scope of this regulation.

Comment: With respect to whether non-practitioner-owned facilities and suppliers should be subject to a higher level of screening than their practitioner-owned counterparts, a commenter urged CMS to exempt dually-enrolled physicians from enrollment screening requirements applicable to entities only enrolling as DMEPOS suppliers. The commenter believes it would make no sense to consider physicians "limited risk" while simultaneously labeling them either "moderate risk" or "high risk" when they provide DMEPOS to their own patients.

Response: We disagree. As stated previously, the approach taken in this final rule with comment period whereby we assign specific categories of providers and suppliers to screening levels determines by the assessed categorical risk of fraud—rather than determining individual risk—is consistent with the requirements of the ACA. We believe that each provider and supplier category must be considered on its own merits as an entire class, rather than be sub-categorized based on whether or not a particular provider is owned by provider subject to the limited screening level. For reasons we have stated, both in this final rule with comment period and in the past, newly enrolling DMEPOS suppliers are currently subject to a higher level of scrutiny and revalidating DMEPOS suppliers are subject to the moderate level of screening—such as through the need to comply with the supplier standards in § 424.57(c)—because of the heightened risk posed by this class of suppliers as a whole. We therefore decline to exempt certain types of DMEPOS suppliers from either the moderate level of screening for revalidating suppliers or the high level of screening for newly enrolling suppliers.

Comment: A commenter suggested that CMS revise the enrollment applications to include language in the certification statement so that CMS' contractors can conduct a criminal background check on any owner, authorized official, delegated official, managing employees and individual practitioners during the initial enrollment process or subsequently thereafter. The commenter believes that CMS is needlessly limiting its ability to conduct criminal background checks.

Response: We appreciate this comment but decline to adopt this approach. We will perform fingerprint-based criminal history record checks of the FBI's Integrated Automated Fingerprint Identification System consistent with the methodology specified in this rule. We do not intend to amend the CMS–855 to include language that would expand the use of such criminal history record checks beyond the requirements set forth in this final rule with comment period. We think that to conduct the same screening for all provider categories without taking into account the variation in risk of fraud, waste or abuse would be an inappropriate allocation of resources and would be inconsistent with the provisions of the ACA. As stated previously, if CMS re-assigns additional categories of providers to the high level of screening, or expands the use of FBI

criminal history record checks to the other screening levels, CMS will publish a notice in the **Federal Register**.

Comment: A commenter suggested that Medicare, Medicaid, and CHIP consider bankruptcy and credit report scores during the screening process and that CMS deny enrollment where an owner, authorized official, or delegated official has a credit score of less than 720 or has had a personal or business bankruptcy within the last 5 or 10 years. The commenter stated that credit score is indicative a person's ability to manage financial assets.

Response: We decline to adopt this approach in this final rule with comment period. We would need to perform additional study to determine whether credit scores correlate with program integrity risk. Because we do not have evidence to support such a relationship, we decline to adopt this approach at this time.

Comment: Several commenters requested clarification on whether a Federal agency or a private company will process the fingerprint card, how CMS will safeguard this information, and how much additional time fingerprinting will add to the screening process of new applicants. Another commenter urged CMS to ensure that documentation concerning fingerprints be tracked from origination to delivery to prevent loss, and that all information be protected from FOIA disclosure.

Response: The FBI requires that fingerprints be collected and submitted by FBI-approved "authorized channelers." The FBI currently has approved 15 such private companies to collect and submit fingerprints to the FBI CJIS Division's Wide Area Network (WAN), receive the criminal history record information, and submit the record to authorized recipients, in this case CMS (or its FBI approved outsourced contractors) for the determination of eligibility for enrollment. CMS will use of one or more of the pre-approved authorized channelers to collect and submit fingerprints directly to the FBI, and CMS will ensure the written proposal(s) provided by the selected channeler(s) contains the appropriate assurances of compliance with privacy and security considerations mandated by the Compact Council (the national independent authority that regulates and facilitates the exchange of noncriminal justice criminal history record information) and as required by 28 CFR part 906. Additionally, CMS will adhere to the Compact Council's Security and Management Control Outsourcing Standard for Channelers. The use of authorized channelers effectively means CMS never has custody of the submitted fingerprints, only the resulting criminal history record. CMS will, of course, protect the information in the criminal history record according to existing Federal standards and procedures that govern personally identifiable information.

After further consideration of the proposed requirement that all required applicants submit their fingerprints on the FD–258 card, CMS has removed the requirement to use only the FD–258 card from this final rule with comment period. CMS strongly encourages all required applicants to provide electronic fingerprints to the CMS-selected authorized channeler, but will also accept the FD–258 card. As stated previously, CMS and the authorized channeler will safeguard the information as required by the existing requirements of the Compact Council, and specifically the Compact Council's Security and Management Control Outsourcing Standard for Non-Channelers and Channelers and the FBI's Criminal Justice Information System's Security Policy.

We believe the additional time for a contractor's processing of the application in light of the fingerprint-based criminal history record check will be minimal for those applicants who submit electronic fingerprints. Applicants who submit the FD–258 card will experience an extended processing time as the authorized channeler selected by CMS will have to convert the paper print into a electronic submission so that the FBI can quickly process all requests. The FBI processing of the electronic prints occurs within 24 hours of receipt from the authorized channeler, and the authorized channeler will receive and transmit the report to CMS. The report will be reviewed for disqualifying felonies and omitted information as outlined in existing regulations at § 424.530(a) for enrollment and at § 424.535(a) for revalidation and once the fitness determination has been made, the appropriate contractor will process the enrollment application as before. CMS believes this process will not cause significant delays to the enrollment process.

As stated previously, CMS and our Medicare contractors will protect individuals' information under the Privacy Act, 5 U.S.C. 552a and the Privacy Act system of records notice for this information. We recognize that the safeguarding of individual privacy and ensuring the security of fingerprints collected under this regulation is a serious concern. We will ensure that these concerns are addressed and that all necessary safeguards are implemented to protect this information –from both privacy and security standpoints—when we issue guidance on fingerprint-based criminal history record checks following the publication of this final rule with comment period. We will ensure that fingerprint documentation is fully protected to the extent required by Federal law.

As stated previously, the fingerprint-based criminal history record check will be required 60 days following the publication of subregulatory guidance. All other screening requirements are effective on March 25, 2011 for those in the "high" screening level. The delay in the effective date for the fingerprint-based criminal history check will permit CMS to coordinate the implementation of this new process with our law enforcement partners, ensure that all concerns related to privacy are addressed, educate our providers and suppliers about the new process, and ensure that our contractors are adequately prepared to implement this new process so that the implementation of this new process does not cause any undue delay.

Comment: A commenter stated that while CMS assigns CMHCs to the moderate screening level, CMS has not taken steps to implement section 1301 of the Health Care and Education Reconciliation Act of 2010 (collectively, the Affordable Care Act), which requires that CMHCs provide at least 40 percent of its services to individuals who are not eligible for benefits. The commenter recommended that CMS consider CMHCs as a "high" categorical screening risk until CMS implements section 1301 of the ACA.

Response: For reasons already explained, we believe that CMHCs are most appropriately assigned to the moderate screening level. Section 1301 of ACA is not a part of this rule.

Comment: Several commenters requested that CMS consider establishing criteria for making assignments to screening levels before moving forward with this rule.

Response: We explain in the preamble the criteria and factors we used for our placement of various provider and supplier types into particular levels. These factors include our experience with claims data used to identify fraudulent billing practices, as well as the expertise developed by our contractors charged with investigating and identifying instances of Medicare fraud across multiple categories of providers. In addition, we have relied on insights gained from numerous studies conducted by the HHS OIG, GAO, and other sources.

Comment: A commenter requested that a fourth level of "no risk" be established. This is to reflect positively on providers who have had no incidents of fraud, waste or abuse.

Response: We do not believe it is appropriate to create a "no risk" level as the limited level of screening represents the baseline screening requirements for entry into the Medicare program. We believe that fraud, waste and abuse can occur at any time and among any provider or supplier category. Our screening methodology is designed to match an appropriate level of screening to provider or supplier categories based on level of risk of fraud, waste or abuse posed by the provider or supplier category.

Comment: A commenter requested clarification regarding whether CMS will conduct TIN matches with the IRS via an automated match or whether the provider will be required to sign an I–9 verification form. The commenter also asked whether CMS will conduct tax delinquency database matches with the IRS and the authority for such a match. In both cases, the commenter recommended that CMS establish new denial and revocation reasons if the TIN does not match or there is a tax delinquency.

Response: We currently verify the provider's TIN as part of the enrollment process; if the TIN does not match the provider's legal business name, the application will be denied, or, if enrolled, the provider's billing privileges will be revoked. However, we have removed references to tax delinquencies as a component of the screening methodology from this rule. While we do plan to implement provisions that will allow us to coordinate enrollment decisions with data obtained from the Internal Revenue Service—for instance, potentially denying an application based on tax delinquency information from the IRS—such an effort is not a part of this rule.

Comment: A commenter stated that CMS's proposed "limited risk" classification for publicly traded companies does not explicitly afford the same treatment to subsidiaries of publicly traded providers and suppliers. Several commenters recommended that majority owned subsidiaries of publicly traded providers and suppliers be treated the same as their publicly traded parents. Specifically, since subsidiaries of publicly traded providers and suppliers are subject to substantially similar oversight and scrutiny, the commenter proposed that all providers and suppliers—regardless of whether the parent is enrolled—that are at least majority owned, directly or indirectly, by a publicly traded provider or supplier be assigned to the limited risk level for screening. The commenter suggested that proposed § 424.518(a)(2) be revised to read as follows: "(2) When CMS designates a provider or supplier into the "limited" categorical level of screening, the provider or supplier is publicly traded on the New York Stock Exchange (NYSE) or the National Association of Securities Dealers Automated Quotation System (NASDAQ), or the provider or supplier is majority owned, directly or indirectly, by an organization publicly traded on the NYSE or NASDAQ * * *.". Another commenter stated that subjecting different providers under a hospital to different levels of scrutiny could cause confusion and unnecessary hardship.

Response: For reasons already stated, we have eliminated the distinction between publicly traded and private companies and have declined to subcategorize individual providers and suppliers based on their ownership.

Comment: A commenter stated that while subjecting newly enrolling DMEPOS suppliers to stringent screening may be proper, an enrolled DMEPOS supplier that reenrolls following an ownership change should not be subject to the same screening as a newly established supplier. It should instead be treated as moderate risk, just as enrolled suppliers that revalidate their enrollment information. The commenter contended that the seller's business, much of which remains after the purchase, has already been verified and authenticated; if CMS and the NSC subject the purchaser to stringent enrollment screening, they will duplicate the work that they have already done to validate and inspect the purchased business, wasting resources. It could also delay the new owner's receipt of a Medicare number, which could disrupt the continuity of business and patient care. The commenter added that if CMS does not agree that an enrollment following an ownership change of an enrolled DMEPOS supplier should be moderate risk, CMS should formally state that purchasers of enrolled DMEPOS suppliers will receive new Medicare numbers with billing privileges retroactive to the purchase date. In closing, the commenter stated that the proposed rule is a dramatic change to the existing methods of Medicare enrollment; while change to prevent fraud and abuse is advisable, such change should not harm honest providers and suppliers who strive to provide high quality service to Medicare beneficiaries. Another comment stated the purchaser of an existing community pharmacy DME supplier store should be screened as a moderate (not a high) risk supplier during reenrollment.

Response: We disagree that a DMEPOS supplier undergoing a change of ownership should be assigned to the as moderate screening level. For purposes of enrollment, a DMEPOS supplier undergoing a change of ownership is treated and must enroll as a new supplier. Hence, since all newly-enrolling DMEPOS suppliers are subject to a "high" level of screening, we believe DMEPOS suppliers undergoing a change of ownership should also be subject to a "high" level of screening. Further, the screening requirements in the high screening level include a fingerprint-based criminal history record check of any individual with direct or indirect ownership of 5 percent or greater. Therefore, enrollment screening after a change in ownership has clear value to the enrollment process, and we disagree that it would be a waste of resources. Currently-enrolled (revalidating) DMEPOS suppliers are assigned to the moderate level of screening.

Comment: A commenter stated that certified orthotic and prosthetic DMEPOS suppliers and American Board for Certification in Orthotics and Prosthetics (ABC)-accredited DMEPOS suppliers should be assigned to the limited screening level. The commenter stated that accreditation is not an easy standard to meet, and asked CMS to investigate whether there are any studies or other evidence that indicate that ABC Accredited Facilities and/or ABC Certified practitioners as a DMEPOS subcategory pose an elevated risk to the Medicare program. If there are not, such suppliers should be subject to limited screening.

Response: We believe the commenter is asserting that accreditation bodies perform a sufficient level of oversight to ensure that the entities they accredit are a low program integrity risk. We do not believe this is true. The accreditation bodies help verify the supplier's compliance with DMEPOS standards, rather than assess the supplier's risk of fraud, waste and abuse. Accordingly, we decline to assign entities accredited by ABC or any other accrediting organization to the limited screening level solely on that basis.

Comment: A commenter contended that in States without licensure, if a DMEPOS supplier is practitioner-owned and one or more of the practitioners is certified by ABC (accrediting body referenced in section 427 of the Medicare, Medicaid, and SCHIP Benefits Improvement and Protection Act of 2000 (BIPA)), or if the facility itself has been accredited by one of these entities, it should be as assigned

to the limited screening level. The practitioner being credentialed in either of these ways has demonstrated a commitment to quality.

Response: As already stated, we decline to subcategorize individual providers and suppliers based on their ownership and do not believe accreditation—standing alone—should be the foremost indicator of fraud and abuse risk.

Comment: One commenter stated that chain pharmacies should be exempt from the increased screening levels and screening procedures, as they are already subject to significant regulation within their respective States.

Response: We disagree. For the same reason that we cited for eliminating the distinction between publicly traded and non-publicly traded or public or non-public ownership status as a basis for determining screening level, state regulation of chain DMEPOS suppliers is not in itself a sufficient indicator of the risk of fraud, waste or abuse posed by a particular category of provider or supplier. The fact that a particular provider or supplier type may be regulated by the State is not adequate grounds for placing it in a lower screening level.

Comment: A commenter stated that the proposed provisions punish legitimate providers and that the most egregious fraud is committed by scam artists and organized crime. The commenter expressed concern that small practices will be driven out of business. In light of CMS's proposed exemption for public companies, one or two large national companies may be the only ones "left standing" and will have a monopoly. CMS, the commenter argued, will then be unable to objectively compare "best practices" or to objectively evaluate trends in care, and that patients will not have a choice for their care.

Response: As already stated, we have eliminated the distinction between publicly held and private companies. In addition, we believe that the proposed provisions will help stem the fraud that both the commenter and we are concerned about.

Comment: A commenter recommended that CMS provide the analysis for which it based its risk assignment decisions for limited and moderate screening levels. The commenter also recommended that CMS consider the Medicare and Medicaid error rates for each provider or supplier in establishing its screening levels. Finally, the commenter also requested the following data for each type of Medicare provider and supplier for 2008, 2009, and 2010:

- Number of Medicare revocations.
- Number of Medicare payment suspension.
- Number of Medicare overpayment.
- Medicare error rate.
- Medicaid error rate.
- CMPs.
- Convictions by the Department of Justice.
- HHS OIG mandatory exclusions under 1128 of the Act.
- HHS OIG permissive exclusions under 1128 of the Act.

Response: We based our risk assessments on a variety of factors, including some of those listed by the commenter as well as others. However, because our conclusions were not based on any one factor nor any specific combination of factors, but rather on CMS's aggregate experience with each provider and supplier type, providing the data requested by the commenter would not serve to clarify the determinations of risk.

Comment: A commenter stated that the proposed screening approach in the proposed rule is simplistic at best and flawed at worst. The commenter did not believe provider type is the only measure of risk of fraud. To address those individuals and organizations who intend to enroll for the sole purpose of committing fraud, CMS must: (1) Consider the provider's past experience with Medicare, Medicaid, or CHIP; (2) coordinate enrollment and billing issues with commercial health plans, Medicaid and CHIP; and (3) establish more stringent program requirements. The commenter believes that CMS did not offer any enhanced program requirements in the proposed rule, the rule does not reduce the "pay and chase" approach used by CMS and OIG today.

Response: We disagree, and believe that the program safeguard measures outlined in this final rule with comment period will greatly assist in reducing fraudulent activity. We believe several of the elements proposed by the commenter are inherent in this rule. First, under the final rule with comment period, final adverse actions will lead to a high screening level assignment and the use of additional screening tools. Second, with regard to more stringent program safeguards, we believe there is much in this final rule with comment period to bolster our efforts at combating fraud, waste, and abuse For example, in this final rule with comment period, we are expanding the instances in which we can impose a payment suspension. Furthermore, for the first time in the history of the programs, we will be able to impose an enrollment moratorium in order to combat fraud, waste, and abuse. Accordingly, we believe the new authorities that we are implementing under the ACA will assist us in strengthening our program integrity efforts.

Comment: A commenter recommended that the following be placed into the high screening level: (1) Any provider or supplier that is not State licensed, and (2) any owner, authorized official, delegated official, physician or non-physician practitioner who has ever been excluded by the OIG, revoked by Medicare, or had a State license revocation or suspension.

Response: We stated previously that merely because a particular provider or supplier type may be regulated by the State is not in and of itself adequate grounds for placing it in a lower screening level. By the same token, we do not believe that a failure to be licensed by the State should automatically place the provider or supplier in a high screening level, as the State may not have licensure requirements for that particular provider or supplier type. In addition, the standards for licensure vary among the States and Territories such that these are largely out of our control. With regard to the commenter's second suggestion, we again note that § 424.518(c) of the final rule with comment period states that a provider or supplier will be moved from the "limited" or "moderate" level to the "high" level if it has had final adverse actions imposed against it.

Comment: A commenter recommended that CMS explain why it did not consider comments regarding publicly traded companies in the final rule with comment period; Home Health Prospective Payment System Rate Update for Calendar Year 2011; Changes in Certification Requirements for Home Health Agencies and Hospices, when developing the proposed policy found in the proposed rule to this final rule with comment period.

Response: This rule and the rule that the commenter references deal with different issues. Each was developed and considered on its own merits.

Comment: A commenter supported CMS's placement of hospitals and physicians into the limited screening level. However, the commenter disagreed that publicly traded DMEPOS suppliers or HHAs would have less risk. The commenter also stated that the providers and suppliers that are designated as "high risk" or "moderate risk" but which are members of, operate as a part of, or are owned by a hospital or a health system, should instead fall under the same risk assignment as the hospital. Such providers and suppliers

are part of larger established organizations that have high levels of accountability to their internal governance structures and have longstanding relationships with and responsibility to their local communities.

Response: For reasons already stated, we have eliminated the distinction between publicly traded and private companies and have declined to subcategorize individual providers and suppliers based on their ownership.

Comment: Several commenters requested greater specificity regarding what level of managing employees would be subject to the screening requirements for high risk providers and suppliers. Some of them requested that for large provider organizations, only the highest-level managing employees who operate or manage, or who oversee the operation of the entire healthcare organization—and not lower-level managers of individual departments or functions—should be subject to the enhanced screening procedures.

Response: In this final rule with comment period, we will only apply the screening requirements for high screening level providers and suppliers to individuals with a 5 percent or greater direct or indirect ownership interest. Officers, directors, and managing employees—to the extent that they do not have a 5 percent or greater ownership interest—will not be subject to fingerprint-based criminal background checks. However, we intend to monitor the situation and may seek to extend the scope of fingerprint-based criminal background checks in the future if circumstances warrant.

Comment: A commenter stated that hospitals should be exempted from all screening levels—even the limited screening level—if they are State-licensed and accredited.

Response: We disagree with this commenter. To exempt a provider or supplier from any screening level would be the equivalent of stating that the provider need not undergo even the most basic verification requirements used under the limited risk level of screening.

Comment: Several commenters supported site visits as a tool to improve program integrity, but believes that they could disrupt or administratively burden a legitimate provider or supplier's business operations. They recommended that CMS limit the purpose of these site visits to verifying that the provider/supplier exists and is operational; other matters that would require significant management and clinical staff time should be handled through separately scheduled site visits. Several other commenters believe that site visits were appropriate, but said that the number of such visits must be reasonable for the circumstances and should only increase if inappropriate activity is suspected. In addition, another commenter suggested that as part of a DMEPOS site visit, the auditor should confirm with the owner of the warehouse or facility the terms of the lease; for HHAs, the auditor should confirm that the HHA has been using the OASIS form and that a sample of Patient Plan of Care medical records/files can be directly linked to an OASIS document.

Response: We decline to state that site visits will always be limited to verifying whether the provider or supplier is operational. We must retain the flexibility to conduct a closer on-site review if warranted.

Comment: One commenter stated that classifying DMEPOS suppliers that are physician-owned as high risk could pose a significant disincentive to office-based physicians to continue offering DMEPOS supplies to their patients. The commenter stated that there has been little to no documentation of fraud, waste, or abuse in this category of DMEPOS, and that these suppliers should be exempted from the high risk level of screening.

Response: For reasons already stated, we have declined to subcategorize individual providers and suppliers based on their ownership.

Comment: Several commenters stated that the risk assessments of specific providers should not be made public.

Response: To the extent allowed by Federal law, we will not release to the general public the risk assessment of an individual provider or supplier. Thus when an individual provider or supplier is elevated in screening level as a result of a triggering event in § 424.518 and § 455.450, we will not publish the individual provider's or supplier's name.

Comment: Several commenters supported the creation of limited, moderate, and high screening levels, as well as the proposal to place physicians into the limited screening levels. They added that CMS should use public notice and comment prior to modifying the process or revising level assignments based on new criteria.

Response: We appreciate the commenters support and will publish notice in the **Federal Register** regarding changes in assignment or levels of screening specified at § 424.518 and § 455. 450. However, as mentioned previously, we will not publish information about an individual provider or supplier that meets certain triggering events as described in these sections.

Comment: A commenter opposed "geographical circumstances" as a possible criterion for adjusting a provider or supplier's screening level. This would deny all providers and suppliers in the specified geographic area basic due process and could seriously damage beneficiary access to health care providers and services in the impacted area.

Response: We are not adopting "geographic circumstances" as a criterion for adjusting a provider or supplier's screening level at this time. We believe that should circumstances arise where we have concerns about a provider or supplier type in a geographic area, the authority to impose an enrollment moratorium, as detailed in this rule, will provide program integrity protection. However, we do retain the authority to add geographic location as a criterion for adjusting a provider or supplier's screening level through future rulemaking.

Comment: Several commenters opposed the proposal to re-assign physicians from the "limited" or "moderate" screening level to the "high" screening level when CMS has evidence from or concerning a physician that another individual is using their identity within the Medicare program. Classifying physicians who have been the victims of identity theft to the high screening level would stigmatize the physician and create a presumption that he/she has engaged in conduct warranting heightened scrutiny. They urged CMS to establish a fourth level, which signifies a heightened level of risk to Federal health care programs as a result of compromised physician identity or identity theft. Another commenter requested that CMS clarify that it will be the offender who is subjected to additional scrutiny and that the victim will not be penalized for the actions of the offender. Another commenter, however, supported CMS's proposal to adjust the categorical screening level if a practitioner notifies CMS or its contractor that another individual is using his or her identity within the Medicare program, and to require fingerprinting of high risk provider and supplier types (but not of individual practitioners who have been the victim of identity or provider number theft).

Response: We stress that we will work closely with law enforcement against those individuals who are perpetrating Medicare identity theft. We do not plan to use screening tools to address identity theft concerns as it would not be an adequate response. We believe

identity theft concerns are most appropriately handled by our law enforcement partners.

Comment: A commenter requested clarification as to the screening level assignment of in-home supportive services (IHSS). If they fall into the "moderate" level, as do home health agencies, the commenter expressed concern that site visits could burden program recipients.

Response: Medicare does not recognize "in home supportive services" as a specific category of provider or supplier. To the extent that the IHSS supplier is or will be enrolling in Medicare or Medicaid as a HHA, it will be subject to the same requirements and standards as all other HHAs. As for the site visits, they will generally be conducted at the HHA's physical locations.

Comment: Several commenters expressed concern with the proposal to re-assign physicians (and other providers/suppliers) from the "limited" or "moderate" screening levels to the "high" screening level if a physician has had billing privileges revoked by a Medicare contractor within the previous ten years. Billing privileges can be revoked for a number of reasons unrelated to fraud, waste, or abuse, such as a failure to respond to a request for revalidation documentation within stringent contractor imposed deadlines. They urged CMS to differentiate between a temporary revocation of billing privileges and revocations based on actual misconduct by a provider or supplier.

Response: As stated earlier, revocation is undertaken as an administrative remedy only if clearly justified. Also, there is an appeals process in place for provider revocations. Should a revocation be rescinded, the provider or supplier would be restored to its previous screening level.

Comment: A commenter urged CMS to exercise the temporary moratorium authority judiciously and to exempt physicians from re-assignment from level I (limited) to level III (high) if physicians are ever subject to the temporary moratorium; this would include an exemption for physicians enrolled as DMEPOS suppliers if the latter are subject to a moratorium.

Response: We believe this commenter is addressing a concern that if a moratorium is imposed on a category of providers that includes physicians or physician-owned DMEPOS suppliers, that when the moratorium is lifted the provider or supplier category to which the moratorium applied would be moved to the high screening level for 6 months following the lifting of the moratorium. The commenter is asking for an exception to this proposal. A moratorium may be imposed if there is a heightened risk of fraud, waste or abuse in a particular geographic area or involving a certain provider or supplier type. If a particular provider or supplier type posed such a risk as to warrant a moratorium, it would be inappropriate for us to automatically exempt it from enhanced screening once the moratorium ends. In the event that we were to impose a temporary moratorium on physicians or physician-owned DMEPOS suppliers, the moratorium would be as narrowly tailored as possible to address specific fraudulent activity.

Comment: A commenter believes that the moderate and high screening level assignments for community pharmacies are inappropriate and contended that: (1) all existing community pharmacy DME suppliers, as well as new locations of existing community pharmacy DME suppliers, should be designated as limited risk, and (2) newly enrolling community pharmacy DME suppliers should be treated as posing a moderate risk. The commenter stated that community pharmacies are already heavily regulated by the States and Federal government through State boards of pharmacy, CMS supplier standards and surety bonds, and argued that community pharmacies are not a major source of fraud. The commenter also urged CMS to incorporate into its final rule the same exemption criteria that CMS's uses to exempt certain community pharmacies from DME supplier accreditation requirements. In addition, the commenter stated that CMS should designate community pharmacies as limited risk suppliers if: (1) They have had a supplier number for at least 5 years; (2) their DME sales are less than 5 percent of their total sales over the last 3 years; and (3) they have not received a final adverse action against them in the past 5 years. Another commenter stated that DMEPOS sales are but a small portion of genuine community pharmacy sales. Accordingly, the proposal regarding unannounced pre- and/or post-enrollment site visits for moderate risk suppliers and criminal background checks and fingerprinting for high risk suppliers may prove unbearably costly and burdensome to community pharmacies. The commenter added that it could lead to community pharmacies to stop supplying DME products, causing access problems.

Response: As already stated, all newly-enrolling DMEPOS suppliers, regardless of sub-type or ownership, will be placed in the high level of categorical screening. This includes new DMEPOS locations, which have long been treated as initial enrollments. Moreover, we do not believe it is appropriate to apply the community pharmacy exemption for accreditation to the risk classifications, as the standards for accreditation are different from the criteria we are using for the risk classifications.

Comment: A commenter urged CMS to more narrowly tailor its risk assignments of provider or supplier types by geography, so that DMEPOS suppliers in many areas of the country are not unfairly grouped into a higher screening level merely because those same DME supplier types pose major fraud risks in other limited areas of the country.

Response: We disagree. While some areas of the country are undeniably more prone to fraud than others, fraudulent activity can occur anywhere. Furthermore, we believe it most objective to apply the same standard to all parts of the country and use other tools to narrowly tailor our approach when necessary, including the enrollment moratoria provision set forth in this final rule with comment period.

Comment: A commenter requested clarification on whether an existing community pharmacy DME supplier that seeks to add a new DMEPOS supplier store would fall under the moderate or high screening level under the proposed rule. The commenter believes this should fall within the moderate screening level.

Response: As already stated, the addition of a new DMEPOS location would be subject to the level or screening specified for providers and suppliers assigned to the high screening level.

Comment: A commenter expressed concern that the Medicare contractor may not know which companies are publicly traded.

Response: We have eliminated the distinction between publicly traded and non-publicly traded companies; as such, this comment is no longer applicable.

Comment: One commenter stated that on June 23, 2010, the Director of the Office of Management and Budget published a memorandum titled, "Enhancing Payment Accuracy" through a "Do Not Pay List"; this Presidential document stated that, "At a minimum, agencies shall, before payment and award, check the following existing databases (where applicable and permitted by law) to verify eligibility: the Social Security Administration Death Master File, the GSA's EPLS, the Department of the Treasury's Debt

Check Database, the Department of Housing and Urban Development's (DHUD) Credit Alert System or Credit Alert Interactive Voice Response System and the DHHS OIG LEIE." The commenter stated that CMS should explain why the proposed rule does not mention these verification sources.

Response: Medicare contractors have long been required to review the EPLS and the LEIE prior to enrolling a provider or supplier in Medicare. In addition, providers, suppliers and their owners and managers are currently reviewed against the SSA Death Master File. As for the DHUD Credit Alert System and the Department of the Treasury's Debt Check Database, we understand the Presidential memorandum requires review of these systems prior to payment or award and will integrate their use as appropriate in our protocols.

Comment: Several commenters supported the placement of hospitals in the limited screening level. However, they added that high risk or moderate risk providers and suppliers that are members of, operate as a part of, or are owned by a hospital or a health system, should instead fall under the same limited risk assignment that CMS proposes for hospitals.

Response: Again, for reasons already mentioned, we have declined to subcategorize individual providers and suppliers based on their ownership.

Comment: Several commenters stated that in States with orthotic and prosthetic licensure, orthotic and prosthetic DMEPOS suppliers should be designated as limited risk, as there is no evidence of significant elevated risk for such licensed professionals. In States without orthotic and prosthetic licensure, several commenters stated that the supplier should be treated as limited risk if: (1) One or more of the supplier's practitioners are certified by the American Board for Certification of Orthotics, Prosthetics and Pedorthics or the Board of Certification/Accreditation International, or (2) the supplier itself has been accredited by one of these entities. Other commenters stated that if the orthotic and prosthetic supplier is not practitioner owned, but has been in business at least 3 years, it should be considered limited risk due to a demonstrated lack of inappropriate billings over time; if it is not practitioner-owned and has not been in business at least 3 years, it should be rated as a moderate risk. Finally, the commenters objected to the proposed risk provision for this risk assignment provision because: (1) Orthotics and prosthetics is not part of DME, and has significantly lower fraud and abuse risks; and (2) there has not been sufficient consideration of the impact of number of years in business, or accreditation/certification status as factors that diminish risk.

Response: As stated earlier, we do not believe certification or accreditation to be dispositive of risk for fraud and decline to adopt this suggestion. While we appreciate the commenter's suggestion that we should look at length of time in business as a means of supporting the assessment of risk, we believe that OIG and GAO reports and experiences are instructive and rely on those as well as our own data to support the assignment to levels of screening that we finalize in this rule.

Comment: A commenter expressed concern that the time and cost necessary to comply with the requirements in the proposed rule is a significant burden on small providers, in light of all of the other requirements they are subjected to. The commenter stated that for reasons of reduced risk, time in business and demonstrated commitment to quality, no certified practitioner or accredited orthotist or prosthetist facility should be subject to background checks and fingerprinting.

Response: We decline to adopt this suggestion; to do so would foreclose the possibility that any high risk practitioner or orthotic or prosthetic facility would be subject to enhanced scrutiny.

Comment: A commenter questioned whether requirements such as fingerprinting will accomplish CMS's goal of tracking violators, since CMS will have no way to ensure that the person providing the fingerprints is the person rendering the care. The commenter also questioned whether fingerprinting will help prevent identity theft for physicians.

Response: We are confident that fingerprint-based criminal history record checks will enable us to identify individuals who violate CMS existing regulations at § 424.530(a) and § 424.535(a), and appropriately deny or revoke Medicare billing privileges in these circumstances. This screening tool is intended to prevent individuals who pose an elevated risk of fraud, waste, and abuse from enrolling in the programs. Physicians will not be subject to the fingerprint-based criminal history check if they are not in the high screening level. Physicians as a category are in the limited screening level and providers and suppliers in the limited screening level are not subject to fingerprint-based requirements as are individuals and entities in the high screening level. The submission of fingerprints for the purposes of an FBI criminal history record check is not intended to address identity theft concerns.

Comment: A commenter stated that raising a supplier's screening level seems reasonable only if the supplier has come under a payment suspension or if after investigation, the type of provider and the services it will render are not congruent on its enrollment application.

Response: We disagree. There are, as explained in this final rule with comment period, a variety of final adverse actions that we believe warrant the placement of a provider or supplier in a higher screening level. Payment suspensions and inconsistent information on the enrollment application should not be the only two grounds for elevating a provider's screening level.

Comment: A commenter stated that with regard to the "high" screening level, although government enforcement efforts to date have shown fraud, waste and abuse issues with HHAs and DMEPOS suppliers in certain geographical regions (for example, South Florida, Texas, and California), it is not clear that issues with such entities are national. Because the criminal background checks and fingerprints are onerous requirements that are not currently used by Medicare, the commenter stated that CMS should limit itself to introducing such requirements in high risk geographic areas, rather than nationally, at least at this stage. Moreover, the commenter stated that CMS has neither provided the data nor made the convincing case that its proposed changes will deliver results to justify the extent to which the rules would intrude on normal patient care and business practices. With respect to orthotic and prosthetic suppliers, the commenter urged CMS to adopt a more realistic approach that cracks down on fraudulent providers, without either considering every provider to be a crook, or adding huge regulatory burdens that could put honest, legitimate, hard-working orthotic and prosthetic suppliers out of business.

Response: We disagree that our enhanced screening procedures should initially be restricted to high risk geographical areas. While some regions of the country evidence fraud, waste and abuse more than others, fraudulent activity can occur anywhere. In addition, we believe that a national approach is most objective in implementing the screening provisions herein. We will rely on other program integrity tools, including, without limitation, the enrollment moratoria authority contained within this rule, to

address concerns in particular locales. Moreover, CMS will monitor implementation of the final requirements on provider and supplier screening with respect to patient care and business practices.

Comment: A commenter stated that with respect to changing a health care provider's level of screening, the basis for this determination should be on information released during 2011 and beyond.

Response: We disagree. We have found that long-term trends (for example, data from 2005 through 2009) are often good indicators of potential fraudulent activity.

Comment: A commenter suggested that CMS establish certain exemptions to DMEPOS suppliers prior to a company being deemed a moderate or high risk supplier, such as: (1) A multiple year history as a DMEPOS provider; (2) award of a DMEPOS competitive bidding contract (where CMS itself has extensively reviewed the financials of contracted suppliers); and (3) accreditation by a CMS-approved third party.

Response: We did not base our development of levels of screening and the assignment of provider and supplier categories to these levels of screening of fraud, waste or abuse on the past experience of specific individual providers. Rather, it is based on collective experience of provider and supplier categories. Furthermore, we do not believe length of time in business is an appropriate determination of fraud risk. Similarly, as described previously, we do not believe accreditation is—in and of itself—an indication that a provider or supplier should be assigned to the limited screening level. Finally, we decline to accept the commenter's suggestion that the award of a DMEPOS competitive bidding contract should provide an exemption from the assignment specified in this rule. The criteria for competitive bidding are different than those that we are using to determine the appropriate screening level appropriate to particular categories of provider or supplier.

Comment: A commenter stated that any criteria utilized by CMS to assign screening levels should be made public, and that CMS should regularly review its assignment to screening levels. The commenter questioned whether automatically applying the proposed additional screening measures for providers and suppliers assigned to the moderate and high levels will be effective in shutting-out sham suppliers and past violators from participating in Medicare, particularly since these safeguards do not protect Medicare against criminals who use a shell as the owner of record to avoid detection. The commenter believes that the recently implemented accreditation and bonding requirements for DMEPOS suppliers are a stronger deterrent in ensuring that fraudulent suppliers are not able to participate in Medicare, and recommended that CMS first determine whether these requirements adequately deter fraud before imposing additional and arguably less effective safeguards, especially considering the cost and burden of these new requirements.

Response: Criteria for the risk assessments were discussed in the proposed rule and this final rule with comment period. The criteria will be reviewed on a consistent and ongoing basis, and in the event we decide to update the assignment of screening levels, we will publish a regulatory document in the **Federal Register**. We do not believe, though, that we should wait for the results of the accreditation and surety bond requirements before taking additional steps to address program integrity problems related to DMEPOS suppliers. Indeed, it could take several years for the full impact of the surety bond and accreditation requirements to take effect on our anti-fraud efforts. As such, we do not believe it to be premature to assign newly-enrolling DMEPOS suppliers to the high screening level and require enhanced screening pursuant to this rule. It is our expectation that all of these program integrity protections together will lessen the risk of fraud and abuse in the Medicare program.

Comment: A commenter stated that the language in § 424.500, *et seq.*, does not define "Medicare contractor," and the verbiage in the preamble is somewhat vague. The commenter requested clarification as to: (1) The contractors that will be conducting the on-site visits, (2) whether this approach will be uniform across the country, and (3) the training and experience the individuals conducting these visits will have.

Response: Since the term "Medicare contractors," as used strictly in the provider enrollment context, is generally understood and recognized by the provider community to mean the entities that process CMS–855 provider enrollment applications, we do not believe it is necessary to include a formal definition of this term in this final rule with comment period. The contractors that will conduct site visits will vary, as will the scope and breadth of individual visits; however, such site visits will be in accordance with guidance issued by CMS. Those who will conduct site visits will receive appropriate instructions and oversight regarding the performance of the visits.

Comment: Several commenters stated that HHAs and hospices are already subject to a State survey prior to enrollment—as well as on a periodic basis thereafter—thus making a site visit superfluous. As such, initially enrolling HHAs and hospices should be included in the limited screening level rather than in the moderate screening level. A commenter also stated that including all revalidating HHAs, hospices and DME suppliers in the moderate screening level is unfair and inappropriate, as they are already established providers; the commenter believes it should be exempt from the site visit requirement if it has been in existence for at least 5 years and there is no reason to suspect fraudulent activity. The commenter added, however, that additional site visits and increased medical review during the provider's first 5 years of enrollment could be performed to ensure compliance. Another commenter stated that it would be better to conduct HHA site visits, if they had to be performed, with existing or recent patients in their homes, since most care is provided to patients in their homes; care is not provided in the HHA or hospice office.

Response: We do not believe that a site visit is superfluous. Due to the length of the enrollment, survey, and certification processes, we believe it is important for us to institute verification activities at multiple points during this period, and not to restrict its validation efforts to the enrollment process and the State survey. Moreover, we do not believe that site visits should be limited to providers who have been enrolled for less than 5 years, as we do not have data to suggest that those who have been enrolled for 5 years or more present less of a fraud, waste, and abuse concern than newly enrolled providers and suppliers. Finally, and as mentioned earlier, provider enrollment site visits will be conducted at the HHA's physical locations.

Comment: A commenter asked CMS to describe the process the Medicare contractors are using to review State licensing data on a monthly basis. The commenter also requested clarification as to whether the reference to "non-public, non-government owned" applies only to affiliated ambulance services suppliers, or extends to the other provider types listed in the moderate level.

Response: The contractors use various processes to review licensure data; frequently, this is an automated process. With regard to the clarification requested, the term as used in the NPRM applied only to ambulance

suppliers. However, as we have eliminated the distinction between public and non-public ambulance service providers, this comment is no longer applicable.

Comment: A commenter suggested that CMS consider reclassifying providers and suppliers in the "moderate" and "high" screening level to the "limited" risk level if the provider or supplier is subject to State licensure requirements. In addition, the commenter opposed reclassifying providers or suppliers from one screening level to another based strictly on their geographical location. To do so would be arbitrary, and would not reflect the risk associated with particular provider or supplier types.

Response: As already mentioned, we do not believe that State licensure is, in and of itself, indicative of a limited risk of fraud. In addition, we do not plan to reclassify providers or suppliers based solely on geographical location. As stated earlier, if we identify a concern among provider and supplier categories in a particular geographic location, our authority to impose a temporary moratorium will help to address those concerns. However, we do retain the authority to add geographic location as a criterion for adjusting a provider or supplier's screening level through future rulemaking.

Comment: A commenter expressed concern that fingerprinting: (1) Could be very costly; (2) raises privacy and security concerns once an organization begins to collect, maintain, administer access and store a database of fingerprints; and (3) is technologically being replaced by much more modern and reliable identification techniques. The commenter urged CMS to avoid requirements for fingerprinting in screening requirements and to use more modern techniques.

Response: As already mentioned, we believe that fingerprint-based criminal history record checks will be an effective tool in combating Medicare waste, fraud, and abuse. In our view, such criminal history record checks—more effectively than a name-based background check—will prevent ineligible individuals from enrolling in the Medicare program. CMS believes that the cost to both the applicants for the collection of fingerprints, and to CMS for the processing of the prints is not unduly burdensome either to the providers and suppliers or the agency. We would like to clarify that CMS will not be collecting and storing any fingerprints. As mentioned earlier, the selected authorized channeler will collect and transmit the prints electronically directly to the FBI CJIS Division's Wide Area Network to check against the IAFIS, the FBI maintained database. CMS will only receive the criminal history record information, and will protect that information as the Privacy Act requires—both from a privacy and security standpoint. In response to the commenter's third remark, while CMS is aware of the advances in technology in the biometric market, the FBI and State law enforcement standard is currently the fingerprint. Once the FBI or State law enforcement requires a new standard of identification to access the criminal history record information, we will comply with that standard.

Comment: A commenter suggested that in implementing the screening requirements, CMS should minimize duplication of effort. Often the same providers who participate in traditional Medicare are also participating in other plans, such as Medicaid. Having separate screenings could be burdensome and inefficient.

Response: We agree with the commenter that every possible attempt should be made to avoid duplication of effort. To that end, we have attempted to address this concern by providing that the States may rely upon a screening performed by the Medicare program.

Comment: A commenter supported the concept of applying geographical circumstances when adjusting providers or suppliers from one screening level to another, and recommended that anti-fraud efforts be coordinated with other payers—such as through information sharing—because providers and suppliers perpetrating fraud do so across the spectrum of payers, and that reality should be integrated into CMS's overall strategy.

Response: We agree that anti-fraud efforts should be coordinated among payors and we are taking steps to promote greater coordination. As stated previously, we believe our temporary moratoria authority described later in this rule will be an effective tool in particular geographic locations. We may revisit as a factor for enrollment screening level in future rulemaking.

Comment: Several commenters stated that new locations of currently enrolled Medicare DMEPOS providers should be distinguished from other providers that do not have an established record with the Medicare program. CMS should therefore screen new locations of Medicare enrolled suppliers in the same manner as it proposes to screen currently enrolled providers.

Response: We disagree. As previously stated, the addition of a new location is considered an initial enrollment. Consequently, a new DMEPOS location will be subject to the "high" level of categorical screening.

Comment: Several commenters requested that occupational and physical therapists, including those enrolled or applying to enroll as DMEPOS suppliers, be placed in the limited risk level.

Response: As stated earlier, all newly-enrolling DMEPOS suppliers (including those with new practice locations), regardless of sub-type, and including those that are owned by occupational and/or physical therapists, will be subject to a high level of categorical screening. For physical therapists enrolling as individuals or group practices via, respectively, the CMS–855I and CMS–855B applications, these suppliers will be placed in the moderate level of screening. As we explained earlier with respect to physical therapy providers, we believe the classification of physical therapists in the moderate level is supported by a recent OIG report entitled "Questionable Billing for Medicare Outpatient Therapy Services" (December 2010) (*http://oig.hhs.gov/oei/reports/oei-04-09-00540.pdf*), which found, among other things, that Miami-Dade County had three times, and nineteen other counties had at least twice, the national level on five of six questionable billing characteristics.

Comment: A commenter asked whether CMS will identify the contractors that will perform these screenings, or whether it will accept screenings performed by commercial screening services widely used by large employers outside the health care industry.

Response: We believe the commenter is referring to criminal background screenings. To comply with the FBI requirements that only authorized channelers submit fingerprints to the Wide Area Network, and receive the criminal history record information from the FBI, CMS will contract with a pre-approved FBI authorized channeler. In the future guidance, CMS will identify the selected authorized channeler(s) where individuals may have their fingerprints collected, or to whom they may submit the FD–258 card that was completed at a local law enforcement agency. In addition to ensuring compliance with FBI security requirements, such authorized channelers have vendors all over the country where individuals can have their fingerprints electronically collected. In addition, individuals may have their prints taken on the FD–258 paper card at a local law enforcement agency, and then have it sent to the

authorized channeler to have it digitized and submitted to the FBI.

Comment: A commenter had several suggestions for screening levels. The commenter recommended that the limited screening level include providers affiliated with non-profit acute care hospitals or health systems; any not-for-profit providers who have been in existence for at least 20 years and who have filed annual cost reports (if required) for their line of business; and any for-profit providers in business for 20 years as a single site provider. The moderate screening level should include all other providers except those indicated in the high screening level, plus any provider who has entered into a settlement with a government agency (Federal, State or local) within the past 20 years, up through the most recent 5 years, where such settlement covered any over-charge allegations. The high screening level should include any provider who has entered into a settlement with a government agency (Federal, State or local) for any overpayment in the past 5 years; and any provider or group of providers which may currently be under review for possible billing overcharges or other violations who is seeking either a new provider number or seeking a new provider location.

Response: We appreciate these suggestions, and may consider them as part of a future rulemaking effort should circumstances warrant. However, for now, and for the reasons described previously, we believe that the screening level assignments discussed in this preamble will best implement the statute.

Comment: A commenter recommended that CMS refrain from publicly posting risk levels, particularly as they relate to individual providers or group practices. The commenter believes that in some instances this could give a false impression as to the level of risk of any provider or supplier, and that CMS has not clarified how this action will assist the agency with fraud prevention.

Response: To the extent permitted by Federal law, we do not plan to publish risk assessments and the corresponding screening level of individual providers or suppliers.

Comment: A commenter urged CMS to provide contractors with sufficient and targeted resources to handle identity theft screening to ensure that the additional screening precipitated by identity theft will not delay processing of new enrollment applications.

Response: As mentioned throughout this rule, we do not plan to use fingerprint-based criminal history record checks to address identity theft concerns. Identity theft is within the purview of law enforcement and we will make referrals to our law enforcement partners whenever appropriate.

Comment: A commenter requested clarification as to whether a revalidating provider would need to resubmit fingerprints with its application. The commenter believes this would be burdensome, costly, and unnecessary, since fingerprints do not change.

Response: If an individual has provided fingerprints on one occasion, we will not ask such individual to furnish fingerprints a second time unless required by FBI protocols.

Comment: A commenter disagreed that in all cases publicly traded entities pose a "limited" risk while all HHA companies that are not publicly traded pose a "moderate" risk to the program. The commenter supported the "high" risk assignment for those new to the program, but stated that the proposed rule does not consider that companies that have operated successful and compliant HHAs for years would fall into the high screening level if they were to open a new location or branch simply based on the arbitrary assignment of the screening level.

Response: As stated earlier, we believe that newly enrolling HHA locations (for which a CMS–855 is submitted) should be subject to the enhanced scrutiny of the high risk screening level. Further, as stated earlier, we have eliminated the distinction between publicly traded and non-publicly traded companies.

Comment: A commenter urged CMS to expand the definition of limited risk to include entities that file with the Securities and Exchange Commission (SEC), even though they do not have securities traded on the NYSE or NASDAQ. By reason of their debt obligations, such entities are subject to the same disclosure and reporting requirements under Federal securities laws as a company that is subject to section 13 or 15(d) of the Securities Exchange Act of 1934, as amended (the "Exchange Act").

Response: As stated earlier, we have eliminated the distinction between publicly traded and non-publicly traded companies, and the comment is no longer applicable.

Comment: A commenter stated that adjusting HHAs from the "limited" or "moderate" screening level to "high" risk simply because they reside in an area for which CMS imposes a moratorium is arbitrary and punishes good HHAs with no consideration of their compliant service to the Medicare beneficiaries and the program.

Response: As explained elsewhere in this section and also later in the general discussion regarding moratoria, a moratorium may be imposed if there is a heightened risk of fraud, waste, or abuse in a particular area or involving a certain provider or supplier category. If a particular provider or supplier type posed such a risk as to warrant a moratorium, it would be inappropriate for us to automatically exempt it from enhanced screening once the moratorium ends. To do so would, in effect, require us to state that once the moratorium ends, that provider or supplier type no longer poses a risk, a conclusion that we could not necessarily draw.

Comment: A commenter stated that the assignment of risk should be based on defined criteria beyond those proposed, such as compliance history related to billings, medial review, and history of negative audits from the program safeguard contractors. The commenter added that defined criteria should also be used to identify when providers are moved to different screening levels. For instance, brand new HHAs with no previous enrollment history should be part of the high screening level; however, upon 5 years of compliant operation, they should be moved to the moderate screening level. If a company with a 5 year compliance history opens a HHA, it should not be assigned to the high screening level; instead, it should be assigned to the moderate screening level based on its good history with Medicare. Agencies that have a 7 year or more compliance history should be assigned the limited screening level.

Response: Though we do not at this point believe that length of time as a Medicare provider should be a criterion for reducing a provider's or supplier's screening level, we may consider this as part of a future rulemaking effort should circumstances warrant.

Comment: A commenter believes that the phrase "Indian Health Service facilities" should be deleted in favor of "health programs operated by an Indian Health Program (as that term is defined in section 4(12) of the Indian Health Care Improvement Act) or an urban Indian organization (as that term is defined in section 4(29) of the Indian Health Care Improvement Act) that receives funding from the Indian Health Service pursuant to Title V of the Indian Health Care Improvement Act." Such language would encompass all Indian and tribal programs that are carried out pursuant to the Indian Health Care Improvement Act (IHCIA) and Indian Self-Determination and Education Assistance Act (ISDEAA). Moreover, to

ensure that all Indian and tribal health programs are treated as limited risk, the exception in (b)(1) and (c)(1) should be amended to refer to Indian and tribal health programs. The commenter stated that the burden on Indian and tribal providers of meeting new screening requirements would be significant and duplicative of screening requirements imposed already under the Indian Child Protection and Family Violence Act on many of the providers.

Response: We will revise the language in the final regulation as requested by the commenter to ensure that Indian and tribal health programs are described accurately and are assigned to the limited screening level.

Comment: A commenter stated that CMS should designate provider screening levels in the final rule with comment period, and should require changes in the risk level for a provider type to be subject to the rulemaking process.

Response: We have specified the different screening levels in this final rule with comment period. Should a change in a particular provider or supplier type's classification be warranted and should it necessitate a change in existing regulatory language, we will publish notice of it in the **Federal Register**. However, we will not publish notice of the circumstances under which an individual provider or supplier has been moved to an elevated level of screening as described in § 424.518(c) and § 455.450(e).

Comment: A commenter stated that ophthalmologists, optometrists, and opticians who only bill as DMEPOS suppliers for post-cataract glasses and lenses should fall into the limited screening level.

Response: As detailed previously, currently enrolled DMEPOS suppliers will be placed in the moderate level of categorical screening and newly-enrolling DMEPOS suppliers will be assigned to the high level of screening.

Comment: A commenter opposed CMS' proposal to consider assigning all providers or suppliers in a specific geographic location to a higher level of screening, solely because others in that area may be considered moderate or high risk. The commenter believes this type of action was arbitrary, and could cause new, limited risk providers to think twice before entering a geographic market, thus potentially blocking beneficiary access to needed services.

Response: We did not assign any provider or supplier category to a screening level based on geography.

Comment: A commenter did not believe independent laboratories should be placed in the moderate screening level, due to their high level of regulation. The commenter stated that the sheer volume has no bearing on risk and that they are already subject to regular site visits.

Response: We disagree. Based on our experience, we believe that independent laboratories are appropriately assigned to the moderate screening level. We note that newly-enrolling DMEPOS suppliers are, too, subject to site visits, yet they are assigned the high screening level.

Comment: A commenter stated that all physicians should not be placed in the limited screening level. Several specialties are increasingly engaging in abusive self-referral arrangements.

Response: For the reasons stated previously, we believe that physicians and non-physician practitioners are appropriately classified in the limited screening level. Moreover, we note that the final rule with comment period contains provisions for elevating a particular physician's or practitioner's screening level in certain circumstances.

Comment: One commenter disagreed that geographical circumstances should justify the adjustment of FQHC providers and suppliers to elevated screening levels based upon this criterion alone. The commenter stated that FQHC entities are in an entirely different classification and should not be subject to the same categorical movement.

Response: We assume this commenter is concerned about our ability to reassign providers or suppliers after a temporary moratorium is lifted such that FQHCs could be classified as high risk in the event they are located in an area in which a temporary moratorium is lifted. We intend to finalize the elevated risk factors. We believe it important to closely monitor all providers and suppliers in the event a temporary moratorium is imposed—and for a period thereafter. We note that this would only apply to providers and suppliers to which the moratorium applied. Unless the moratorium that was lifted had applied to either all providers and suppliers in a geographic area or to a category of providers or suppliers that included FQHCs or to FQHC specifically, the elevation to the high screening level would not apply to FQHCs or any other provider or supplier category not originally subject to the moratorium.

Comment: A commenter: (1) Expressed concern about potential application delays if the Medicare contractors have insufficient funds to conduct these visits; (2) requested assurances from CMS that adequate funds will exist; and (3) recommended that CMS provide guidance to the Medicare contractors on the timeframes within which enrollment inspections shall occur.

Response: We believe that adequate funds will exist to perform the required site visits, and we will issue guidance to our contractors regarding processing times.

Comment: A commenter expressed concern that tax-exempt, faith-based HHAs will be subject to a higher level of scrutiny than publicly traded for-profit HHAs. The commenter believes that such faith-based HHAs should be placed in the limited screening category.

Response: We have eliminated the distinction between publicly traded and non-publicly traded HHAs. We decline to adopt the commenter's suggestion to assign faith-based HHAs in the limited level of screening as it has not been our experience that faith-based HHAs present a different risk of fraud and abuse than non-faith-based HHAs.

Comment: A commenter stated that the inclusion of CMHCs in the "moderate" risk group seems appropriate given the history of fraud in "for profit" CMHCs. The commenter believes, however, that in the future, "not for profit" CMHCs be considered for status as a "limited" screening level.

Response: We decline to adopt the commenter's suggestion, as it has not been our experience that non-profit CMHCs pose a different risk than for-profit CMHCs. We will monitor CMHCs and other provider and supplier types after this final rule with comment period is implemented and, if need be, make adjustments to various risk classifications.

Comment: A commenter stated that the fingerprint requirement is problematic. The FD–258 fingerprint card could be fairly easy to obtain and complete without the involvement of government officials or by manipulating the form before forwarding it to the concerned government representative which could lead to fraudulent data being accepted by CMS contactors. In order to ensure the validity and acceptability of fingerprint data, the commenter stated that a clear chain of custody will be required for the FD–258 cards, providing for uninterrupted and secure forwarding of the completed cards from an originating law enforcement office to the CMS contractor. The commenter believes that consultation with the FBI and other expert agencies on this subject could prove valuable.

Response: CMS has consulted and will continue to consult with the FBI regarding the use of the FD–258 card. As noted previously, CMS has found that in addition to a longer processing time for

the FD–258, there is a higher cost to CMS for the processing of such cards. However, individuals who have their prints collected by a local law enforcement agency must use the FD–258 card and submit it to CMS' authorized channeler. The authorized channeler will digitize such FD–258 cards obtained at a local law enforcement agency for submission to the FBI. The chain of custody will conform to the FBI Security and Management Control Outsourcing Standard for Channelers and Non-Channelers and the FBI's Criminal Justice Information Services (CJIS) Division's Security Policy.

Comment: A commenter recommended that the proposed screening procedures be applied across the board for all providers and suppliers in or being introduced into any aspect of the Medicare, Medicaid or CHIP system.

Response: We disagree with this comment. Different categories of providers and suppliers pose different risks that must be addressed in distinct ways.

Comment: A commenter recommended that when determining whether to adjust an individual DMEPOS supplier's screening level, CMS should consider the supplier's: (1) Experience in furnishing services; (2) experience in the geographic area; (3) accreditation status and compliance with quality standards; and (4) compliance program, as well as any past fraudulent activity by the supplier or its employees and the category of DMEPOS it furnishes.

Response: We decline to adopt this approach. First, we believe that this could be subject to inherently arbitrary implementation. Second, as has been described previously, we believe the ACA requires us to assign categories of providers and suppliers to a level of screening based on the risk for fraud. The criteria the commenter proposes would necessitate a level of pre-screening that is not feasible for every applicant CMS must process.

Comment: A commenter stated that providers and suppliers should be individually notified of the screening level into which they will be placed and the reasons for such designation. The categorizations should not be made public because that could easily lead to irreparable damage to reputations and the companies' business.

Response: The publication of this final rule with comment period serves as notification to suppliers and providers of the assignment of their category to a particular screening level. The only new screening requirement that requires action on the part of a provider or supplier is the fingerprint-based criminal history record check. As stated, there will be an additional 60 day period after the publication of subregulatory guidance prior to its implementation for DMEPOS and HHAs. In instances where an individual provider or supplier has been reassigned to a higher level of scrutiny under § 424.518(c)(3), we anticipate that each provider or supplier will be individually notified of its newly assigned screening level prior to revalidation. This process will be clarified in the subregulatory guidance that CMS will issue as described in this final rule with comment period. Moreover, to the extent permitted by Federal law, we do not intend to make public a particular provider or supplier's screening level assignment.

Comment: A commenter requested that CMS expand the limited screening level defined in the proposed regulation to include the term "non-physician practitioner." This term is frequently used to describe nurse practitioners, clinical nurse specialists, and physicians' assistants.

Response: This regulation uses the term "non-physician practitioner" in describing categories of providers assigned to a level of screening. *See* § 424.518(a)(1)(i).

Comment: A commenter recommended that, to the extent allowed under law, CMS disclose limited information about the risk model so as to avoid reverse-engineering by individuals intent on defrauding the Medicare program.

Response: We appreciate this comment, but believe it is important that the provider and supplier communities be made aware of what will be required as part of the enrollment process.

Comment: A commenter recommended that reimbursement be provided for the cost of the background check and fingerprint card. With budget cuts and regulatory mandates, providers are struggling to meet the increasing costs of delivering health care services in an environment with decreasing resources. Another commenter suggested, however, that fingerprinting be done at the cost of the provider prior to the Medicare contractor receiving the enrollment application.

Response: A fingerprint-based criminal history record check is part of the Medicare enrollment screening process for specified applicants. The cost of the having the fingerprints taken and supplying the fingerprints to the authorized channeler, whether electronic or on the card, will be borne by the provider or supplier. There will be no cost to the provider or supplier for the subsequent processing of the prints or the background check, as CMS will pay for the processing of the prints and the criminal history record check.

Comment: A commenter recommended that providers be able to have their fingerprints electronically scanned with a vendor contracting with the Federal government.

Response: Shortly after the publication of this final rule with comment period, we will be issuing guidance to the provider and supplier communities regarding the processes for obtaining fingerprints. We anticipate that CMS will contract with an FBI-approved authorized channeler for the collection and transmission of fingerprints. It is our understanding that such authorized channelers use electronic technology to collect and process fingerprints. We will provide more information regarding available technologies and vendors prior to the implementation of this requirement, as announced 60 days prior to the effective date through the publication of subregulatory guidance.

Comment: A commenter stated that CMS needs to ensure that information used in the classification of suppliers is correct and appropriate. Thus, CMS should require that only final agency actions be used as a basis for assigning suppliers. Decisions overturned on appeal should have no bearing or effect on the supplier's screening level.

Response: We do not believe it is appropriate to wait until a particular action is final before shifting a provider into a different screening level. The appeals process can take an extended period, during which a provider intent on defrauding the Medicare program could have more time to do so if permitted to remain in a lower screening level. As already mentioned, should a particular action be rescinded, the provider will be restored to its previous screening level.

Comment: A commenter stated that pharmacies licensed by the State—whether newly enrolling or as part of an additional location—should be specified as limited risk providers.

Response: As we mentioned earlier, State licensure is not automatically indicative of the screening level that should be ascribed to a category of provider or supplier.

Comment: A commenter questioned whether hospice organizations are correctly included within the moderate screening level and should instead be included in the limited screening level. The commenter did not believe that sufficient data exists to justify placing

hospices in the moderate screening level.

Response: For the reasons we explained, we believe that hospices are most appropriately as assigned to the moderate screening level.

Comment: A commenter stated that if an enrollment moratorium were placed on a particular geographic area and then lifted, the Medicare contractor would be required to conduct background checks and fingerprints on all physicians in that area. The commenter urged CMS to reconsider the burdens and costs of doing so for large groups of providers. The delays in processing these applications would deter physicians from enrolling and revalidating their enrollments. The commenter also stated that CMS should limit those physicians placed in the highest level of screening to individuals previously found guilty of crimes against Medicare or where there is publicly available evidence to justify such intrusions.

Response: The situation described in the commenter's first sentence would only apply in the unlikely event that physicians in that area were subject to a moratorium. As stated earlier, CMS does not believe that the collection of the fingerprints for the FBI fingerprint-based criminal history record check will substantially impact the time to process an enrollment application by the relevant Medicare contractor. If, as will most likely be the case with any temporary enrollment moratorium, the moratorium only applies to non-physician provider or supplier types, physicians would not be affected by the lifting of the moratorium. We believe we have clarified this point in the final rule with comment period.

Comment: Regarding fingerprinting and background checks, a commenter requested clarification regarding: (1) How the information will be stored and whether it will be destroyed after a period of time; (2) how the information will be used; (3) what constitutes background information that rises to the level of a threat to Medicare; (4) whether the physician or non-physician practitioner be afforded a copy of the results; (5) the policies that will ensure that the information is protected and secure and, in the event of a security lapse, whether the practitioner will be notified; (6) who will be conducting the background checks; (7) whether the information will be added to State or Federal databases for other purposes; and (8) whether practitioners will know prior to or at the time of application submission that they will be subject to these additional requirements.

Response: We have clarified in this final rule with comment period that the fingerprint requirement will be used in the context of obtaining FBI criminal history record information. This information will be stored according to all Federal requirements as well as the FBI's Security and Management Control Outsourcing Standard for Channelers and Non-Channelers and the CJIS Security Policy. CMS will rely on existing authority to deny and revoke enrollment at § 424.530(a) and § 424.535(a) if an individual who maintains a 5 percent or greater direct or indirect ownership interest in a provider or supplier has certain prior felony convictions, or if an enrollment application contains false or misleading information. The FBI will send the results of the criminal history record check only to the authorized channeler, who will be permitted to send the results only to the authorized recipient, or an FBI approved outsourced third party. In the event of loss of the criminal history record reports, CMS will follow the established protocol for communicating with the public and individuals regarding the loss of personally identifiable information. The criminal history record information is compiled when the FBI receives the fingerprint and links it to an existing record(s) of arrest and prosecution in State and FBI databases. Individuals or entities do not conduct criminal background checks. CMS, through an authorized channeler, will be accessing existing law enforcement data on fingerprinted individuals as required by this final rule with comment period. CMS will inform all relevant individuals of their requirement to submit fingerprints for the purposes of an FBI criminal history check as a condition of enrollment. While we are finalizing this screening method, we do not plan to implement this provision upon the effective date. Instead, we will be issuing additional guidance to providers, suppliers, the general public, and our contractors after the publication of this final rule with comment period to explain the operational aspects of the fingerprint-based criminal history record check requirement. As stated previously, we will delay implementation until 60 days after the publication of subregulatory guidance.

Comment: A commenter asked who will pay the fee for the fingerprinting and, if the physician or practitioner must pay it, whether he or she will be reimbursed, given the restrictions on application fees for certain non-institutional providers.

Response: The relevant individuals who are required to undergo the criminal history record check will incur the cost of having their fingerprints taken. Providers and suppliers will not be reimbursed by Medicare, Medicaid or CHIP for the fingerprint collection costs. CMS will bear the cost of processing the fingerprint-based criminal history record check for providers and suppliers that enroll in Medicare. For Medicaid-only and CHIP-only providers, the States and Federal government will share these costs.

Comment: A commenter stated that fingerprinting is generally limited to certain hours of the day. Due to the demands of physicians' schedules, the commenter asked how CMS will ensure the availability of fingerprinting for those physicians placed in the high screening level.

Response: Physicians who are enrolled in Medicare as practicing physicians will generally not be subject to fingerprinting. Fingerprint-based criminal history record checks will only be required in the case of providers or suppliers that are assigned to the high screening level. Physicians are generally assigned to the limited screening level.

Comment: A commenter urged CMS to ensure that fingerprinting and background checks do not delay the enrollment of legitimate and honest physicians.

Response: Physicians are generally assigned to the limited screening level and, as such, will not be subject to fingerprinting based on their enrollment as a physician. Physicians who choose to enroll as DMEPOS suppliers or HHAs will be required to undergo a fingerprint-based criminal history record check as a requirement of the high screening level but, as stated previously, CMS does not believe this requirement will significantly delay the enrollment of any provider or supplier.

Comment: A commenter stated that hospital-owned HHAs and hospices should be designated as limited risk and, therefore, should not be subject to unannounced and unscheduled pre-enrollment and/or post-enrollment onsite visits.

Response: For the reasons already discussed, newly enrolling HHAs will be placed in the high screening level, regardless of ownership.

Comment: Several commenters stated that implementing the new screening procedures by March 23, 2011 is not feasible due to the coordination efforts required between Medicare and Medicaid. They recommended that the implementation date be moved to March 23, 2012.

Response: We disagree, and believe that all screening procedures except the fingerprint-based criminal history record check required for those in the high level of screening will be in place

beginning on March 25, 2011. As noted previously, we will delay implementation of such high screening level until 60 days after the publication of subregulatory guidance on how this provision will be implemented. Further, we believe the statute requires the implementation dates that we have specified.

Comment: A commenter recommended that CMS reconsider the risks associated with allowing existing enrollees to be exempted from the new screening procedures until March 23, 2012. The commenter believes this creates a potential gap in program integrity.

Response: The ACA specifies the effective dates for the new screening provisions. For newly enrolling providers and suppliers, and for those currently enrolled whose revalidation is scheduled between March 25, 2011 and March 23, 2012, the effective date is March 23, 2011 or the date scheduled for the revalidation. For providers and suppliers assigned to the high screening level, the fingerprint-based criminal history record check requirement will be implemented through subregulatory guidance and will be effective 60 days following the publication of the guidance. All other screening requirements are effective on March 25, 2011 for those in the high screening level. For all other currently enrolled providers and suppliers, the statute established an effective date of March 23, 2012.

Comment: A commenter recommended simplifying the screening process such that all enrolling providers and suppliers are put into the moderate level, and then adjust screening interventions based on specific circumstances related to elevated risk of fraud.

Response: We decline to base the assignment of provider and supplier types to a level of screening on the assumption that every provider or supplier is of equal risk upon enrollment into the Medicare. We see clear differences in risk among categories of providers and suppliers. Therefore, we do not plan to assign all provider and supplier categories to the same screening level. In response to the suggestion that we adjust screening interventions based on specific circumstances, we believe this process is both unwieldy and burdensome to implement for every provider as the baseline screening methods. Although we have identified certain events that will cause a provider to move from "limited" or "moderate" to "high" screening, we do not believe we should conduct individual assessments. As stated previously, CMS will assess an individual provider's risk and potential actions based on the individual provider's enrollment application and may continue to use existing program integrity tools that are not addressed by this rule. We believe this approach is the most objective approach and is consistent with the ACA.

Comment: A commenter requested clarification on how States will be notified of providers' risk classifications and any changes thereto.

Response: We will disseminate guidance to the States on this topic shortly after the publication of this final rule with comment period.

Comment: A commenter recommended that CMS explain whether it is replacing or removing the current revalidation basis in § 424.535(a)(6) with the proposed new § 424.535(a)(6).

Response: We are neither replacing nor removing the current revalidation basis. We simply proposed an additional reason at § 424.535(a)(6)(i) for the revocation of Medicare billing privileges. Specifically, we proposed that billing privileges may be revoked if "An institutional provider does not submit an application fee or hardship exception request that meets the requirements set forth in § 424.514 with the Medicare revalidation application," or the hardship exception is not granted. We will renumber the subsections in § 424.535(a) accordingly.

The commenter refers to the current revalidation basis but cites to the revocation regulation. To clarify, as stated previously, the proposed rule proposed to require that a provider or supplier revalidate its enrollment at any time pursuant to § 424.515. This new authority to permit off-cycle revalidations does not replace the current cycle for revalidation (3 years for DMEPOS and 5 years for all other providers).

Comment: To reduce the paperwork burden imposed on providers and suppliers and to reduce the administrative expense associated with processing a revalidation application, several commenters recommend that CMS allow providers and suppliers in good standing to submit an annual attestation, rather than a full revalidation application. The attestation, in other words, would be used in lieu of revalidation, and would require the provider or supplier to notify CMS of any changes or to attest that there were no changes within the prior year. This approach would promote compliance without requiring the provider or supplier to submit a full revalidation application and a fee.

Response: The burden associated with submitting Medicare enrollment applications A, B, I, R and CMS–855S is currently approved under Office of Management and Budget (OMB) control numbers 0938–0685 and 0938–1057, respectively. Such an attestation, as proposed by the commenter, would not fulfill the screening requirements of this final rule with comment period, as re-screening is a condition of revalidation. The screening requirement and associated application fee are required by the ACA to minimize the risk of fraud, waste and abuse to the Medicare, Medicaid programs and CHIP, and cannot be circumvented by a process that would limit the scope of such screenings.

Comment: One commenter stated that CMS did not furnish sufficient justification or rationale for its proposal in § 424.515 that CMS may require a provider or supplier to revalidate its enrollment at any time. The commenter added that the proposed revision seems punitive and overly broad because CMS does not furnish ample discussion for the public to fully evaluate the proposal. The commenter recommended that CMS remove its proposal because CMS did not: (1) Justify its reasons for establishing this new authority, (2) describe its existing authorities and how this proposal is different, and (3) explain or justify the number of times that CMS can require revalidation within a given period of time.

Response: We proposed at § 424.515 that we have the ability to require that a provider or supplier revalidate its enrollment at any time, and stated that this proposal was designed to help ensure that the statutory effective date of March 23, 2013 is met. We fully intend to implement the new authorities provided by the ACA by the deadlines that have been set out by the Congress.

We stated in the proposed rule that DMEPOS suppliers are required to re-enroll every 3 years, and other providers and suppliers are required to revalidate their enrollment every 5 years. For purposes of clarity, we also proposed language at § 424.57(e) that changes all references to "re-enroll" or "re-enrollment" to "revalidate" or "revalidation." We have existing authority at § 424.515(d) to require off-cycle validations in addition to the regular 5 year revalidations and may request that a provider or supplier recertify the accuracy of the enrollment information when warranted to assess and confirm the validity of the enrollment information maintained by us. Such off-cycle revalidations may be triggered as a result of random checks, information indicating local health care

fraud problems, national initiatives, complaints, or other reasons that cause us to question the compliance of the provider or supplier with Medicare enrollment requirements. Off cycle revalidations may be accompanied by site visits. The new authority to conduct off-cycle validations of providers and suppliers will enable us to apply the new screening requirements to all currently enrolled providers and suppliers by the statutory effective date.

The proposed rule stated that once a provider has been subject to an off-cycle validation under § 424.515(e), the current cycle for revalidation would apply. This means that if a provider subject to the 5-year revalidation cycle had to revalidate in 2013, the provider or supplier would next have to revalidate in 2018. However, a provider or supplier may be required to revalidate under § 424.515(d) during that time period if there are indicators of the noncompliance for a particular provider.

Comment: A commenter stated that CMS currently requires contractors to review State licensing board data on a monthly basis. As such, it would be more efficient to access a centralized, federated database to provide CMS with the most comprehensive data on physician licensure status.

Response: As previously mentioned, we are currently in the process of re-assessing the provider enrollment process and systems that are used to support screening and enrollment. We are exploring a number of options to take advantage of technological advances to improve the provider screening process. Increased automation of the process is one of the areas on which we are focusing.

Comment: A commenter stated that, given the ongoing Medicare backlogs, CMS should provide information regarding: (1) The number of revalidations started and completed by CMS or its contractors in 2007, 2008, 2009, and 2010, (2) how an estimated 93,000 revalidations per year beginning in 2010 will impact the processing of new applications by providers and suppliers, and (3) the amount of money obligated on provider screening activities for each fiscal year between 2005 and 2010, and (4) how much money CMS expects to obligate for these activities in 2011. Another commenter recommended that CMS furnish the number of revalidation applications processed by the National Supplier Clearinghouse, MACs, carriers, and fiscal intermediaries for each of the last 5 years.

Response: This final rule with comment period specifically increases the number of providers and suppliers that will be revalidated through the use of off-cycle revalidations, for the explicit purpose of applying the new screening requirements to currently enrolled providers. Therefore, the number of revalidations processed in the past 4 or 5 years and the money obligated to that process is irrelevant to the evaluation of our ability to process additional revalidations as required by this final rule with comment period. Additionally, we have undertaken steps to streamline the enrollment process, both for newly enrolling and revalidating providers and suppliers. We recognize that there have been challenges in implementing the new authorities to safeguard the integrity of Medicare, Medicaid and CHIP, and have demonstrated a willingness to work with providers and suppliers to reduce unnecessary burdens and risks that may have accompanied the enrollment processes in the past. We have communicated with providers via Medicare Learning Networks and provider Open Door Forums, and will continue to do so throughout the implementation of the ACA.

We believe that additional resources will be available to enable the processing of the increased numbers of enrollment applications. We have actively taken steps to reduce processing times as much as feasible. Furthermore, we have undertaken many activities to streamline the enrollment process to reduce the burden upon providers and suppliers.

Comment: A commenter recommended that CMS employ an expanded data-driven screening process by using open-source data during the enrollment and re-enrollment business processes. Such data could include the current operational status of the firm; chain of ownership or corporate family linkages; identification of tax liens; presence of open bankruptcies; and records of government enforcement actions. The commenter also suggested that each provider and supplier be registered for post-enrollment data monitoring, which "pushes" one or more high risk updates (for example, bankruptcy filing; a criminal filing involving a provider executive; or sudden increase in the risk of financial failure) to CMS automatically. CMS could use such high risk alerts for the selection and prioritization of unscheduled and unannounced site visits. Finally, the commenter recommended additional database checks that would vary by screening level. These included, but were not limited to, verifying: (1) Corporate chain of ownership, (2) tax liens, (3) non-HHS government enforcement actions, (4) extent of any government contracting, and (5) any open lawsuits.

Response: As stated previously, we are continually exploring additional improvements to our data systems. We are committed to working with both private and public partners to continue to evaluate technologies that can provide the scalability and safeguards to beneficiary access that we need to ensure accurate payments to legitimate providers for appropriate services.

Comment: A commenter urged CMS to release a proposal for comment that provides additional detail regarding what CMS believes should constitute background information relevant to Medicare provider enrollment that would prevent a practitioner from enrolling in the Medicare program.

Response: At some point it may be necessary to modify our existing regulations that address felonies that are relevant to enrollment of billing privileges. However, we have not yet proposed expansion of our existing authorities codified in the Code of Federal Regulations. The requirements for Medicare enrollment are established in other regulations and manual instructions, and are not—unless otherwise stated herein—being modified in this final rule with comment. The criminal background check is intended to verify certain information provided on the Medicare enrollment application. Under our existing regulatory authority, we could impose a denial of enrollment or a revocation of billing privileges based upon the results of the background check in certain instances. Illustratively, if, through the background check, CMS learned of a felony conviction that met the criteria at § 424.530(a)(3) or § 424.535(a)(3), billing privileges could be denied or revoked, respectively.

Comment: One commenter stated that in its FY 2011 performance budget, we say that we will create a limited number of MACs to carry out provider enrollment, and that each contractor would enroll providers for designated regions of the country. Given the publication of the proposed rule, the commenter recommended that we explain how reducing the number of MACs and increasing the workload will help providers and suppliers and reduce Medicare fraud, waste, and abuse in the Medicare program. The commenter also requested that CMS furnish an update on this consolidation effort. Another commenter asked CMS to explain how it will consolidate provider enrollment activities, conduct 93,000 revalidations, and handle initial applications without disrupting the provider enrollment

process and creating additional backlogs and processing delays for providers of service and suppliers.

Response: We recognize that provider enrollment is a large and complicated task that requires not only internal consistency but also understanding and ease of interaction with the provider and supplier community. As a result, we are currently engaged in a thorough assessment of the provider enrollment process and in making improvements as needed to eliminate delays in enrollment and improve overall system performance. As part of this process, we are working toward consolidation of the number of enrollment contractors as a means to achieve economy of scale and greater consistency in the enrollment process. In developing the provisions of this final rule with comment period and other regulatory and subregulatory policies, we are mindful of the overall re-assessment of the provider enrollment process and supporting systems.

Comment: A commenter urged CMS to refine its provider enrollment specialty categories to accurately reflect the existing varieties of practitioners—particularly the categories for dentistry and the dental specialties—in order to reduce the likelihood that practitioners such as dentists will be inappropriately categorized and subject to unwarranted higher levels of screening.

Response: We do not believe it is necessary to further refine the provider enrollment specialty. Dentists should submit the CMS–855I if they intend to submit claims directly to Medicare. Further, dentists would be in the limited screening level.

Comment: A commenter stated that the proposed rule does little to prevent: (1) Identity theft; (2) health care fraud; (3) money laundering; and (4) bank fraud. The commenter believes that the screening levels were too broad and simplistic. To prevent fraud and abuse, the commenter recommended that CMS: (1) Implement section 6401(a)(3) of the ACA immediately; (2) consider and adopt distinct screening criteria and program requirements for non-physician owners of medical clinics and that these providers be placed into a high screening level, and (3) use the statutory authority in section 6401(a)(3) of the ACA to make sure that the claims being submitted are valid.

Response: We believe the commenter is referring to new section 1866(j)(3) of the Act, which addresses a provisional period of enhanced oversight for new providers of services or suppliers. We will implement all authorities granted under the ACA using the proper procedures. We disagree with the commenter that the proposed rule and this final rule with comment period will do little to prevent health care fraud, and believe that issues of money laundering and bank fraud are beyond the scope of this final rule with comment period. We strongly believe that additional site visits, both announced and unannounced, will help to identify fraudulent providers and suppliers before they are permitted to enroll in Medicare, Medicaid or CHIP. The temporary moratoria and payment suspension provisions give us the ability to act as soon as a problem is detected, preventing money from being paid while balancing the rights and needs of providers, suppliers, and beneficiaries.

Comment: One commenter stated that CMS's proposed ability to reenroll DMEPOS suppliers more frequently than every three years could be burdensome for CMS and the DMEPOS supplier, and suggested that CMS revalidate every 3 years from the most recent revalidation, rather than every 3 years from the date billing privileges were granted.

Response: As stated previously, the proposed rule and this final rule with comment period permit us to require revalidation of DMEPOS suppliers on or after March 23, 2012 to meet the statutory effective date for the screening requirements; after that, DMEPOS suppliers would then be subject to revalidation every 3 years. DMEPOS could be subject to off-cycle revalidation under existing authority at § 424.515(d) when CMS has reason to question the compliance of the provider or supplier with Medicare enrollment requirements.

Comment: One commenter stated that identity theft is a huge problem in the United States and that Medicare, Medicaid and CHIP should do everything possible to protect physicians' identities. The commenter recommended that CMS provide data on the number of physicians and non-physician practitioners who have practice locations in multiple States—including States with connecting State boundaries and States without connecting State boundaries. The commenter also suggested that CMS explain what efforts, if any, are used to verify a physician that is establishing a practice location in multiple States and that the individual's identity is authenticated. Another commenter stated that it is unclear how fingerprinting and background checks will achieve the goal of preventing identity theft for physicians.

Response: We agree with the comment that Medicare, Medicaid and CHIP should use all available authorities to protect physicians' identities. However, as we have noted previously, we will not use this screening regulation to identify instances of identity theft. We disagree that the publication of the number of physicians and non-physician practitioners who have practice locations in multiple States will address the issue of identity theft. We also have a process in place to verify a physician is legitimately establishing practice locations in multiple States, and have found there are multiple legitimate reasons why this may be the case.

We believe that criminal history record checks will enable us to verify information that has been submitted on an enrollment application is accurate and complete. As stated previously, using fingerprints to perform such a record check is the only accepted method by the FBI for non-criminal justice purposes, as it is believed to be the most accurate link between an individual and their criminal history record.

Comment: A commenter stated that in the proposed rule, CMS does not justify or explain the rationale for many of its positions, such as: (1) Placing providers and suppliers into various screening categories, and (2) its rationale for creating a new revalidation reason (*see* § 424.515(e)). The commenter recommended that CMS not finalize this proposed rule, but rather publish a new proposed rule using the information from this rule.

Response: We disagree that the proposed rule did not explain our rationale for our approaches. As mentioned earlier, we relied on our extensive experience to identify categories of providers with a higher incidence of fraud, waste and abuse. In addition, we used the expertise of our contractors charged with identifying and investigating instances of fraudulent billing practices in making our decisions regarding the appropriate risk classification of various providers. In some instances, we also relied on the data analysis and expertise of the OIG, GAO, and other sources to develop a process designed to increase scrutiny for specific categories of providers and suppliers that represent a higher risk to the Medicare program. Furthermore, we stated the new reason for off-cycle validation is to enable us to apply the new screening requirements to all applicable providers and suppliers by the statutory effective date of March 23, 2013.

Comment: In response to a request for comments, a commenter stated that harmonization between Medicare, Medicaid, and MA would be beneficial

only to the extent that the programs have enrollment and re-validation reciprocity and that adequate resources and time were allocated to ensure that harmonization does not wreak havoc among state Medicaid programs and MA plans. Reciprocity would ensure that physicians are not subject numerous times to the same or similar onerous requirements; this would also represent significant savings for Federal health care programs.

Response: We agree that harmonization between program requirements will be beneficial for State Medicaid agencies, providers, and CMS. This final rule with comment period implements several changes that minimize the burden on States and providers, including the reciprocity of Medicare screening for dually enrolled providers and State responsibility to screen only Medicaid and CHIP-only providers.

Comment: A commenter requested special consideration and/or exemptions for States with comprehensive licensure statutes for orthotists and prosthetists.

Response: We do not agree that licensed orthotists and prosthetists should receive special consideration or exemptions as compared to orthotists and prosthetists that happen to be located in a State without what could be deemed 'non-comprehensive' licensure statutes. CMS did not make a distinction based on licensure requirements for any other category of provider.

Comment: A commenter opposed the proposed language at § 424.515(e) allowing CMS to require additional off-cycle revalidations, stating it could allow CMS to initiate revalidations frequently and on a whim. At a minimum, off-cycle revalidations should be exempt from the $500 application fee.

Response: We disagree with this comment. Section 424.515(e) was added for a specific purpose and we could not require a provider or supplier to revalidate off-cycle pursuant to § 424.515(e) more than once. The application fee was included in the statute to cover exactly the type of screenings that will be performed during the revalidations, and we do not believe it is appropriate or necessary to exempt the revalidations from the fee.

Comment: A commenter suggested that CMS tie an enrollment ban to those who are trying to enroll in the Medicare program and not just for those who are already enrolled. That way, fraudulent providers would never be allowed to enter the program.

Response: We believe the commenter is referring to an enrollment bar for providers and suppliers whose applications are denied, similar to that which is currently in place for providers and suppliers whose Medicare billing privileges are revoked. We appreciate this suggestion. We are currently not in a position to adopt it, as additional research is needed to determine its potential effectiveness and the various circumstances under which it might apply. That said, we may consider it as part of a future rulemaking effort.

c. Final Screening Provision—Medicare

This final rule with comment period finalizes the provisions of proposed rule in regards to the Medicare screening requirements with the following modifications:

- In § 424.518(a)(1), we are adding Competitive Acquisition Program/Part B Vendors to the limited risk screening level.
- In § 424.518(a)(1), we are adding pharmacies that are newly enrolling or revalidating via the CMS–855B to the "limited" level of screening.
- In § 424.518(a)(1), in response to comments, we have changed the description for Indian health service providers to state, "health programs operated by an Indian Health Program (as defined in section 4(12) of the Indian Health Care Improvement Act) or an urban Indian organization (as defined in section 4(29) of the Indian Health Care Improvement Act) that receives funding from the Indian Health Service pursuant to Title V of the Indian Health Care Improvement Act, hereinafter (IHS facilities)."
- In 424.518(a)(2), we are clarifying that occupational therapy and speech pathology providers are assigned to the limited screening level.
- In 424.518(a)(1), we are removing physical therapists and physical therapist groups from the category of non-physician practitioners that are within the limited screening level.
- In 424.518(a)(1), we are removing non-public, non-government owned or affiliated ambulance suppliers from the limited screening level.
- In § 424.518(a)(2), we are adding portable x-ray suppliers to the moderate screening level.
- In 424.518(a)(2), we are adding physical therapists and physical therapist groups to the moderate screening level.
- In 424.518(a)(2), we are assigning all ambulance suppliers to the moderate screening level, regardless of whether they are public or government affiliated.
- In § 424.518(a)(1), we are adding pharmacies that are newly enrolling or revalidating via the CMS–855B to the limited screening level.
- In § 424.518, we also eliminated the distinction between: (1) Publicly traded and non-publicly traded, and (2) publicly owned and non-publicly owned as criteria for assignment of any provider type to a level of screening.
- In § 424.518(c)(2)(ii)(A), we have removed the requirement that fingerprints must be submitted using the FD–258 fingerprint card. Also, the fingerprints must be collected from all individuals who maintain a 5 percent or greater direct or indirect ownership interest in the provider or supplier.
- In § 424.518(c)(2)(ii)(B), we have replaced "conducts a criminal background check" with "Conducts a fingerprint-based criminal history report check of the Federal Bureau of Investigations Integrated Automated Fingerprint Identification System on all individuals who maintain a 5 percent or greater direct or indirect ownership interest in the provider or supplier."
- In § 424.518(d), we have identified owners with a 5 percent or greater direct or indirect ownership as responsible for providing fingerprints, and the methodology of how to submit the fingerprints.
- § 424.518(c)(3), we have added "final adverse action" as a basis for reassigning a provider or supplier to the high screening level at § 424.518(c)(3)(iii)(B).
- In § 424.518(c)(3), we have added six months as the length of time a provider or supplier category will be assigned to the high screening level following the lifting of a temporary enrollment moratorium.
- Finally, in § 424.518(c)(3), we have removed denial of Medicare billing privileges in the previous ten years as a basis for reassigning a provider or supplier to the high screening level at § 424.518(c)(3)(iii)(B).

As we have stressed throughout this preamble, we will monitor these new procedures and their effectiveness and may reconsider or modify our approach in the future as we gain experience with these procedures. We further reiterate that nothing in this rule is intended to abridge our established screening authority under existing statutes and regulations, or to diminish the screening that providers and suppliers currently undergo. The provisions specified in this final rule with comment period are intended to enhance—not replace—our existing authority. The screening laid out here reflects the minimum requirements. For example, a contractor may undertake database checks in addition to the ones listed below as deemed appropriate. Nothing in this rule should be interpreted as limiting the amount of scrutiny CMS or its

contractors may give to an applicant. Tables 5 through 8 below outline the levels of screening by category that we are finalizing.

TABLE 5—FINAL LEVEL OF REQUIRED SCREENING FOR MEDICARE PHYSICIANS, NON-PHYSICIAN PRACTITIONERS, PROVIDERS, AND SUPPLIERS

Type of screening required	Limited	Moderate	High
Verification of any provider/supplier-specific requirements established by Medicare	X	X	X
Conduct license verifications, (may include licensure checks across States)	X	X	X
Database Checks (to verify Social Security Number (SSN); the National Provider Identifier (NPI); the National Practitioner Data Bank (NPDB) licensure; an OIG exclusion; taxpayer identification number; death of individual practitioner, owner, authorized official, delegated official, or supervising physician	X	X	X
Unscheduled or Unannounced Site Visits		X	X
Fingerprint-Based Criminal History Record Check of law enforcement repositories			X

TABLE 6—FINAL MEDICARE PROVIDERS AND SUPPLIERS CATEGORIES DESIGNATED TO THE "LIMITED" LEVEL FOR SCREENING PURPOSES

Provider/supplier category
Physician or non-physician practitioners and medical groups or clinics, with the exception of physical therapists and physical therapist groups.
Ambulatory surgical centers, competitive acquisition program/Part B vendors, end-stage renal disease facilities, Federally qualified health centers, histocompatibility laboratories, hospitals, including critical access hospitals, Indian Health Service facilities, mammography screening centers, mass immunization roster billers, organ procurement organizations, pharmacies newly enrolling or revalidating via the CMS-855B, radiation therapy centers, religious non-medical health care institutions, rural health clinics, and skilled nursing facilities.

TABLE 7—FINAL MEDICARE PROVIDERS AND SUPPLIERS CATEGORIES DESIGNATED TO THE "MODERATE" LEVEL FOR SCREENING PURPOSES

Provider/supplier category
Ambulance suppliers, community mental health centers; comprehensive outpatient rehabilitation facilities; hospice organizations; independent diagnostic testing facilities; independent clinical laboratories; physical therapy including physical therapy groups and portable x-ray suppliers.
Currently enrolled (revalidating) home health agencies.

TABLE 8—FINAL MEDICARE PROVIDERS AND SUPPLIERS CATEGORIES DESIGNATED TO THE "HIGH" LEVEL FOR SCREENING PURPOSES

Provider/supplier category
Prospective (newly enrolling) home health agencies and prospective (newly enrolling) suppliers of DMEPOS.

4. General Screening of Providers—Medicaid and CHIP—Proposed Provisions and Analysis of and Responses to Public Comments

Section 1902(kk)(1) of the Act requires that States comply with the process for screening providers established by the Secretary under section 1866(j)(2) of the Act.[4] Section 2107(e)(1) of the Act provides that all provisions that apply to Medicaid under sections 1902(a)(77) of the Act,[5] the State plan mandate for compliance with provider and supplier screening, oversight, and reporting requirements in accordance with 1902(kk), and 1902(kk) of the Act, the specific State plan requirements regarding provider and supplier screening, oversight, and reporting, shall apply to CHIP. We proposed in new § 457.990 that all the provider screening, provider application, and moratorium regulations that apply to Medicaid providers will apply to providers that participate in CHIP. In addition, in this final rule with comment period, we refer to State Medicaid agencies as responsible for screening Medicaid-only providers. In some States, CHIP is not administered by the Medicaid agency. Throughout this final rule with comment period, with respect to those instances, "State Medicaid agency" should be read to encompass "Children's Health Insurance Program agency" where the two are separate entities.

Because it would be inefficient and costly to require States to conduct the same screening activities that Medicare contractors perform for dually-enrolled providers, we proposed that a State may rely on the results of the screening conducted by a Medicare contractor to meet the provider screening requirements under Medicaid and CHIP. Similarly, we proposed in § 455.410 that State Medicaid agencies may rely on the results of the provider screening performed by the State Medicaid programs and CHIP of other States. For Medicaid-only providers or CHIP-only providers, we proposed that States follow the same screening procedures that CMS or its contractors follow with respect to Medicare providers and suppliers.

As previously noted, section 1902(kk)(1) of the Act requires that State screening methods follow those performed under the Medicare program. For the sake of brevity, we will not restate those methods verbatim. We proposed that States follow the rationale that we have set forth for Medicare in section II.A.3. of this final rule with comment period, and that we use as the basis for § 455.450. For the types of providers that are recognized as a provider or supplier under the Medicare program, States will use the same screening level that is assigned to that category of provider by Medicare. For those Medicaid and CHIP provider types that are not recognized by Medicare, States will assess the risk posed by a particular provider or provider type. States should examine their programs to identify specific providers or provider types that may present increased risks of fraud, waste or abuse to their Medicaid programs or CHIP. States are uniquely qualified to understand issues involved with balancing beneficiaries' access to medical assistance and ensuring the fiscal integrity of the Medicaid programs and CHIP. However, where applicable, we expect that States will assess the risk of fraud, waste, and abuse using similar criteria to those used in Medicare. For example, physicians and non-physician practitioners, medical groups and clinics that are State-licensed or State-regulated would generally be categorized as limited risk. Those provider types that are generally highly

[4] As noted previously, we believe that the reference to section 1886(j)(2) of the Act in section 6401(b)(1) of the ACA is a scrivener's error, and that the Congress intended to refer instead to section 1866(j)(2) of the Act.

[5] Section 1902(a)(77) is only broadly referenced in the final regulations under section § 455.400, as a statutory section being implemented by the regulation.

dependent on Medicare, Medicaid and CHIP to pay salaries and other operating expenses and which are not subject to additional government or professional oversight would be considered moderate risk, and those provider types identified by the State as being especially vulnerable to improper payments would be considered high risk. States will then screen the provider using the screening tools applicable to that risk assigned. However, we did not propose to limit or otherwise preclude the ability of States to engage in provider screening activities beyond those required under section 1866(j)(2) of the Act, including, but not limited to, assigning a particular provider type to a higher screening level than the level assigned by Medicare.

As with the proposed screening provisions for Medicare, we solicited comments on the applicability of these proposals for Medicaid as well. We solicited comment on the proposed assignment of specific provider types to established risk categories, including whether such assignments should be released publicly, whether they should be reconsidered and updated according to an established schedule, and what criteria should be considered in making such assignments.

Based on the level of screening assigned to a provider or provider type, we proposed that States conduct the following screenings:

TABLE 9—PROPOSED LEVEL OF RISK AND REQUIRED SCREENING FOR MEDICAID AND CHIP PROVIDERS

Type of screening required	Limited	Moderate	High
Verification of any provider/supplier-specific requirements established by Medicaid/CHIP	X	X	X
Conduct license verifications (may include licensure checks across State lines)	X	X	X
Database Checks (to verify SSN and NPI, the NPDB, licensure, a HHS OIG exclusion, taxpayer identification, tax delinquency, death of individual practitioner, and persons with an ownership or control interest or who are agents or managing employees of the provider)	X	X	X
Unscheduled or Unannounced Site Visits		X	X
Criminal Background Check			X
Fingerprinting			X

Not all States routinely require persons with an ownership or control interest or who are agents or managing employees of the provider to submit SSNs or dates of birth (DOBs). Without such critical personal identifiers, it is difficult to be certain of the identity of persons with an ownership or control interest or who are agents or managing employees of the provider, and it may be difficult for States to conduct the screening proposed under this rule. Accordingly, and to be consistent with Medicare requirements, pursuant to our general rulemaking authority under section 1102 of the Act, we proposed in § 455.104 to require that States will require submission of SSNs and DOBs for all persons with an ownership or control interest in a provider. In addition to the amendment to § 455.104, we proposed to revise that section for the sake of clarity both for the disclosing entities' provision and the States' collection of the disclosures. We recognize that there may be privacy concerns raised by the submission of this personally identifiable information as well as concerns about how the States will assure individual privacy as appropriate; however, we believe this personally identifiable information is necessary for States to adequately conduct the provider screening activities under this final rule with comment period. We solicited comment specifically on this issue.

Although the level of screening may vary depending on the risk of fraud, waste or abuse the provider represents to the Medicaid program or CHIP, under section 1866(j)(2)(B)(i) of the Act, all providers would be subject to licensure checks. Therefore, we proposed that States be required to verify the status of a provider's license by the State of issuance and whether there are any current limitations on that license.

As stated previously, pursuant to section 2107(e)(1) of the Act, all provisions that apply to Medicaid under sections 1902(a)(77) and 1902(kk) of the Act apply to CHIP. Because we proposed a new regulation in Part 457 under which all provider screening requirements that apply to Medicaid providers would apply to providers that participate in CHIP, these requirements for provider screening and assigning of categories of risk of fraud, waste, or abuse, as well as verification of licensure, under § 455.412 and § 455.450 will apply in CHIP.

Comment: Commenters expressed concerns about new and existing disclosure requirements under § 455.104, including our proposal to add to the disclosure requirements collection of SSNs and DOBs of persons with an ownership or control interest in the disclosing entity. Some States support the proposal, already having instituted the disclosure requirement in their enrollment application procedures. Other States support the proposal but request additional time for implementation, including forms and system changes. Two States expressed concern about the impact the requirement might have upon beneficiary access to providers.

Response: We will not address the comments directed at the existing language of § 455.104. The regulation was rearranged for ease of application by States and disclosing entities, but with the exception of the addition of SSNs and DOBs, as well as changes suggested by a few commenters regarding corporate entity addresses and familial relationships, the language is substantially unchanged from the language currently in effect. We acknowledge the commenters' concerns about collection of SSNs and DOBs, however, collection of SSNs and DOBs is necessary to complete the screening process and be certain of the identity of the party being screened. We recognize that the addition of SSNs and DOBs and other improvements in disclosure collection will require systems and forms changes and States will need time for implementation. We encourage States to contact us about their specific timeframes. Furthermore, we do not believe that this requirement will have an adverse impact on beneficiary access as the majority of disclosure requirements have not changed, and our experience with the same requirement in Medicare indicates that such a requirement does not adversely impact beneficiary access.

Comment: Other commenters made recommendations on language changes that would clarify § 455.104(b)(1)(i) regarding the address of corporate entities with ownership or control of disclosing entities; § 455.104(b)(2) regarding familial relationships; and § 455.104(b)(4) regarding SSNs and DOBs of managing employees.

Response: We agree with the commenters that § 455.104(b)(1)(i) should be clarified regarding addresses

of corporate entities with ownership or control of disclosing entities and accordingly will revise § 455.104(b)(1)(i) to clarify from whom the name and address must be provided and to require the disclosing entity to supply primary business address as well as every business location and P.O. Box address, if applicable. We agree that § 455.104(b)(2) should be clarified regarding to whom the spouse, parent, child, or sibling is related, and we are revising § 455.104(b)(2) accordingly. We agree that § 455.104(b)(4) should be clarified to require managing employees to provide SSNs and DOBs, as that was the intent of the proposal, and we are revising § 455.104(b)(4) accordingly.

Comment: Several commenters expressed concern regarding collection of disclosures under § 455.104. One commenter expressed concern about the confidentiality and privacy of board member identity and the protection from disclosure to the general public. Other commenters were concerned that not-for-profit board members were volunteers and might not serve were they compelled to provide their SSNs and DOBs as a condition of the entity being enrolled.

Response: We have previously provided guidance to States that § 455.104 requires disclosures from persons with ownership and control interests in the disclosing entity, which includes officers and directors of a disclosing entity that is organized as a corporation, without regard to the for-profit or not-for-profit status of that corporation. That guidance is available at *http://www.cms.gov/FraudAbuseforProfs/Downloads/bppedisclosure.pdf*. We are sensitive to the concerns related to confidentiality of identifiable information such as SSNs. We are also concerned about issues that arise out of identity theft. We encourage States to institute appropriate safeguards to protect the information they gather as required by these rules. However, collection of disclosures including the SSNs and DOBs of persons with ownership and control interests in a disclosing entity, and of managing employees, is necessary to protect the integrity of the State Medicaid programs. Therefore, we are finalizing the proposal requiring provision of SSNs and DOBs.

Comment: One commenter sought clarification whether the disclosure requirements in § 455.104 apply to IHS providers.

Response: This rule does not make any changes about whom disclosures must be provided, but rather simply adds additional items of information that must be disclosed. The boards of IHS facilities were not previously subject to the—disclosure requirements in § 455.104, and accordingly, are not subject to the additional disclosure requirements imposed by this rule.

Comment: Commenters expressed concern about the applicability of § 455.104 to public school districts. Public schools deliver Medicaid school based health services to Medicaid eligible children and therefore are enrolled as Medicaid providers. The commenters objected to the proposed requirement in § 455.104 that the schools provide the SSNs and DOBs of persons with controlling interests of the provider, which they interpreted to include the SSNs and DOBs of school board members. The majority of the commenters stated that the public school districts were closely regulated by numerous checks and balances and there was a low likelihood that fraud would be perpetrated in schools, therefore, the collection of SSNs and DOBs from public school districts was unnecessary.

Response: As previously noted, this rule does not change about whom disclosures must be provided, but rather what information must be disclosed. Except to the extent that any public school districts may be organized as corporations, they were not previously required to make disclosures about their boards, nor are they required to under this new rule.

Comment: Several commenters expressed concern regarding the license verification requirement in § 455.412. One commenter noted that it would be administratively inefficient, costly, and unrealistic for States to verify each provider applicant's licensure status in another State. Another commenter offered that searching its database containing multi-State licensure data would be more efficient than requiring States to search State by State.

Response: Holding a valid professional license should be a prerequisite in any State prior to assignment of a Medicaid provider identification number. Medicaid beneficiaries have a right to be treated only by those providers that have been deemed by the licensing boards of their States to be eligible to treat them. As a matter of public policy, it is not unreasonable to expect that licensure status of all in-State and out-of-State providers be checked prior to enrollment, and that any limitations on their licenses be checked as well. Out-of-State provider applicants submit licensure information including status to the Medicaid agency with their application. While verification of out-of-State licensure may be challenging, all those Medicaid agencies that enroll out-of-State providers have the obligation to verify licensure status of out-of-State providers as well. We appreciate the commenter's suggestion of its database of provider information. We are aware that State licensing boards maintain publicly available information that neighboring States may access. It is within the States' discretion which databases to check.

Comment: A commenter requested clarification of whether license verification was required when the chart at 75 FR 58214 states that license verification "may include licensure checks across State lines" thereby implying that licensure checks across State lines are permissive, not mandatory.

Response: The State Medicaid agency must verify the licensure of a provider applicant in the State in which the provider applicant purports to be licensed. If an out-of-State provider submitted an application for enrollment, the State Medicaid agency would be required to verify license across State lines.

a. Database Checks—Medicaid and CHIP

States employ several database checks, including database checks with the Social Security Administration and the NPPES, to confirm the identity of an individual or to ensure that a person with an ownership or control interest is eligible to participate in the Medicaid program.

A critical element of Medicaid program integrity is the assurance that persons with an ownership or control interest or who are agents or managing employees of the provider do not receive payments when excluded or debarred from such payments. Accordingly, in § 455.436, we proposed that States be required to screen all persons disclosed under § 455.104 against the OIG's LEIE and the General Services Administration's EPLS. We proposed that States be required to conduct such screenings upon initial enrollment and monthly thereafter for as long as that provider is enrolled in the Medicaid program.

We also proposed at § 455.450, as well as § 455.436, that database checks be conducted on all providers on a pre- and post-enrollment basis to ensure that providers continue to meet the enrollment criteria for their provider type.

As previously stated, pursuant to section 2107(e)(1) of the Act, all provisions that apply to Medicaid under sections 1902(a)(77) and 1902(kk) of the Act also apply to CHIP. Because we proposed a new regulation in Part 457

under which all provider screening requirements that apply to Medicaid providers will apply to providers that participate in CHIP, this requirement for database checks under § 455.436 and § 455.450 apply in CHIP.

We received many comments on the database requirements in § 455.436 from States concerned about the administrative burden presented by searching several databases upon enrollment, and both the LEIE and the EPLS on a monthly basis by the names of both the provider and those with ownership or control interests in the provider and managing employees of the provider.

Comment: Some commenters questioned whether there were costs associated with accessing the databases. The commenters suggested that CMS establish a centralized database that States could access, including using an automated, rather than manual, search, all at no cost to States. One State suggested that the databases be accessible through automated data exchanges and that any cost to the States be waived to avoid barriers to compliance with the rule. Two other States questioned whether there were costs associated with accessing the databases that must be considered. Other commenters suggested a delay or elimination of the proposed requirement at § 455.436(c)(2) until CMS established such a centralized database.

Response: We are aware that there may be costs to the State Medicaid agency associated with checking some databases. However, § 455.436 enumerates databases that most State Medicaid agencies already check in their routine provider enrollment operations. In addition, we have previously issued guidance to State Medicaid Directors recommending searching the LEIE on a monthly basis by the names of enrolled providers and for providers, by the names of their employees and contractors. Those guidance documents are available here: *http://www.cms.gov/smdl/downloads/SMD061208.pdf* and *http://www.cms.gov/SMDL/downloads/SMD011609.pdf.* Many States have already adopted the recommendations in their enrollment policies. More recently, in September 2010, we provided guidance to program integrity directors on the availability of the LEIE and EPLS for exclusion searches. That guidance document is available here: *http://www.cms.gov/FraudAbuseforProfs/Downloads/bppedisclosure.pdf.*

Accordingly, we are finalizing § 455.436 to require State Medicaid agencies to conduct Federal database checks.

Comment: A commenter questioned whether other databases will be prescribed in the final rule with comment period or whether States will be notified of requirements in another fashion.

Response: In § 455.436(b), we proposed that the States be required to check "any such other databases as the Secretary may prescribe." We are not prescribing additional databases in the final rule with comment period. However, in response to evolving circumstances, the Secretary may issue guidance to States regarding checking specific databases.

Comment: One commenter sought clarification on which of a provider's managing employees the State Medicaid agency must search in the exclusions databases. The commenter noted that some large providers like hospitals have many managing employees that may be subject to the proposed database checks.

Response: We recognize the burden that conduct of database checks of managing employees may pose for providers with managing employees at multiple levels or locations in its organizations. Nevertheless, database checks must be conducted for all persons disclosed under § 455.104, including managing employees who could compromise or place in jeopardy a provider's compliance with Medicare, Medicaid, or CHIP requirements.

Comment: One commenter noted that State vital statistics information may be more accurate than the Social Security Administration's Death Master File. The commenter suggested allowing States to check against their own vital records systems and not require the States to check against the Social Security Administration's file.

Response: While on an anecdotal basis State records may be more accurate than the Social Security Administration's Death Master File, it is the Death Master File that is the national file of record. Therefore, we are finalizing the requirement that State Medicaid agencies check the Social Security Administration's Death Master File. However, under § 455.436(c)(1) a State may also consult other appropriate databases to confirm identity upon enrollment and reenrollment.

Comment: Another commenter noted that the Social Security Administration only allows SSN verification for W–2 purposes. The commenter recommended removing the reference to checks of "applicable" Social Security Administration databases from the database check requirement.

Response: We express no opinion as to the accuracy of the commenter's statement regarding SSN verification, but agree with the commenter that the database check requirement in this rule should be more explicit. Accordingly, we are revising § 455.436 to indicate a check of the "Social Security Administration's Death Master File" rather than "applicable databases".

Comment: A few commenters requested clarification regarding which database States must check for verification of tax identifications and tax delinquencies and how the States would use that information as a tool for screening providers.

Response: Although we believe that verifying taxpayer identification and checking for tax delinquencies may be useful indicators of fraud to a State Medicaid program, access to that information is limited and may not be feasible in the short term. Therefore, we are not finalizing those requirements as suggested by Table 5 under "Type of Screening Required".

Comment: One commenter asked whether it was our intention to require providers also to check their employees for exclusions on a monthly basis. The proposed regulation at § 455.436 does not require providers to check their employees for exclusions.

Response: We issued guidance on June 12, 2008, to State Medicaid Directors recommending that they check their enrolled providers for exclusions on a monthly basis. We followed up that guidance on January 16, 2009, with guidance to State Medicaid Directors recommending that they require their enrolled providers to check the providers' employees and contractors for exclusions on a monthly basis. Those letters are available at: *http://www.cms.gov/smdl/downloads/SMD061208.pdf* and *http://www.cms.gov/SMDL/downloads/SMD011609.pdf.* Many States made our recommendations their policy.

Section 455.436 does not mandate that States require their providers to check the LEIE and EPLS on a monthly basis to determine whether the providers' employees and contractors have been excluded. We do, however, recommend that States consider making this a requirement for all providers and contractors, including managed care contractors in their Medicaid programs and CHIP.

b. Unscheduled and Unannounced Site Visits—Medicaid and CHIP

Section 1866(j)(2)(B)(ii)(III) of the Act states that the Secretary, based on the risk of fraud, waste, and abuse, may conduct unscheduled and unannounced

site visits, including pre-enrollment site visits, for prospective providers and those providers already enrolled in the Medicare and Medicaid programs and CHIP.

Some States already require site visits, often for provider categories at increased risk of fraud, waste or abuse such as home health and non-emergency transportation. According to FY 2008 State Program Integrity Assessment (SPIA) data, at least 16 States report that they perform some type of site visits. However, such efforts vary widely across the country and are subject to budget shortfalls.

We proposed to require in § 455.432 and § 455.450(b) that States must conduct pre-enrollment and post-enrollment site visits for those categories of providers the State designates as being in the "moderate" or "high" level of screening.

Further, in § 455.432, pursuant to our general rulemaking authority under section 1102 of the Act, we proposed that any enrolled provider must permit the State Medicaid agency and CMS, including CMS' agents or its designated contractors, to conduct unannounced on-site inspections to ensure that the provider is operational at any and all provider locations.

We maintain that site visits are essential in determining whether a provider is operational at the practice location found on the Medicaid enrollment agreement. We expect these requirements to increase the number of both pre-enrollment and post-enrollment site visits for those provider types that pose an increased financial risk of fraud, waste, or abuse to the Medicaid program.

We proposed that failure to permit access for site visits would be a basis for denial or termination of Medicaid enrollment as specified in § 455.416.

As stated previously, pursuant to section 2107(e)(1) of the Act, all provisions that apply to Medicaid under sections 1902(a)(77) and 1902(kk) of the Act apply to CHIP. Because we proposed a new regulation in Part 457 under which all provider screening requirements that apply to Medicaid providers will apply to providers that participate in CHIP, this requirement for site visits under § 455.432 apply in CHIP.

Comment: Some commenters were supportive of the proposal for pre-enrollment and post-enrollment site visits in § 455.432, although they noted that they would need additional funding for travel or for contractors to conduct the site visits. Some commenters stated that the States should have the discretion to define which providers are subject to pre- and post-enrollment site visits and when the site visits are conducted, for example, by established risk categories or an automatic flag that demonstrates that billing has gotten to a certain threshold thus requiring an onsite visit. A few commenters stated that the site visits were an undue burden on States. One commenter stated that the site visits were unnecessary given that other more cost-effective methods could prevent enrollment of providers who are using fraudulent identity, such as annual re-enrollment, license verification, and follow-up when a duplicate provider ID or address is used. Another commenter noted that pre-enrollment site visits could delay enrollment as a result of inclement weather.

Response: We recognize that conduct of site visits will place a burden on State budgets and staff time, and may be difficult to accomplish in rural areas or in inclement weather. However, site visits are a requirement depending on the risk the provider represents to the Medicaid program. In response to the commenters that suggested that States should have the discretion to define which providers are subject to pre- and post-enrollment site visits: The site visits are required for those providers that are determined to be a moderate or high categorical risk of fraud, waste, or abuse. In addition to the required site visits for providers in the moderate and high screening levels, the State may also conduct site visits at its discretion. While there may be other means to verify whether a provider is a going concern or whether a provider has a business location, conduct of site visits is one method that is required by this regulation. The State has the discretion to utilize other additional methods to prevent enrollment of non-existent providers or to ensure that spurious applications are not processed.

Comment: A few commenters sought clarification on what the expectations were for site visits when the provider performed services in the beneficiary's home, for example, personal care services; or for out-of-State providers or rural providers.

Response: If a Medicaid-only provider is in the moderate or high screening level, the State Medicaid agency does not have the discretion whether to conduct a site visit: It is required under § 455.432(a) and § 455.450(b). However, pursuant to § 455.452, States are permitted to establish additional or more stringent screening measures than those required by this final rule with comment period. Thus, for providers that are in the limited screening level, the State has the discretion to determine whether to conduct site visits, based on whatever factors the State deems appropriate. We recognize that the appropriate location of the site visit may differ based upon the provider type. For example, the personal care services agency is the enrolled provider, so its location would likely be subject to a site visit. While its employee the personal care attendant may not be an enrolled provider with the State Medicaid agency, it may also be appropriate to conduct a site visit in a beneficiary's home where the personal care attendant is providing services to ensure that services are in fact being provided appropriately. It would be within the discretion of the State Medicaid agency to determine whether to conduct an additional site visit for a provider in the limited screening level. With respect to providers in rural locations, the mere fact that the provider is in a rural location does not absolve the State Medicaid agency of its responsibility to conduct site visits. Similarly, for out-of-State providers, the mere fact that a provider in the moderate or high screening level is located in another State would not negate the requirement for a site visit, although we note that § 455.410 permits States to rely upon the screening performed by Medicare and by other State Medicaid programs and CHIP. Therefore, no additional site visit would be required if the provider is also enrolled by Medicare or in Medicaid or CHIP in its home State.

c. Provider Enrollment and Provider Termination—Medicaid and CHIP

States may refuse to enroll or may terminate the enrollment agreement of providers for a number of reasons related to a provider's status or history, including an exclusion from Medicare, Medicaid, or any other Federal health care program, conviction of a criminal offense related to Medicare or Medicaid, or submission of false or misleading information on the Medicaid enrollment application. Failure to provide disclosures is another reason for termination from participation in the Medicaid program.

Federal regulations beginning at § 455.100 require certain disclosures by providers to States before enrollment. States require additional disclosures prior to enrollment. Some States require periodic re-enrollment and disclosure at that time. However, States vary in the frequency of such re-disclosures. Providers are also inconsistent in keeping their enrollment information current, including items as elementary as their address.

We proposed, at § 455.414, pursuant to our general rulemaking authority

under section 1102 of the Act, that all providers undergo screening pursuant to the procedures outlined herein at least once every 5 years, consistent with current Medicare requirements for revalidation.

In § 455.416, we proposed to establish termination provisions, requiring States to deny or terminate the enrollment of providers: (1) Where any person with an ownership or control interest or who is an agent or managing employee of the provider does not submit timely and accurate disclosure information or fails to cooperate with all required screening methods; (2) that are terminated on or after January 1, 2011 by Medicare or any other Medicaid program or CHIP (*see* section II.F. of this final rule with comment period); and (3) where the provider or any person with an ownership or control interest or who is an agent or managing employee of the provider fails to submit sets of fingerprints within 30 days of a State agency or CMS request. We proposed to permit States to deny enrollment to a provider if the provider has falsified any information on an application or if CMS or the State cannot verify the identity of the applicant. We also proposed to require States to deny enrollment to providers, unless States determine in writing that denial of enrollment is not in the best interests of the State's Medicaid program, in these circumstances: (1) The provider or a person with an ownership or control interest or who is an agent or managing employee of the provider fails to provide accurate information; (2) the provider fails to provide access to the provider's locations for site visits, or (3) the provider, or any person with an ownership or control interest, or who is an agent or managing employee of the provider has been convicted of a criminal offense related to that person's involvement in Medicare, Medicaid, or CHIP in the last 10 years. We believe that providers can significantly reduce the likelihood of fraud, waste or abuse by providing and maintaining timely and accurate Medicaid enrollment information. We believe the Medicaid program will be better protected by not allowing persons with serious criminal offenses related to Medicare, Medicaid, and CHIP to serve as providers.

We proposed at § 455.416 that the State be allowed to deny an initial enrollment application or agreement submitted by a provider or terminate the Medicaid enrollment of a provider, including an individual physician or non-physician practitioner, if CMS or the State is not able to verify an individual's identity, eligibility to participate in the Medicaid program, or determines that information on the Medicaid enrollment application was falsified.

In § 455.420, we proposed to require that any providers whose enrollment has been denied or terminated must undergo screening and pay all appropriate application fees again to enroll or re-enroll as a Medicaid provider.

We proposed at § 455.422 that in the event of termination under § 455.416, the State Medicaid agency must give a provider any appeal rights available under State law or rule.

As stated previously, pursuant to section 2107(e)(1) of the Act, all provisions that apply to Medicaid under sections 1902(a)(77) and 1902(kk) of the Act apply to CHIP. Because we proposed a new regulation in Part 457 under which all provider screening requirements that apply to Medicaid providers will apply to providers that participate in CHIP, these requirements for provider enrollment, provider termination, and provider appeal rights under § 455.414, § 455.416, § 455.420, and § 455.422 apply in CHIP.

Comment: Several commenters expressed concern regarding the requirement under § 455.414 related to a 5 year re-screening process. Some commenters stated that they already required a periodic re-enrollment process and CMS should take into consideration the States' existing processes and grant the States the flexibility to employ those existing processes.

Other commenters noted that the additional enrollments would place administrative and fiscal burdens on the States. Several commenters noted that they would need an extended period to implement the new requirements of the proposed rule, including the requirement set forth at § 455.414.

One commenter sought clarification whether all providers currently enrolled and that have been enrolled for 5 years would be up for revalidation when the regulation became effective; and whether currently enrolled providers could be revalidated over a 5-year timeframe to diminish the administrative burden on State Medicaid agency staff.

Another commenter sought clarification whether the requirement was for re-screening or for re-enrollment at least every 5 years; whether the requirement would apply to all enrolled providers including rendering providers, or just to ordering or referring physicians and other professionals who are the subject of the requirements set forth at § 455.410 and § 455.440; and whether CMS would give affected providers notice of the need to re-enroll.

Response: Periodic re-validation of enrollment information affords States the opportunity to ensure their provider rolls do not contain providers that have been excluded from participation in the Federal health care programs. The State Medicaid agencies can cull from their provider rolls those providers that have not submitted claims for payment or referred claims for payment in several years. Without removing those providers' numbers during a periodic re-enrollment process, those providers' numbers might be used at a later date in a fraudulent scheme: The providers may have been unwitting victims of identity theft or may have participated in selling their provider numbers.

The proposed requirement at § 455.414 describes screening of all providers at least every 5 years. Screening, as performed by the Medicare Administrative Contractors for all dually participating providers, and by the State Medicaid agency or CHIP for those providers that are not also participating in the Medicare program, should be distinguished from enrollment, a function performed by the State Medicaid agency or CHIP to participate in the Medicaid program or CHIP of a given State. Screening would involve various assessments commensurate to the risk the provider posed to the Medicaid program or CHIP, including license verification, database checks, site visits, background checks, and fingerprinting. Enrollment may involve all of those, as well as collection of disclosures required under § 455.104, § 455.105, and § 455.106, and a host of State-specific requirements.

We applaud States that already require periodic re-enrollment of Medicaid providers. For the sake of consistency with the Medicare program, however, we are finalizing § 455.414 as a 5 year re-validation of enrollment information, which includes re-screening as well as the collection of updated disclosure information, for providers regardless of provider type, including, but not limited to, rendering, ordering, and referring physicians, and other professionals. The screening component of the 5 year re-validation will be conducted by either the Medicare Administrative Contractors (for dually-participating providers) or by the States (for Medicaid-only or CHIP-only providers). The collection of updated enrollment information, including, but not limited to, disclosure information will be the province of the State Medicaid agencies, and subject to their existing procedures, therefore, we will not issue notices of the need to

revalidate enrollment information to the affected providers.

State Medicaid agencies should complete the first re-validation cycle by 2015, with 20 percent of providers being re-validated each year beginning 2011. State Medicaid agencies have the discretion to determine which providers or provider types to re-validate enrollment first. However, they may want to consider re-validating enrollment in the first years of the cycle those providers or provider types that pose the greatest risk of fraud, waste or abuse to the Medicaid program and CHIP.

Comment: We received comments from States supportive of the proposed bases for denial of enrollment or termination of enrollment in § 455.416, but concerned about the time they would need for implementation to amend State laws and rules and to amend provider agreements. One State commented that it would be administratively inefficient, costly, and unrealistic for each State to independently confirm providers' enrollment status or termination history in another State's Medicaid program or CHIP.

Response: We believe that the bases for denial of enrollment or termination of enrollment in § 455.416 are necessary to protect the integrity of the Medicaid program. Therefore, prompt implementation of these additional bases for denial or termination will serve each State and Medicaid programs nationally. We acknowledge the additional burden that new bases for denial and termination will create for State Medicaid programs, for example, in changes to systems and forms, and changes to provider agreements. We are currently examining to what extent we can support a centralized information sharing solution for provider enrollment across programs and across States. However, we note that termination based on termination by Medicare or by another State's Medicaid program is a statutory requirement effective January 1, 2011.

Comment: One commenter recommended that the reasons for provider termination should be outlined and given to the provider upon denial or termination. The commenter noted that the provider would then have the ability to address or correct deficiencies prior to resubmitting its enrollment application. This requirement, the commenter noted, would be in addition to any appeal rights.

Response: We have provided for a right of appeals to the extent they are available under a State's existing laws or rules. While we recognize that the commenter's suggestion may be helpful, and States may elect to adopt it, we will not be disrupting a State's procedures under its existing laws or rules with this regulation.

Comment: One State recommended an addition to the language of § 455.416(g)(1) to recognize that a provider's omissions may be as egregious as its falsified statements.

Response: We appreciate the commenter's suggestion to cover all possible situations when a provider may have misled the State in the application process. However, § 455.416(d) addresses termination for a failure to submit timely and accurate information which would include omissions to provide information. Therefore we decline to revise section § 455.416(g)(1).

Comment: A State requested clarification on how rigorous the State's efforts must be to verify the identity of the provider applicant or whether a background check is sufficient.

Response: The State Medicaid agencies have the discretion to determine the steps that are appropriate to verify the identity of the provider applicant, which may include, but would not be limited to, verification of licensure, database checks, and criminal background checks.

d. Criminal Background Checks and Fingerprinting—Medicaid and CHIP

Section 1866(j)(2)(B)(ii)(II) of the Act allows the Secretary to use fingerprinting during the screening process; and while several States have implemented procedures to require fingerprinting of physicians and non-physician practitioners as a condition of licensure, we maintain that if a State designates a provider as within the high level of screening as described previously, each person with an ownership interest in that provider should be subject to fingerprinting.

Adding fingerprinting to State screening processes for those providers that pose the greatest risk to the Medicaid program will allow CMS and the State to: (1) Verify the individual's identity; (2) determine whether the individual is eligible is participate in the Medicaid program; (3) ensure the validity of information collected during the Medicaid enrollment process; and (4) prevent and detect identity theft. Ensuring the identity of "high" risk Medicaid providers through fingerprinting protects both the Medicaid program and providers whose identities might otherwise be stolen as part of a scheme to defraud Medicaid.

In addition, while § 455.106 requires providers to submit information to the Medicaid agency on criminal convictions related to Medicare and Medicaid and title XX, current regulations do not require States to verify data submitted as part of the Medicaid enrollment application and they are sometimes not able to verify information that was purposefully omitted or changed in a manner to obfuscate any previous criminal activity. According to fiscal year (FY) 2008 SPIA data, at least 20 States report that they conduct some type of criminal background check as part of their Medicaid enrollment practices.

Elements of a robust criminal background check could include, but not are necessarily limited to: (1) Conducting national and State criminal records checks; and (2) requiring submission of fingerprints to be used for conducting the criminal records check and verification of identity.

We proposed in § 455.434 and § 455.450 for those categories of providers that a State Medicaid agency determines is within the high level of screening, the State must: (1) Conduct a criminal background check of each provider and each person with an ownership or control interest or who is an agent or managing employee of the provider, and (2) require that each provider and each person with an ownership or control interest or who is an agent or managing employee of the provider to submit his or her fingerprints. The State Medicaid agency has the discretion to determine the form and manner of submission of fingerprints.

At § 455.434, we proposed that the State Medicaid agency must require providers or any person with an ownership or control interest or who is an agent or managing employee of the provider to submit fingerprints in response to a State's or CMS' request.

We solicited public comment on the appropriateness of using criminal background checks in the provider enrollment screening process, including the instances when such background checks might be appropriate, the process of notifying a provider or individual that a criminal background check is to be performed, and the frequency of such checks.

We also solicited comment on the use of fingerprinting as a screening measure. We recognize that requesting, collecting, analyzing, and checking fingerprints from providers are complex and sensitive undertakings that place certain burdens on affected individuals. There are privacy concerns and operational concerns about how to assure individual privacy, how to check fingerprints against appropriate law enforcement fingerprint data bases, and how to store

the results of the query of the databases and also how to handle the subsequent analysis of the results. As a result, we solicited comments on how CMS or a State Medicaid agency should maintain and store fingerprints, what security processes and measures are needed to protect the privacy of individuals, and any other issues related to the use of fingerprints in the enrollment screening process. We expressed interest in comments on this and other possible circumstances in which fingerprinting would be potentially useful in provider screening or other fraud prevention efforts. Our proposed screening approach contemplated requesting fingerprints from providers assigned to the high level for screening. We solicited comments on whether this is an appropriate requirement, the circumstances under which it might be appropriate or inappropriate, and any alternatives to the proposed approach regarding fingerprints. Our proposed approach would allow States to deny enrollment to newly enrolling providers and to terminate existing providers if the provider or if individuals who have an ownership or control interest in the provider or who are agents or managing employees of the provider refuse to submit fingerprints when requested to do so. We solicited comments on this proposal including its appropriateness and utility as a fraud prevention tool.

In addition, we solicited comment on the applicability and appropriateness of using, in addition to or in lieu of fingerprinting, other enhanced identification techniques and secure forms of identification including but not limited to passports, United States Military identification, or Real ID drivers licenses. As technology and secure identification techniques change, the tools we or State Medicaid agencies use may change to reflect changes in technology or in risk identification. We solicited comment on the appropriate uses of these techniques and the ways in which we should notify the public about any tools CMS or State Medicaid agencies would adopt. We also welcomed comments on whether there should be differences allowed between Federal and State techniques, or among States, and if so, on what basis.

As stated previously, pursuant to section 2107(e)(1) of the Act, all provisions that apply to Medicaid under sections 1902(a)(77) and 1902(kk) of the Act apply to CHIP. Because we proposed a new regulation in Part 457 under which all provider screening requirements that apply to Medicaid providers will apply to providers that participate in CHIP, these requirements for criminal background checks and fingerprinting under § 455.434 will apply in CHIP.

Comment: A number of commenters noted the undue and significant burden on the States and providers that the criminal background check requirement in § 455.434, and specifically the fingerprint requirement, would pose. These commenters noted that State Medicaid agencies do not have the staff or expertise to conduct the checks. One commenter stated that enforcement of this provision will have deleterious effects on the Medicaid provider network and act as a barrier to care, and recommended removing the fingerprinting and background check requirements for high risk providers.

Other commenters were supportive of the proposal to conduct criminal background checks and collection of fingerprints, noting that the proposal was intended to screen out unscrupulous providers. One commenter recognized that the proposal to add fingerprinting of high risk entities was a way to evaluate the background of potential providers, to identify fraud and prevent individuals with known criminal backgrounds from participating in Medicaid.

Other commenters were concerned about the relative cost and efficiency of conducting the criminal background checks. Several commenters suggested that the background checks be at the States' discretion. One commenter suggested that CMS conduct any necessary fingerprinting, regardless of whether the person or entity is enrolled in Medicare. Another commenter recommended that CMS consider limiting FBI criminal background checks to cases in which there is reasonable cause to believe the subject may have a criminal record in another State.

Response: We have considered all the comments received and are sensitive to the burden the criminal background checks and fingerprinting will pose to the State Medicaid agencies and the affected providers. However, we believe that criminal background checks are an effective means of evaluating a high risk provider. Furthermore, we believe that fingerprinting high risk providers and their owners are worthwhile endeavors to determine identity and whether the provider and other individuals have been involved in criminal activities that would adversely impact the Medicaid program. While we are finalizing the requirement to conduct criminal background checks and collect fingerprints for high risk providers, the requirement will be limited to providers and persons with a five percent or more direct or indirect ownership interest in the provider. There will be no requirement to conduct criminal background checks on, or collect the fingerprints of, persons with a control interest in the provider or the agents or managing employees of high risk providers. However, we intend to monitor the situation and may seek to extend the scope of fingerprint-based criminal background checks in the future if circumstances warrant. We are making the appropriate changes to § 455.434. States will not be required to implement criminal background checks and fingerprinting until we issue additional guidance. To the extent that States have the ability to conduct background checks and collect fingerprints at this time, it is within their discretion to do so prior to the delayed implementation date. States have the discretion to impose more stringent requirements for Medicaid-only and CHIP-only providers than those we are requiring.

Comment: One commenter asked how results of criminal background checks would be communicated in data available to States from CMS.

Response: We are currently examining to what extent we can support a centralized information sharing solution for provider screening results across programs and across States. The individual results of a criminal background checks performed, however, would likely be sent directly to the agency requesting the background check from the entity that performed the check.

Comment: One commenter asked whether there would be standard criteria that define the types of convictions that warrant denial of a provider's application.

Response: Whether to deny enrollment or to terminate enrollment are decisions that are within the discretion of each State Medicaid agency in accord with § 455.416. Thus, the types of convictions that warrant denial of enrollment would be at the discretion of the State Medicaid agency.

Comment: Some commenters asked what level of background check was required, for example, were State Medicaid agencies expected to do a Federal criminal background check or a State criminal background check.

Response: While it is within the State Medicaid agency's discretion to decide whether to conduct State or Federal background checks for Medicaid-only providers, we recommend that the State conduct Federal criminal background checks which would provide information that is national in scope and therefore would be more complete.

Comment: A few commenters questioned which databases a States should consult to compare fingerprints against in order to do the screening under this provision, in the event that law enforcement is not available to review the fingerprints?

Response: We are not aware of databases that the State Medicaid agencies might search, however, there are vendors that provide the service for a fee.

Comment: One commenter questioned whether the State Medicaid agency must perform a criminal background check in its State only or in the neighboring State for a provider applicant that only provides services in the neighboring State.

Response: The States have the discretion to decide, however, we would recommend conducting a FBI criminal history record check, which would provide information that is national in scope and therefore would be more complete and would be preferable to a State background check in either the enrolling State or the neighboring State.

Comment: Some commenters noted that fingerprints created a logistical concern for the State Medicaid agencies. Once they have obtained the fingerprint cards from the providers, should the States maintain the files, how should they maintain the cards, and for how long? If electronic files, how should the States maintain those files?

Response: The State Medicaid agencies should follow their existing records retention laws and procedures, however we recommend that the State Medicaid agencies retain the files for at least 5 years, until the provider's revalidation. To the extent that a State Medicaid agency itself receives the fingerprints submitted, we expect them to maintain those files in a secure manner to protect the privacy of the individual who submitted the fingerprints.

Comment: One commenter suggested that the provision be revised so that it does not require two copies of the fingerprint card but allows for collection of two copies if the State determines that two copies are needed.

Response: We agree, and are making that change to § 455.434.

e. Deactivation and Reactivation of Provider Enrollment—Medicaid and CHIP

Section 1902(kk)(1) of the Act requires the screening of Medicaid providers to ensure they are eligible to provide services and receive payments. In an effort to further protect the Medicaid program and to be consistent with longstanding Medicare requirements, we proposed in § 455.418 that any Medicaid provider that has not submitted any claims or made a referral that resulted in a Medicaid claim for a period of 12 consecutive months must have its Medicaid provider enrollment deactivated. Further, under § 455.420, we proposed that any such provider wishing to be reinstated to the Medicaid program must first undergo all disclosures and screening required of any other applicant. In addition, we proposed that the provider must pay any associated application fees under § 455.426.

As stated previously, pursuant to section 2107(e)(1) of the Act, all provisions that apply to Medicaid under sections 1902(a)(77) and 1902(kk) of the Act apply to CHIP. Because we proposed a new regulation in Part 457 under which all provider screening requirements that apply to Medicaid providers will apply to providers that participate in CHIP, the proposed requirements for deactivation and reactivation of provider enrollment under § 455.418 and § 455.420 would apply in CHIP.

Comment: A few commenters supported the proposed requirement as written. A number of commenters were supportive of the spirit of this proposed requirement but suggested that we lengthen the timeframe to 24 months. Other commenters expressed concern regarding the applicability of the application fee when reactivating enrollment and suggested that Medicaid follow a streamlined reactivation process similar to what occurs in the Medicare program.

One State commenter expressed concern that the requirement to deactivate providers would necessitate deactivating one third of the State's enrolled providers. Other State commenters noted that out-of-State providers would routinely be deactivated because their billings are so infrequent.

Response: We recognize that many out-of-State providers provide occasional emergency treatment to Medicaid beneficiaries, and that requiring States to deactivate those providers after a year without billings would cause administrative burdens for the States and the providers. We believe States should have the discretion to police their own provider enrollment, although we recommend that States deactivate provider numbers that have not been used for an extended period of time.

After reviewing the comments received and other operational considerations we are not finalizing the requirement for deactivation of provider numbers after 12 months in § 455.418 at this time.

f. Enrollment and NPI of Ordering or Referring Providers—Medicaid and CHIP

Section 1902(kk)(7) of the Act provides that States must require all ordering or referring physicians or other professionals to be enrolled under a Medicaid State plan or waiver of the plan as a participating provider. Further, the NPI of such ordering or referring provider or other professional must be on any Medicaid claim for payment based on an order or referral from that physician or other professional.

Providers and suppliers under Medicare and providers in the Medicaid program are already subject to the requirement that the NPI be on applications to enroll and on all claims for payment, pursuant to section 6402(a) of the ACA, amending section 1128J of the Act, and under § 424.506, § 424.507, and § 431.107, as amended by the May 5, 2010 interim final rule with comment period (75 FR 24437).

In § 455.410, we proposed that any physician or other professional ordering or referring services for Medicaid beneficiaries must be enrolled as a participating provider by the State in the Medicaid program. We proposed that this would apply equally to fee for service providers or MCE network-level providers.

Additionally, we proposed to amend § 438.6 to require that States must include in their contracts with MCEs a requirement that all ordering and referring network-level MCE providers be enrolled in the Medicaid program, as are fee for service providers, and thus are screened directly by the State.

Although the NPI requirements in section 6402(a) of the ACA did not extend to CHIP providers, section 6401 of the ACA does apply equally to CHIP, and the proposed requirement for ordering and referring physicians or other professionals under the Medicaid program apply equally under CHIP.

In addition, in § 455.440, we proposed that all claims for payment for services ordered or referred by such a physician or other professional must include the NPI of the ordering or referring physician or other professional. We proposed that this would apply equally to fee for service providers or MCE network-level providers.

It is essential that all such claims have the ordering or referring NPI and that the State has properly screened the ordering or referring physician or other professional. Without such assurances,

it is difficult for CMS or the State to determine the validity of individual claims for payment or to conduct effective data mining to identify patterns of fraud, waste, and abuse.

As stated previously, pursuant to section 2107(e)(1) of the Act, all provisions that apply to Medicaid under sections 1902(a)(77) and 1902(kk) of the Act apply to CHIP. Because we proposed a new regulation in Part 457 under which all provider screening requirements that apply to Medicaid providers will apply to providers that participate in CHIP, these requirements for provider enrollment and NPI under § 455.410 and § 455.440 apply in CHIP.

Comment: Many commenters expressed concern regarding whether the ordering and referring requirements in the proposed rule applied in the managed care environment. Many State, MCO, and association commenters also expressed concern regarding the impact that mandatory enrollment under § 455.410 would have upon Medicaid beneficiary access to providers. These commenters stated concerns about the ability to contract with providers and other professionals if there was a requirement for those providers to be enrolled with the State as participating providers. The MCO and association commenters also cited their concerns about network level providers wanting to control their practices and not being mandated to participate in the Medicaid program when their preference was to serve in a Medicaid MCO. In addition, a State commenter expressed the concern that they be able to attract MCOs to their programs to provide choice to beneficiaries.

Several State commenters also noted that adding managed care ordering and referring providers to their rolls in addition to the proposed requirement for re-enrollment every 5 years, as well as the other proposed screening requirements would impose administrative and fiscal burden on State resources.

A few association commenters suggested that States implement a registration process whereby MCO network level providers would engage in a process short of full enrollment with the Medicaid agency, solely for the purpose of screening. Several commenters also expressed concerned related to: (1) Consistency of screening across Medicare and Medicaid, and across the MAOs and Medicaid managed care; and (2) who would conduct the screening. There was some confusion about whether the MAOs and MCOs would conduct the screening of the network level providers, or whether Medicare contractors and State Medicaid agencies would conduct the screening. There was also the issue of MAO providers not being specifically required to be enrolled to order or refer for the items and services they ordered or referred for Medicare beneficiaries to be paid.

A few commenters noted the adequacy of current credentialing performed by Medicaid MCOs and the absence of any statement to the contrary justifying enrollment of network level ordering and referring providers.

Several State commenters questioned how the NPI requirement would apply in a managed care environment, when risk-based health plans file claims for payment for the services of their subcontracted network level providers based on the contract between the State and the risk-based health plan. The network level providers ordering or referring items or services do not file claims for payment as fee-for-service providers do.

Response: After careful consideration of the comments we received, as well as the statutory language, we have determined that the new requirements for ordering and referring physicians should not apply in a risk based managed care context. We do not believe it was the intent of the Congress to impose stricter requirements on the Medicaid program than are imposed in Medicare. To require Medicaid managed care providers that order or refer items or services for Medicaid beneficiaries to enroll as Medicaid participating providers when MAO providers are not also required to enroll in the Medicare program to order or refer items or services for Medicare beneficiaries would be to treat the programs unequally.

In consideration of the concerns for beneficiary access and the administrative burden that enrollment of MCO ordering and referring physicians and other professionals would impose on State Medicaid agencies, and in consideration of the parity of requirements for the Medicaid and Medicare programs, we are not requiring that ordering and referring physicians and other professionals in managed care risk based health plans enroll as participating providers by State Medicaid programs. Consequently, we are not finalizing the proposed change to § 438.6 that would have required State managed care contracts to require network level providers enroll with the Medicaid agency as participating providers.

We are limiting the exemption to risk based managed care. Section 1902(kk)(7) requires that States must require all ordering or referring physicians or other professionals to be enrolled under a Medicaid State plan or waiver of the plan as a participating provider. We want to give the greatest effect to the statute while creating the least adverse impact on beneficiaries. Had we extended the exemption to all forms of managed care, for example, we would have allowed physicians or other professionals that participate in primary care case management programs that operate under State plan waivers to avoid enrollment with a State's Medicaid program; or we would have allowed home and community based services program providers that order or refer to avoid enrollment, to the extent that a State requires such enrollment. We also gave consideration to the comments we received regarding access, burden on State processes, and credentialing. The State and managed care organization commenters expressed concerns about beneficiary access to managed care networks and providers, which would be likely to occur in the risk-based forms of managed care, but not in primary care case management, for example. The States also expressed concerns about the burden of enrolling as participating providers those physicians and other professionals in managed care. Again, we interpret their concerns to be about risk-based forms of managed care, rather than forms of managed care in which the provider or entity bears no risk, because in the vast majority of States network level providers in risk-based forms of managed care are not enrolled with the Medicaid agency. Primary case care managers, however, are already enrolled with the Medicaid agency as fee-for-service providers. In addition, risk-based managed care entities conduct credentialing required under Federal regulations and subject to the terms of the contracts between the States and the MCOs, PIHPs, or PAHPs. Providers that participate in non-risk-based forms of managed care are subject to the various enrollment requirements that each State may designate.

Given that managed care services are recorded in encounter claims, we recognize that it is not always possible for such an ordering or referring physician's or other professional's NPI to be reflected on such a claim. We leave it to the State's discretion, based in part on the capability of the State's systems, to require entrance of the NPI on the encounter record.

Comment: A commenter requested clarification on whether the requirement for ordering and referring physicians or other professionals to be enrolled with a State Medicaid agency would apply to professionals who may not be eligible to

enroll in a State's Medicaid program but who provide services under the supervision of an enrolled provider and whose services are billed under the provider identification number of that eligible Medicaid enrolled provider.

Response: The requirement for other ordering or referring professionals to enroll with a State's Medicaid program as a participating provider would depend on whether a State's Medicaid program recognized the professional as a Medicaid provider. If it did not, there would be no requirement to enroll.

Comment: Several commenters expressed concern about the applicability of § 455.410 and § 455.440 to public school districts. Public schools deliver Medicaid school based health services to Medicaid eligible children and therefore are enrolled as Medicaid providers. Commenters expressed concern about public school-based providers, for example, speech language therapists, school psychologists, occupational therapists, and physical therapists, employed by public school districts being required to enroll with the Medicaid agency as ordering and referring physicians or other professionals. The commenters noted that public school based providers are able, but have not been required in the past, to get an NPI. Public school districts have included their NPI on claims and the clinicians are assigned unique provider identification numbers to facilitate identification of providers and services. Therefore, the commenters encourage an exemption for public school based providers from the NPI requirement.

Response: Public school based providers are subject to the ordering and referring requirements set forth in § 455.410 and § 455.440. However, as a way to minimize the administrative burden of enrolling additional providers, State Medicaid agencies may implement a streamlined enrollment process for those providers who only order or refer, that is, who do not bill for services, similar to the CMS–855–O process in the Medicare program. Additionally, State Medicaid agencies may delegate to State or local governmental agencies, such as public school districts, the responsibility to screen public school based providers and to assign unique provider identification numbers for claims identification.

Comment: Several commenters noted that the regulations at § 455.410 do not address whether CMS will provide a reliable mechanism or national database in which screening results can be shared. Without a method to obtain results from these other entities, States will have to screen all Medicaid providers at considerable cost. One commenter noted that Medicare and CHIP do not define providers the same way which will lead to confusion over who has been screened through Medicare and the sister agencies.

Response: We are currently examining to what extent we can support a centralized information sharing solution for provider enrollment across programs and across States.

Comment: Several commenters responded that the proposed regulation would be burdensome on both States and providers, requiring providers who do not normally work with the Medicaid program and new groups of providers to enroll. One commenter suggested that rather than being required to enroll with the Medicaid program, providers be permitted to use the NPI as evidence of successful Medicare screening and enrollment.

Response: We are sensitive to the additional burden that obtaining an NPI will pose, however, inclusion of the NPI on all Medicaid claims is a statutory requirement. The commenter suggested that providers enroll with Medicare and use the NPI as evidence of successful screening and enrollment. Providers should be aware that the NPI is not evidence of successful Medicare screening and enrollment, but providers who are actually enrolled in Medicare will not have to be screened again by the States to be enrolled in the Medicaid programs. The States may implement a streamlined enrollment process for those providers who only order or refer, that is, who do not bill for services, similar to the CMS–855–O process in the Medicare program.

Comment: One commenter described a scenario of a salaried hospital physician who was not enrolled by the State Medicaid agency, but the hospital that employed the physician was an enrolled, participating Medicaid provider. The commenter questioned whether the referral rule applied to the physician.

Response: Yes, the salaried hospital physician must enroll with the State Medicaid agency to order or refer for Medicaid beneficiaries.

Comment: A commenter sought clarification whether the order or referral rule applied when an order or referral was made prior to the Medicaid beneficiary being eligible for Medicaid.

Response: No, if the order or referral was made before the beneficiary was Medicaid eligible, then the beneficiary may have the order filled or the referral fulfilled and the claim for the order or referral will be paid.

Comment: A commenter asked whether the ordering and referring rule applied to Medicare crossover claims.

Response: Yes, the beneficiary's claims would be Medicaid claims, therefore the provider who ordered or referred the Medicaid beneficiary's services would be required to be enrolled as a Medicaid participating provider.

Comment: One commenter requested clarification on whether CMS will be changing claims forms to accommodate the collection of information regarding ordering and referring providers.

Response: To the extent it is necessary for the State Medicaid agencies to make changes to their claim forms to accommodate the new requirement regarding ordering and referring providers, and then the States should make those changes.

Comment: Several commenters sought clarification on whether the terms "ordering and referring physicians or other professionals" included prescribing providers.

Response: We interpret the statutory terms "ordering" and "referring" to include prescribing (either drugs or other covered items) or sending a beneficiary's specimens to a laboratory for testing or referring a beneficiary to another provider or facility for covered services.

Comment: Some of the commenters sought clarification on the definition of the term "other professional." For example, does it include rendering providers, non-professional providers, or providers in waiver programs?

Response: Under § 455.410(b) and section 1902(kk) of the Act, the phrase "ordering and referring physicians and other professionals" does not include rendering providers, as these authorities impose a new enrollment requirement with respect to physicians and other professionals that order or refer items or services for Medicaid beneficiaries. Other professionals include any person or entity recognized to be enrolled by a State Medicaid agency, and that may order or refer. Of course, to be able to submit a claim to a State Medicaid agency, for services rendered or items supplied to a Medicaid beneficiary, a provider must be enrolled as a participating provider with that State Medicaid agency.

Comment: One commenter sought clarification whether the requirement for all ordering and referring physicians or other professionals to be enrolled with the Medicaid agency as participating providers applied to IHS providers.

Response: IHS providers are required to comply with § 455.410(b). However,

as a way to minimize the administrative burden of enrolling additional providers, State Medicaid agencies may implement a streamlined enrollment process for those providers who only order or refer, that is who do not bill for services, similar to the CMS–855–O process in the Medicare program.

Comment: A commenter questioned whether a provider that has enrolled as a participating provider to comply with § 455.410(b) must submit fee-for-service claims to the Medicaid agency, or is the provider's status as an enrolled provider sufficient for compliance.

Response: Under § 455.410(b), a physician or other professional need not submit fee-for-service claims to the State Medicaid agency to remain enrolled as a Medicaid provider.

Comment: With respect to § 455.440, one State asked whether the provider's NPI must be on each and every claim or whether it is sufficient for the provider's NPI to be on file with the State Medicaid agency, and whether the prescribing provider's NPI would be required on pharmacy claims.

Response: Under § 455.440, "all claims for payment for items and services that were ordered or referred" must contain the NPI. This is based upon the statutory requirement in section 1902(kk)(7)(B) of the Act that States require the NPI "of any ordering and referring physician or other professional to be specified on any claim for payment that is based upon an order or referral of the physician or other professional." Therefore, the provider's NPI must be on every claim, including pharmacy claims; it is not sufficient for the provider's NPI to be on file.

g. Other State Screening—Medicaid and CHIP

Section 1902(kk)(8) of the Act establishes that States are not limited in their abilities to engage in provider screening beyond those required by the Secretary. Accordingly, in § 455.452, we proposed that States may utilize additional screening methods, in accordance with their approved State plan.

As stated previously, pursuant to section 2107(e)(1) of the Act and specified in our regulations in Part 457, all provisions that apply to Medicaid under sections 1902(a)(77) and 1902(kk) of the Act apply to CHIP. Because we proposed a new regulation under which all provider screening requirements that apply to Medicaid providers will apply to providers that participate in CHIP, this requirement for other State screening under § 455.452 applies in CHIP.

h. Final Screening Provisions—Medicaid and CHIP

We are adopting the Medicaid and CHIP provider screening requirements as proposed with the following modifications:

- We clarified § 455.104(b)(1) regarding the elements of corporate addresses.
- We clarified § 455.104(b)(2) with regard to whom the spouse, parent, child, or sibling is related.
- We clarified § 455.104(b)(4) to require managing employees to provide SSNs and DOBs.
- We clarified § 455.104(c)(1), and § 455.104(c)(1)(i) and (ii) to include submission of disclosures from disclosing entities as well as providers.
- We clarified § 455.104(c)(1)(iii) to require submission of disclosures upon the request of the Medicaid agency during the revalidation of enrollment process.
- We are adopting § 455.450 with modifications, having clarified that the State agency must screen applications both in re-enrollment and re-validation of enrollment in the introductory paragraph; deleted the reference to publicly traded companies in § 455.450(a); deleted reference to persons with controlling interests, agents and managing employees who are required to provide fingerprints in § 455.450(d); and clarified the basis for adjusting a screening level related to moratoria § 455.450(e)(2).
- At § 455.414 we clarified that States must revalidate the enrollment information of all providers at least every 5 years.
- We are adopting § 455.416 with modifications clarifying terminations of persons with 5 percent of more direct or indirect ownership interests in the provider; and deleting reference to persons with controlling interests, agents and managing employees under bases for termination for failure to provide fingerprints.
- We clarified § 455.434 to require criminal background checks from providers or persons with a five percent or more direct or indirect ownership interest in the provider who meet the State Medicaid agency's criteria as a high risk to the Medicaid program; and to require fingerprints from providers and person with a five percent or more direct or indirect ownership interest in the provider, upon the State Medicaid agency's or CMS' request.
- We are not finalizing the proposed provision that States deactivate the enrollment of any provider that has not billed for 12 months.
- And finally, we are not finalizing the proposed requirement at § 438.6(c)(5)(vi) that required all ordering and referring Medicaid Managed Care network providers to be enrolled as participating providers based on commenters' concerns regarding access to services for beneficiaries.

5. Solicitation of Additional Comments Regarding the Implementation of the Fingerprinting Requirements

While this final rule with comment period is effective on the date indicated herein, we strongly believe that certain issues warrant further discussion. Accordingly, we will continue to seek comment limited to our implementation of the fingerprinting provisions contained in § 424.518 and § 455.434 of this rule.

Specifically, we seek comment on methods that we can use to ensure the privacy and confidentiality of the records that will be generated pursuant to adopting the criminal history records check provisions specified herein. As described, we will adopt all protocols issued by the FBI. However, we are interested in any other privacy concerns that interested parties may have in addition to thoughts on how best to address these concerns.

In addition, we seek comment on the means by which we can measure the effectiveness of our adoption of criminal history records checks. That is, we are seeking comments on tangible, measureable methods we should use to demonstrate the effectiveness of these provisions.

In addition, we seek comment on whether we should adopt additional technology to identify providers and suppliers that are enrolling in the program. In the proposed rule, we solicited specific comments on this topic. However, we are interested in receiving additional input from providers, suppliers, and other interested parties in light of the provisions set forth in this final rule with comment period.

As noted, we are only seeking comment on the limited areas previously described. We will accept public comment for 60 days following publication of this final rule with comment period. To reiterate, we are finalizing the requirement that providers and suppliers will be subject to criminal history records checks in the event they are considered within the "high" level of risk as described in this rule. Providers and suppliers, and all other commenters, are encouraged to submit comments within the 60-day window to assist us in best implementing the requirements that we are finalizing surrounding this

technology. We are interested in hearing input from all stakeholders, including the beneficiary advocacy community, law enforcement, providers, and suppliers that are subject to the requirements set forth in this final rule with comment period, and any other interested parties.

B. Application Fee—Medicare, Medicaid, and CHIP

1. Statutory Changes

Section 6401(a) of the ACA, as amended by section 10603 of the ACA, amended section 1866(j) of the Act and requires the Secretary of DHHS to impose a fee on each "institutional provider of medical or other items or services or supplier." The fee would be used by the Secretary to cover the cost of screening and to carry out screening and other program integrity efforts, including those under section 1866(j) and section 1128J of the Act. Since section 10603 of the ACA excludes eligible professionals, such as physicians and nurse practitioners, from paying an enrollment application fee, we maintain that an "institutional provider" would be any provider or supplier that submits a paper Medicare enrollment application using the CMS–855A, CMS–855B (not including physician and non-physician practitioner organizations), CMS–855S or associated Internet-based PECOS enrollment application.

Section 1866(j)(2)(D)(i) of the Act states that the new screening procedures implemented pursuant to section 6401 of the ACA would be applicable to newly enrolling providers, suppliers, and eligible professionals who are not enrolled in Medicare, Medicaid, or CHIP by March 25, 2011. Accordingly, the enrollment application fees for newly enrolling institutional providers and suppliers would be applicable on that date as well.

Section 1866(j)(2)(D)(ii) of the Act states that the new screening procedures will apply to currently enrolled Medicare, Medicaid, and CHIP providers, suppliers, and eligible professionals beginning on March 23, 2012. However, because the new procedures are applicable beginning on March 25, 2011 for those providers, suppliers, (and eligible professionals) currently enrolled in Medicare, Medicaid, and CHIP that revalidate their enrollment information, we will begin collecting the application fee for those revalidating entities for all revalidation activities beginning after March 25, 2011.

Section 1866(j)(2)(C)(ii) of the Act permits the Secretary, acting through CMS, to, on a case-by-case basis, exempt a provider or supplier from the imposition of an application fee if CMS determines that the imposition of the enrollment application fee would result in a hardship. It also permits the Secretary to waive the enrollment application fee for Medicaid providers for whom the State demonstrates that imposition of the fee would impede Medicaid beneficiaries' access to care.

Section 1866(j)(2)(C)(i)(I) of the Act establishes a $500 application fee for providers and suppliers in 2010. For 2011 and each subsequent year, the amount of the fee would be the amount for the preceding year, adjusted by the percentage change in the consumer price index for all urban consumers (all items; United States city average), (CPI–U) for the 12-month period ending with June of the previous year. To ease the administration of the fee, if the adjustment sets the fee at an uneven dollar amount, we will round the fee to the nearest whole dollar amount.

2. Proposed Application Fee Provisions

In § 424.502, we also proposed to establish a definition for an "institutional provider" as it relates to the submission of an application fee. We proposed that an "institutional provider" means any provider or supplier that submits a paper Medicare enrollment application using the CMS–855A, CMS–855B (but not physician and nonphysician practitioner organizations), or CMS–855S or associated Internet-based PECOS enrollment application.

For purposes of Medicare, Medicaid, and CHIP, we interpret the statutory reference to "institutional provider[s] of medical or other items or services or supplier" to include, but not be limited to: The range of ambulance service suppliers; ASCs; CMHCs; CORFs; DMEPOS suppliers; ESRD facilities; FQHCs; histocompatibility laboratories; HHAs; hospices; hospitals, including but not limited to acute inpatient facilities, inpatient psychiatric facilities (IPFs), inpatient rehabilitation facilities (IRFs), and physician-owned specialty hospitals; CAHs; independent clinical laboratories; IDTFs; mammography centers; mass immunizers (roster billers); OPOs; outpatient physical therapy/occupational therapy/speech pathology services, portable x-ray suppliers; SNFs; radiation therapy centers; RNHCIs; and RHCs.

In addition to the providers and suppliers listed previously, for purposes of Medicaid and CHIP, we proposed that a State may impose the application fee on any institutional entity that bills the State Medicaid program or CHIP on a fee-for-service basis, such as: Personal care agencies, non-emergency transportation providers, and residential treatment centers, in accordance with the approved Medicaid or CHIP State plan.

We proposed that an application fee will not be required from an eligible professional who reassigns Medicare benefits to another individual or organization, since it would not create a new enrollment of an institutional provider or supplier that would result in an application fee. In addition, we proposed that in no case would the application fee be required from any individual physician or Part B medical group/clinic.

We proposed that an application fee will be required with the submission of an initial enrollment application, the application to establish a new practice location, as a part of revalidation, or in response to a CMS revalidation request.

We proposed that prospective institutional providers and suppliers as well as currently enrolled providers who are revalidating their enrollment in Medicare must submit the applicable application fee or submit a request for a hardship exception to the application fee at the time of filing a Medicare enrollment application on or after March 25, 2011 in the case of prospective providers or suppliers, and in the case of revalidations. We believe that it is essential that we are able to receive and deposit the application fee or consider the institutional provider's request for a hardship exception prior to initiating an application review. Therefore, we would not begin processing an application for either a new provider or supplier, or for a provider or supplier that is currently enrolled, until the enrollment application fee is received and is credited to the United States Treasury.

The fee would accompany the certification statement that the provider or supplier signs, dates, and mails to CMS via the appropriate Medicare contractor if the provider or supplier uses Internet-based PECOS to enroll or revalidate. The fee would accompany the paper CMS–855 provider enrollment application if the provider or supplier enrolls or revalidates by paper. Because the statutory provisions are effective for newly enrolling providers and suppliers effective March 25, 2011 institutional providers and suppliers will not be required to furnish the application fee with applications submitted before that date. However, because the ACA provides that the new procedures will be applicable beginning on March 25, 2011 for those providers and suppliers, (and eligible professionals) currently

enrolled in Medicare, Medicaid, and CHIP that revalidate their enrollment information, we will begin collecting the application fee for those revalidating entities for all revalidation activities beginning after March 25, 2011. We will not collect the fee from individual physicians and eligible professionals.

We proposed that CMS reject and return to the provider or supplier an initial enrollment application submitted by a provider or supplier, without further review as to whether the provider or supplier qualifies to enroll in the Medicare program, when the Medicare enrollment application or the Certification Statement is received by the Medicare contractor and the provider or supplier did not include a request for hardship exception to the application fee, did not include the application fee or the appropriate number of application fees, if applicable. We do not believe that it is appropriate for CMS to begin the application review process without first having received the application fee.

We proposed that the CMS reject any initial enrollment applications submitted after March 23, 2011, if a provider or a supplier did not furnish the application fee at the time of filing, using § 424.525(a)(3) as the legal basis for the rejection.

In § 424.525(a)(3), we proposed adding a new reason why CMS could reject an initial enrollment application or an application to establish a new practice location. Specifically, we proposed a new § 424.525(a)(3) to state, "The prospective institutional provider or supplier does not submit an application fee in the appropriate amount or a hardship exception request with the Medicare enrollment application at the time of filing."

We also believe CMS should be allowed to reject an initial enrollment application received from a provider or supplier on or after March 25, 2011, using § 424.525(a)(1) as the legal basis, if, for any reason, CMS is not able to deposit the full application amount into a government-owned account or the funds are not able to be credited to the U.S. Treasury. In the case where a provider or supplier did not submit the application fee because they requested a hardship exception that is not granted, a provider or supplier has 30 days from the date on which the contractor sends notice of the rejection of the hardship exception request to send in the required application fee and application forms.

In § 424.535, we proposed adding a new reason why a CMS can revoke Medicare billing privileges. Specifically, we proposed a new § 424.535(a)(6)(i) to state that billing privileges may be revoked if "An institutional provider does not submit an application fee or hardship exception request that meets the requirements set forth in § 424.514 with the Medicare revalidation application or the hardship exception is not granted."

In addition, in § 424.535, we proposed a new § 424.535(a)(6)(ii) to state that billing privileges shall be revoked if "CMS is not able to: deposit the full application amount into a government-owned account or the funds are not able to be credited to the U.S. Treasury."

In § 424.514(b), we proposed that currently enrolled institutional providers and suppliers that are subject to CMS revalidation efforts must submit the applicable application fee or submit a request for a hardship exception to the application fee at the time of filing a Medicare enrollment application on or after March 23, 2011.

In § 424.514(d)(2)(iii), we proposed that institutional providers submit the application fee with each initial application, application to establish a new practice location, or with the submission of an application in response to a CMS revalidation request.

In § 424.514(d)(2), we proposed that the application fee be based on the amount calculated by CMS using the CPI–U for the 12-month period ending June 30 of the previous year and adjusted annually to be effective January 1st of the following year. In § 424.514(d)(2)(v), we proposed that the application fee be non-refundable. Neither the Federal government, its Medicare contractors, State Medicaid agencies or CHIP should be liable for reimbursement of the application fee to the provider or supplier if the application fee has been received by the Medicare contractor and deposited into a government-owned account and, later, during the course of verifying, validating, and processing the information in the enrollment application, CMS appropriately denies the enrollment application. Appropriate denial requires a substantive reason and applications will not be denied over inconsequential errors or omissions or over errors or omissions corrected timely.

In § 424.514(d)(4)(vi), we proposed that a provider or supplier must submit a new application fee if the provider or supplier resubmits a Medicare enrollment application because a previously submitted enrollment application was appropriately denied or rejected. In some cases, a rejected application would be returned to the provider or supplier along with the application fee; in other cases, the application would be denied and the application fee retained by the Federal government because the processing of the application would have already begun. In those latter cases, CMS funds would have been expended for some or all of the required screening involved in processing the application. For example, if a home health agency enrollment application is rejected because the enrollment application, or the certification statement generated by Internet-based PECOS, was not signed, the enrollment application would be rejected and it and the check for the application fee would both be returned to the home health agency. If a home health agency enrollment application is denied based on non-compliance with a provider enrollment requirement or because the HHA did not meet the conditions of participation for its provider type, the enrollment would be denied and the application fee would be retained by the Federal government. If the HHA wishes to send a new enrollment application, it would have to include another application fee with that new enrollment application. Similarly, we propose that a provider or supplier would be required to submit to the Medicare contractor a new application fee with a subsequent enrollment application if, among other things, the previous enrollment application was rejected because the provider or supplier did not timely furnish the Medicare contractor with the applicable supporting documentation or information necessary to complete its review and verification of the previous enrollment application.

In § 424.514(d)(6)(vii), we proposed that the application fee must be able to be deposited into a government-owned account before an enrollment application will be approved.

Because we proposed that a State may rely on the results of the screening conducted by the Medicare contractor to meet the screening requirements for participation in a State Medicaid program or CHIP, we proposed that, for dually participating providers, the application fee would be imposed at the time of the Medicare enrollment application, consistent with the procedures described previously. Additionally, because the purpose of the application fee is to, in part, cover the costs of conducting the provider and supplier screening activities, we proposed that a provider or supplier enrolled in more than one program (that is, Medicare and Medicaid or CHIP, or all three programs) would only be subject to the application fee under Medicare and that the fee would cover

screening activities for enrollment in all programs.

Section 1866(j)(2)(C)(iii) of the Act also permits the Secretary to grant, on a case-by-case basis, exceptions to the application fee for institutional providers and suppliers enrolled in the Medicare and Medicaid programs and CHIP if the Secretary determines that imposition of the fee would result in a hardship. One instance that might support a request for hardship exception is in the event of a national public health emergency where a provider or supplier is enrolling for purposes of furnishing services required as a result of the national public health emergency situation. Such requests will be considered on a case-by-case basis, as required by the statute. In addition, we solicited comments on the appropriate objective criteria that should be used in making a hardship determination and if there are any other circumstances in which such exemptions should be allowed. We also solicited comment on the kinds of documents to be submitted to CMS or its contractor to exhibit hardship, including any comments on the financial or legal records that might be needed to make a determination of hardship. Section 1866(j)(2)(C)(iii) of the Act also permits the Secretary to waive the application fee for providers enrolled in a State Medicaid program for whom the State demonstrates that imposition of the fee would impede beneficiary access to care. We solicited comments on how waivers from the application fee should be implemented for Medicaid-only or dually-participating Medicare and Medicaid providers and suppliers specifically those seeking to furnish services where beneficiary access issues are prevalent, either geographically or in the provision of the services.

We are committed to assuring access to care for program beneficiaries. We are in the process of developing promising practices related to ensuring access in the Medicaid program and CHIP. We also solicited comments on the appropriate criteria that we should consider for purposes of the proposed fee. We were particularly interested in hearing from States, providers, advocates, and other stakeholders relating to concrete examples based on experiences in using specific access criteria.

Based on the statutory requirements for calculating the application fee, we offer the following example for purely illustrative purposes. The initial application fee beginning in 2010 is established by law at $500. However, for the following year, when the annual Consumer Price Index (CPI–U) is calculated for the period ending June 2010, we would recalculate the application fee using the CPI–U. Thus, if the CPI increased by 2.34 percent for the 12 month period ending June 2010, the application fee would be calculated by multiplying the fee for the year by the CPI–U. The $500 application fee established by law on in 2010 would be multiplied by 1.0234 to give $511.70. We would then round to the nearest dollar amount of $512.00. This would be the amount of the fee in effect for 2011, and would apply to applications received after the effective date of the statute—March 25, 2011 for newly enrolling providers and suppliers and for revalidating providers and suppliers. A similar process, based on the CPI–U for the period of July 1, 2010 through June 30, 2011 would be used to calculate the fee that would become effective on January 1, 2012, and that would apply to new and currently enrolled providers or suppliers that submit applications on or after March 23, 2012. In § 424.514(d)(2), we proposed that the annually recalculated application fee amount would be effective for the calendar year during which the application for enrollment is being submitted.

The amount of the application fee that is required of enrolling providers or suppliers, would be the amount that is in effect on the day the provider or supplier mails an enrollment application or Certification Statement, postmarked by the USPS, or if mailed though a private mail service the date of receipt by the Medicare contractor. Because the application fee will become an integral part of the enrollment process, we believe that it is essential that we notify State Medicaid Agencies and the public about any changes in the application fee prior to implementing a change in the fee. Accordingly, we would afford States and the public with at least 30 days' notice of any impending change in the application fee. We will make such notification annually in the **Federal Register** and by issuing guidance to the State Medicaid and CHIP Directors, issuing CMS provider and supplier listserv messages, making announcements at CMS Open Door Forums, and placing information on the CMS Provider/Supplier Enrollment Web page (*http://www.cms.gov/MedicareProviderSupEnroll*).

We proposed that a provider or supplier that believes it is entitled to a hardship exception from the application fee enclose a letter with the enrollment application or, if using Internet-based PECOS, with the Certification Statement, explaining the nature of the hardship. Further, we proposed that we would not begin to process an enrollment application submitted with a letter requesting a hardship exception from the application fee until it makes a decision on whether to grant the exception. Further, we proposed that we a make hardship exception determination within 60 days from receipt of the request from an institutional provider and CMS contractor notify the applicant or enrolled institutional provider or supplier by letter approving or denying the request for a hardship exception. Moreover, if we deny the request for hardship exception, we would provide our reason(s) for denying the hardship exception.

In § 424.530(a)(9), we proposed adding a new reason why CMS can deny Medicare billing privileges. Specifically, we proposed a new § 424.530(a)(9) to state, "An institutional provider's or suppliers "hardship exception" request is not granted and the provider or supplier does not submit the application fee within 30 days of notification that the hardship exception request was not approved."

In § 424.535(a)(6)(i), we proposed adding a new reason why CMS can revoke Medicare billing privileges. Specifically, we proposed a new § 424.535(a)(6)(i) to state, "An institutional provider does not submit an application fee or "hardship exception" request that meets the requirements set forth in § 424.514 with the Medicare revalidation application or the hardship exception request is not granted and the institutional provider does not submit the applicable application form or the application fee within 30 days of being notified that the hardship exception request was denied."

We also proposed that an institutional provider may appeal the determination not to grant a hardship exception from the application fee using the provider enrollment appeals process established in § 405.874 and found in 1866(j)(2) of the Act.

In § 455.460, we proposed that, for those providers who do not participate in Medicare, the State may collect the fee established by the Secretary as outlined previously as the State will be responsible for conducting the provider screening activities for these providers. Total fees collected will be used to offset the cost of the Medicaid and CHIP screening programs. The fees represent an applicable credit under OMB Circular A–87, entitled "Cost Principles for State, Local, and Indian Tribal Governments" (August 31, 2005 (70 FR 51910)), codified at 2 CFR part 225, and made applicable to States by 45 CFR

92.22(b). The cost principles require that the costs a State claims must be reduced by "applicable credits," or "those receipts or reduction of expenditure-type transactions that offset or reduce expense items allocable to Federal awards as direct or indirect costs", (Paragraphs C.1.i., C.4.a. and D.1. of Appendix A to 2 CFR part 225). If the fees collected by a State agency exceed the cost of the screening program, the State agency must return that portion of the fees to the Federal government. CMS will direct these fees to support program integrity efforts as permitted by the ACA.

3. Analysis of and Responses to Public Comments

Below is a summary of the comments we received regarding the proposed enrollment application fee.

Comment: Through section 6401 of the ACA, CMS is authorized to collect and retain an application fee. Some commenters stated that CMS did not explain or justify the purpose behind the enrollment application fee, for enrolled providers of service and suppliers, beyond stating that the Congress mandated it. The commenters urged CMS to explain whether the revalidation/enrollment fee is meant to ensure compliance with a provider's or supplier's reporting responsibilities or to collect monies for the Federal Government.

Response: The ACA authorizes the collection of an application fee to cover costs of screening, including screening required for providers and suppliers that are revalidating their enrollment. The ACA specifies that the fees are to be collected from institutional providers and are to be used for program integrity efforts, including the costs of screening.

Comment: Several commenters questioned whether CMS has the statutory authority to exempt medical clinics and group practices from the application fee. They contended that while section 10603 of the ACA strikes the provision found in section 6401 of the ACA relating to individual provider application fees, section 10603 of the ACA does not establish a waiver for organizational suppliers, such as groups or clinics. They also stated that CMS furnished only a limited discussion of why it decided to give medical groups and clinics an application fee waiver. They stated that CMS should explain why it is giving medical groups and clinics a significant financial benefit by excluding them from the application fee. Another commenter stated that if CMS retains its policy to exempt medical groups and clinics from the application fee, CMS should estimate the annual loss in revenue to the Federal government and explain what this will mean to CMS' efforts to fight fraud, waste and abuse. Another commenter stated that if CMS retains this provision, it should exclude the reference to physician and non-physician practitioner organizations in the proposed definition of institutional provider.

Response: Section 6401(a) of the ACA that adds section 1866(j)(2) of the Act specifically excluded physicians from paying the application fee. Physicians and non-physician practitioners in medical groups and clinics reassign their Medicare billing privileges to those medical group and clinics. As such they would be exempt from the fees.

Comment: One commenter asked if a small group practice would be considered institutional, and whether every practice location would need to submit a separate application fee.

Response: We will clarify that the application fee is not applicable to physicians and non-physician practitioners, regardless if the physician or non-physician practitioner is organized in a small group practice.

Comment: A commenter urged CMS to consider exceptions to the required application fee, which, the commenter stated, could impose a hardship on small home and community based service providers.

Response: We are committed to ensuring access to care and services for beneficiaries and will clarify that a State, in consultation with the Secretary, may waive the application fee for Medicaid-only or CHIP-only providers if the State demonstrates that imposition of such a fee will impede beneficiary access to care.

Comment: A commenter suggested that CMS develop and issue a standard enrollment fee "hardship exception form" that a provider can use when requesting an exception to the fee.

Response: Whereas a standard form might be useful, there could be many situations that justify exception from the fee. We do not want to limit the basis for fee exceptions for providers and suppliers to a pre-established list of circumstances. Accordingly we have not listed options for providers and suppliers to request hardship exceptions from application fees. As indicated in the preamble to the proposed rule, each request will be considered on its own merit on a case-by-case basis.

Comment: A commenter suggested that to avoid processing delays associated with depositing the application fee into a government-owned account, CMS should allow newly-enrolling Medicare, Medicaid and CHIP providers to submit the application fee in advance of submitting a new enrollment application.

Response: We disagree with the commenter's suggestion. We think payments should be clearly associated with the CMS–855 application form. We believe that payments submitted before the CMS–855 could have a greater likelihood of being disassociated with the appropriate CMS–855.

Comment: One commenter stated that since the application fee must be credited to the United States Treasury, CMS should explain how long it will take before the application fee is paid by a provider or supplier and when CMS will receive this money to fight fraud, waste and abuse.

Response: The Treasury Department has existing regulations in place governing the time frame in which received funds must be deposited and made available in the U.S. Treasury. We will be working with the Office of Management and Budget and Department of HHS budget officials to assure that the full amount collected from application fees will accrue to CMS for HHS's program integrity work as required by section 1866(j)(2)(C)(iii) of the Act.

Comment: A commenter requested that CMS explain why an application fee is required by a Competitive Acquisition Program (CAP) Part B Drug Vendor, since this entity does not bill the Medicare program.

Response: Only institutional providers, as defined in the proposed rule, are subject to the application fee. Providers and suppliers that do not bill Medicare on a fee-for-service basis are not subject to the application fee.

Comment: A commenter stated that in exempting medical groups/clinics from the application fee, CMS does not distinguish between clinics owned by physicians/practitioners and non-physicians/non-practitioners.

Response: We did not distinguish between medical groups/clinics on the basis of ownership. Medical groups and clinics are exempt from the fee because as noted previously, they are paid through reassignment of payments from physicians and non-physician practitioners. Physicians, non-physician practitioners and other individual practitioners are not subject to the fee by statute.

Comment: A commenter stated that FQHCs should be exempted from the application fees for two reasons. First, FQHCs, unlike other providers, are not permitted to submit one Medicare enrollment application for all sites, and that consequently, these low-risk entities would pay the majority of the

application fees. Second, a significant portion of an FQHC's budget includes section 330 grant funds. These funds are primarily intended for the care of uninsured and indigent patients. The application fees would take a significant portion of those funds away from the neediest individuals.

Response: While we understand the commenter's concerns, the statute did not exempt FQHCs from the application fee requirement. However, FQHCs can request a hardship exception to the fee.

Comment: A commenter recommended that CMS update the CMS–855A, CMS–855B, and CMS–855S forms to add information about the application fee, including the basis for this fee, the amount of the fee, and where the fee should be mailed.

Response: We agree that providers and suppliers need additional information about the process for submitting the application fee, its basis and intended use. We plan to have such materials available by the effective date of the final regulation. We will make these materials available through our Web site, listservs, open door forums, and other communication methods. We will also share these documents with professional and provider and supplier associations in an effort to provide additional information.

Comment: A commenter noted that section 1866(j)(2)(D)(ii) of the Act states that the application fee would not apply to current providers or suppliers until two years after enactment. However, the commenter argued, CMS was silent on this statutory provision in the proposed rule. The commenter recommended that CMS explain why section 1866(j)(2)(D)(ii) of the Act does not apply to current providers and suppliers and why CMS has decided to apply the provisions in section 1866(j)(2)(D)(iii) of the Act instead.

Response: Section 1866(j)(2)(D) of the Act contains conflicting effective dates for currently enrolled providers and suppliers. In 1866(j)(2)(D)(iii), providers and suppliers that are revalidating are subject to the fee and the other provisions of the proposed rule 180 days after enactment, or September 19, 2010. In section 1866(j)(2)(D)(ii) of the Act the new screening provisions including the fee are effective for currently enrolled providers and suppliers on March 23, 2012. For newly enrolling providers and suppliers the provisions are effective on March 25, 2011. We recognize the conflicting effective dates for the same group of currently enrolled providers and suppliers. As a result, in an effort to promote consistency in the application of the rule, we proposed two effective dates for the provisions of the rule for currently enrolled providers and suppliers. On March 25, 2011, the fees and other requirements of the regulation are applicable for currently enrolled providers that are revalidating their enrollment in the period between March 25, 2011 and March 23, 2012. For all other currently enrolled providers and suppliers, the fees and other provisions of the proposed rule are effective on March 23, 2012, as specified in the statute. The statute authorizes us to begin collecting fees from providers and suppliers that are revalidating as early as September 23, 2010.

Comment: A commenter recommended that—consistent with section 10603 of the ACA–CMS establish an application fee exemption for physicians who are sole proprietorships or sole owners and who provide DMEPOS "incident to" their medical service.

Response: Physicians who are enrolled in Medicare as physicians are exempt from the fee. DMEPOS suppliers, whether owned by physicians or otherwise, are institutional suppliers and as such, are subject to the application fee.

Comment: Several commenters urged an exception from the enrollment fee for: (1) Existing providers, or (2) new providers in under-served areas. A commenter added, however, that such exceptions should be limited to nonprofit and governmental entities with low overall margins. The commenter also stated that CMS should allow enrollment fee exceptions: (1) For existing providers when it is clearly equitable and in the public's interest—since to do otherwise simply transfers limited resources needed for patient care to the enrollment process and constitutes a tax on an otherwise nontaxable entity—and (2) for any new nonprofit or public provider that is proposing to establish services in an underserved area. The commenter did not believe that for-profit providers should qualify for fee waivers because their business model is based on their capacity to generate sufficient capital to start a business and operate profitably.

Response: We recognize that the application fees are a new financial obligation on nonprofit and public providers and suppliers; however, the statute provides no blanket exception for providers and suppliers by financial status. However, the law and rule contain provisions that would allow institutional providers and suppliers to apply for hardship exception to the fees for circumstances that are appropriate to their respective situations. We encourage any provider or supplier that cannot pay the fee to notify us and provide us with justification for the exception.

Comment: A commenter stated that the application fee should be waived for providers that routinely update their Medicare enrollment information more than once in a five-year period (3 years for DMEPOS).

Response: While we do not discourage providers and suppliers from submitting revalidation applications more frequently than the regulatory-prescribed timeframes, we do not believe that the fee should be waived for providers that do so. As stated in the preamble, the application fee is to be used by the Secretary to cover the cost of screening. If the provider or supplier submits a revalidation application on its own volition, we believe it is appropriate to require a fee that would cover the cost of processing that application.

Comment: A commenter, expressing concern about the time it can take for Medicare contractors to process applications, recommended that payment of the enrollment fee be tied to a corresponding obligation of the Medicare contractor to complete the enrollment process within a specified period of time. Specifically, the commenter requested that CMS create a hardship category that would permit an enrollment fee to be refunded to the provider or supplier if the Medicare contractor fails to process the application within a specified period of time (for example, 30 days from the date a completed enrollment is received by the Medicare contractor). The commenter stated that such a policy would create the proper incentive for Medicare contractors to process these applications in a timely fashion. Other commenters, too, stated that the fee should be refunded if the Medicare contractor does not process the application in a timely manner.

Response: We are concerned about any delay in processing enrollment applications. Our enrollment contractors have clear standards in their contracts regarding processing enrollment applications. In fact, we are currently in the process of strengthening such performance standards for all of our contractors. However, the ACA provides that a provider may be exempted from the fee only when the imposition of the fee itself would result in a hardship. We do not interpret the ACA as linking the application fee to contractor performance standards.

Comment: One commenter stated that it appears that physicians who also enroll as DMEPOS suppliers so they can furnish DMEPOS to their own patients

would be expected to pay an enrollment fee. The commenter believes that this would be inconsistent with the congressional decision to exempt physicians and other health professionals from the enrollment fee. It might also cause some physicians and other health professionals to decide against enrolling as DMEPOS suppliers, thus they would no longer be in a position to provide their patients with Medicare-covered DMEPOS. The commenter also stated that CMS should modify its enrollment procedures so that physicians who also wish to provide DMEPOS to their own patients would only need to enroll once, not twice. This approach would simplify the enrollment process for both physicians and CMS.

Response: Physicians that supply DMEPOS services to patients are currently required to enroll as both a physician (for medical services) and as a DMEPOS supplier. The screening required of any DMEPOS supplier, even one that is incident to a physician's practice, is more resource intensive than screening for physicians. Accordingly, we think applying the fee to all DMEPOS suppliers is justified. Moreover, we think it is a necessary component of our efforts to assure overall benefit integrity in Medicare to have all DMEPOS suppliers meet the supplier standards for DMEPOS suppliers. Accordingly, we have no plans to change the requirements as suggested by the commenter. We note in addition that a decision to make any such changes would be outside the scope of this rule.

Comment: A commenter asked why CMS is proposing to exempt a physician or non-physician practitioner organizations from the application fee when they submit a CMS–855B application, but the same physician or non-physician practitioner organization would be required to pay an application fee if they enrolled using the CMS–855S.

Response: The ACA specifically excluded physicians and nonphysician practitioners from paying the application fee. Physicians or non-physician practitioner organizations that elect to apply to enroll in Medicare as an institution or other entity, for example, submitting an CMS–855S to enroll as a DMEPOS supplier, are applying to enroll as an institutional provider not a physician or non-physician practitioner. Accordingly, applications to enroll as institutional providers are subject to submitting the application fee.

Comment: Several commenters stated that a $500 application fee for DMEPOS suppliers who are orthotists and prosthetists is not reasonable, especially on top of the required annual payment for a surety bond, accreditation and to maintain licensure. One of these commenters opposed the proposed rule because it seems redundant in light of other requirements such as accreditation, licensure, non-mandatory OIG compliance plans, and HIPAA. The commenter stated that with reimbursements being cut, expenses increasing, and the government constantly imposing new, unnecessary fees, it is becoming difficult for small businesses to survive in this economy. Several other commenters stated that the fee should be waived for the smallest providers. For community pharmacies, another commenter urged CMS to either: (1) Impose a $500 fee upon initial enrollment and in the case of the addition of new practice locations without imposing any fees for revalidation, or (2) impose a lower fee of $200 if the fee will apply to revalidation, as well as initial enrollment and adding new locations.

Response: The ACA sets the initial fee at $500.00 for all types of institutional providers or suppliers and for revalidating providers. Because the ACA specifies that the money be used for program integrity activities, including screening, we believe it is reasonable and appropriate to impose a fee on new practice location applications which require us to expend resources to screen for example onsite visits or background checks may be required. Also, the ACA specifies the formula for updating the fee. Affected providers and suppliers can request an exception from the fee if they can demonstrate that it poses a hardship.

Comment: A commenter requested clarification as to whether a returned, rejected, or denied application would trigger the need for a provider to resend another fee when it resubmits its application. The commenter also asked whether a provider going from one state to another within Medicare would only be required to submit the fee once.

Response: The proposed rule itemized circumstances when additional fees would be required. The answer to the commenter's question about returned, rejected, or denied applications and whether these actions would trigger a requirement for a new fee will vary depending upon the circumstances. Providers and suppliers that submitted applications that were denied because the provider or supplier did not meet the requirements to enroll would be subject to an additional fee for any new application they submit. Providers and suppliers that submitted an application that could not be processed because of a temporary moratorium would not be required to submit an additional fee. Applications that were accompanied by a request for hardship exception waiver to the fee and for which the hardship waiver request was denied would be required to submit a fee in order for the application to be processed. If, in this latter circumstance, the provider or supplier submitted the fee with the application and the hardship exception waiver request, and the fee was not returned, the provider or supplier would not be required to submit a new fee payment. Providers establishing a new practice location in a different enrollment jurisdiction or as a new provider type would be required to submit a fee for each new practice location or provider type.

Comment: A commenter stated that CMS should allow application fees to be held in escrow when an application is denied.

Response: We think it is important for the fee to be associated clearly and specifically with the application for new enrollment or revalidation at the time the application for enrollment or revalidation is being processed. In this way we avoid any administrative errors involved in associating a fee held in escrow with an instant application. There are a number of reasons it might be complicated to associate an escrowed fee with an application, particularly if the provider or supplier has a different name or identifier, or a large amount of time has elapsed between applying for enrollment or revalidation.

Comment: A commenter believes it was inequitable that institutional providers in the limited level of screening are still subject to the same $500 application fee as providers in the high level of screening. The commenter recognized that this is a matter of statute, but stated that a more equitable policy would be to link the application fee amount to the assigned level of screening, with a zero or minimal fee applicable for facilities in the limited screening level and higher scaled fees applied to the moderate and high screening levels. The commenter also recommended that CMS use the application fee collected from "limited risk" providers to develop prioritized and expedited processes and timeframes for contractor review and approval of initial enrollment applications and revalidations for "limited risk" providers.

Response: The ACA established a flat rate of $500 for application fees to be imposed upon institutional providers and suppliers. In addition, the ACA does not include provisions to link the

fee to assigned screening level. Accordingly, the proposed rule implementing the statute did not link the fee to assigned screening level.

Comment: A commenter stated that for DMEPOS suppliers, requiring a $500 application fee at the time of submission of an enrollment application for each Medicare PTAN is unsupported and improper. A simple $500 fee per company, or paying for up to four facility locations (but not more) per company, or $500 for the first location and $50 for the next 10 makes sense. A flat $500 per location does not make sense according to the commenter, since clearly larger companies with multiple locations pose lower risk.

Response: As mentioned previously, the fee amount is included in the ACA. In addition, the ACA requires each institutional provider to pay the fee. Providers and suppliers will be charged the fee for each form CMS–855 they submit for enrollment or revalidation.

Comment: A commenter stated that CMS should not allow contractors to revoke a provider's billing privileges if an application fee or hardship waiver does not accompany a revalidation application.

Response: We disagree. We believe that the failure to submit an application fee or hardship waiver with a reenrollment or revalidation application should be treated as the equivalent of the non-submission of the application, which is grounds for revocation under regulation § 424.535(a)(6). However, we understand the concern expressed and will instruct our enrollment contractors to contact any enrolling or revalidating provider or supplier that does not submit the fee with the enrollment application and afford an opportunity to submit the fee. Thirty days after the date of the notification, the enrollment contractor would reject the application and revoke the billing privileges of the enrolled provider or supplier that has not submitted the fee. We have modified the regulation provisions in § 424.514(g) to include the 30 day period.

Comment: Several commenters requested clarification that changes of information, reactivations, and contractor-solicited, off-cycle revalidations do not require an application fee.

Response: The ACA authorizes fees for new enrollment and revalidation of enrollment. Simple changes in the CMS–855, for example, new phone numbers, new bank account information, new billing address(es), change in name of provider or supplier, or other such updates, do not constitute a new enrollment or a revalidation of an enrollment and therefore would not be subject to an additional fee.

Comment: A commenter stated that there is no justification to assess new fees to providers to support CMS enforcement activities that should be ongoing in any event. Moreover, CMS' proposed actions, the commenter contended, ignore the much more practical and effective measures to stem fraud and abuse outlined in H.R. 2479, and instead of stopping the fraud at the outset (as seems to be the stated objective) rely unduly on straightforward delays in delivering payments to all providers. This punishes all legitimate providers, and without any assurance that delays will solve the fraud problem.

Response: Section 1866(j)(2)(C) of the Act authorizes the the Secretary to collect application fees from institutional providers and suppliers. This section also specifies that "the amounts collected as a result of the imposition of a fee under this subparagraph shall be used by the Secretary for program integrity efforts, including to cover the costs of conducting screening under this paragraph and to carry out this subsection and section 1128J of the Act." We are implementing the provisions of the statute. The application fees collected will be used for program integrity efforts as specified in the statute.

Comment: A commenter stated that imposition of the fee on physicians who are enrolled as DMEPOS suppliers is unambiguously beyond the scope of CMS's statutory authority, would frustrate congressional intent, and is not warranted, since the vast majority of physicians would not be subject to additional screening.

Response: The fees are only paid by institutional providers and suppliers. If a physician is enrolled as a physician and also as a DMEPOS supplier, the fee is required only for the DMEPOS supplier enrollment.

Comment: A commenter supported CMS's proposal to exempt physicians and non-physician practitioners from the application fee. The commenter stated that with a potential Medicare provider shortage on the horizon, introducing an application fee to these suppliers would only serve to drive more providers out of the Medicare system.

Response: The ACA exempts physicians and non-physician practitioners from paying the application fee.

Comment: A commenter stated that an appropriate course would be to process the application and require that if the application is accepted but the hardship waiver is denied, the application fee will be deducted from future payments. This certainly creates the risk that some applications would be considered for which no application fee payment was ultimately available, but that outcome is offset by the need to avoid draconian requirements with illusory protections.

Response: The ACA requires institutional providers and suppliers that submit an application to enroll in or revalidate their enrollment in Medicare to pay the fee. Contractors should not process applications for new enrollment or revalidation of enrollment without a fee accompanying the application. In the case of an application that is accompanied by a request for a hardship waiver that is denied, the contractor will notify the provider or supplier that a fee is required for further processing. The provider or supplier has the option to submit the fee with the application and waiver request as a contingency to expedite processing should the hardship waiver be denied and the provider or supplier is concerned about delays associated with the time required to provide the fee.

Comment: A commenter expressed concern that there was no exception for governmental providers, including those that are funded by Federal agencies. To permit Medicare and Medicaid, for instance, to impose enrollment fees on Indian and tribal providers merely transfers funds from one health system to Medicare and Medicaid.

Response: Neither the ACA nor the proposed rule provide a blanket exemption from the fee for Federal institutional providers. Accordingly, we are unable to grant such an exception. However, Federal health care providers have the option to seek a hardship exception to the fee, and could request such an exception with any applications submitted to enroll in Medicare as an institutional provider.

Comment: A commenter stated that if an application fee or hardship waiver request is missing from an application, the contractor should—consistent with § 424.520—treat this as a request for additional information and give the provider 30 days to furnish the missing items.

Response: We agree. Consistent with § 424.514(g)(3)(ii), contractors will be instructed to give providers and suppliers 30 days after the provider or supplier receives notification that the request for a hardship waiver is denied to submit the enrollment fee.

Comment: A commenter stated that requiring two enrollment fees for a provider enrolling as two different

Medicare provider types—such as DMEPOS suppliers and mass immunizers—would be inconsistent with CMS' proposed one-fee policy for dually enrolled providers, that is those enrolled in Medicare and Medicaid. Similarly, a commenter stated that if physicians functioning as DMEPOS suppliers for their patients are subjected to the additional screening mechanisms in the "Moderate" and "High" screening levels, many physicians will simply relinquish the services they provide as DMEPOS suppliers with minimal to no benefit to CMS's anti-fraud efforts.

Response: The ACA specifically excludes physicians and nonphysician practitioners from paying the application fee. Physicians or non-physician practitioner organizations that elect to apply to enroll in Medicare as something other than a physician or nonphysician practitioner, for example, submitting an CMS–855S to enroll as a DMEPOS supplier, are applying to enroll as an institutional provider not as a physician or nonphysician practitioner. Accordingly, applications to enroll as institutional providers are subject to submitting the application fee. Individual institutional providers that enroll in Medicare and Medicaid will be required to pay only one application fee per enrollment. Entities or individuals that enroll only in Medicare or only in Medicaid as more than one kind of institutional provider, for example, a DMEPOS supplier and a home health agency, will be required to submit the fee for each enrollment.

Comment: A commenter suggested that providers submit one application for all commonly-owned entities, with addenda to address each specific entity as needed. A single fee for each provider would be paid by the parent. The commenter added that if multiple application fees are required for providers and suppliers wholly owned by the parent entity, a cap of $5,000.00 per year in application fees should be instituted.

Response: The ACA requires each institutional provider to pay the fee, in the amount specified in the statute. In general, most providers and suppliers must report each practice location on the enrollment Form CMS–855; however, the provider or supplier may list multiple practice locations on one Form CMS–855. The rules for DMEPOS suppliers, FQHCs and IDTFs are different; these entities must enroll each practice site separately—with separate for CMS–855. Because of these differences among the different categories of providers and suppliers, we believe it is most prudent to rely upon the requirement that a provider or supplier will simply pay the application fee whenever a Form CMS–855 is submitted.

Comment: A commenter suggests that CMS specifically exempt physical therapists in private practice from paying an enrollment fee when enrolling as a DMEPOS supplier with NSC. The commenter acknowledges that physical therapists in private practice are listed under "eligible professionals."

Response: As with physicians, physical therapists that enroll as individual practitioners will be exempt from the fee. DMEPOS suppliers that are owned by a physical therapist are institutional providers and as a result are subject to the fee.

Comment: A commenter stated that CMS should exempt recertification, re-enrollment, or other actions not related to a change in ownership from the application fee.

Response: The ACA specifically provides for the fee to be paid for revalidating institutional providers, section 1866(j)(2)(C) of the Act.

Comment: A commenter suggested that a provider or supplier enrolled in more than one program (that is, Medicare, Medicaid or CHIP) be subject to only one application fee.

Response: We agree. Dually-participating providers and suppliers will only be subject to the application fee at the time of Medicare enrollment or revalidation.

Comment: A commenter requested clarification on whether a fee is charged: (1) For each individual provider associated with a facility or institution, or (2) per facility. The commenter recommended a sliding fee based on the size and number of employees the facility has.

Response: Under the ACA, a fee is required only from institutional providers. Therefore, if the commenter is referring to individual physicians or non-physician practitioners who are associated with an institutional provider or supplier, the individual physician or non-physician practitioner would not be required to submit an application fee. Only the facility or institutional provider with which they are associated would be required to submit the fee. If the commenter was referring to affiliated entities that would be considered institutional providers, then each of those institutional providers would be required to submit the fee as would the institutional provider with which they are associated.

Comment: The same commenter also recommended a sliding scale for the fee that would be based on the size of the provider or facility and the number of employees.

Response: The application fee is derived from a statutorily-mandated formula. Neither CMS nor the States have the discretion to change the amount of the fee.

Comment: A number of commenters requested clarification regarding whether a State is required to collect the application fee for Medicaid-only or CHIP-only providers, or if the collection of this fee is at a State's discretion. One commenter stated that it should continue to be at a State's discretion.

Response: Section 1866(j)(2)(C)(ii) of the Act requires that the fee be imposed for institutional providers, and the State will be required to collect the fee in the case of Medicaid-only and CHIP-only institutional providers. In addition to the providers and suppliers subject to the application fee under Medicare, Medicaid-only and CHIP-only institutional providers would include nursing facilities, intermediate care facilities for persons with mental retardation (ICF/MR), psychiatric residential treatment facilities, and may include other institutional provider types designated by a State in accordance with their approved State plan. Under section 1866(j)(2)(C)(iii) of the Act, we may grant case-by-case exceptions to the application fee, based upon a demonstration of hardship, and in those instances, the State would not be required to collect the fee from Medicaid-only and CHIP-only institutional providers. Additionally, section 1866(j)(2)(C)(iii) of the Act permits the Secretary to waive the application fee for providers enrolled in a State Medicaid program for whom the State demonstrates the imposition of the fee would impede beneficiary access to care. If a State is concerned that the imposition of the application fee may adversely impact beneficiary access to care, we encourage them to seek a waiver of the fee in those circumstances.

Comment: One commenter asked whether a State could choose to lower the fee from $500 to a different amount, for example, $250.

Response: The amount of the application fee is derived from a statutorily-mandated formula. States do not have discretion to change the amount of the fee that is collected from Medicaid-only or CHIP-only institutional providers.

Comment: One commenter asked that if a State elects not to collect the application fee, would the cost of screening be eligible for FFP.

Response: As stated previously, Section 1866(j)(2)(C)(ii) of the Act requires that the fee be imposed for institutional providers, and the State will be required to collect the fee in the

case of Medicaid—only and CHIP—only institutional providers. However, to the extent that the costs associated with performing the screening exceed the amounts collected as a result of the application fees, these costs would be eligible for FFP.

Comment: One commenter requested that CMS describe the process for determining whether the Medicaid and CHIP application fee exceeds the cost of provider screening.

Response: States will be required to account for the costs of the provider screening program and measure it against total fees collected. If the cost of the program exceeds fees collected, then the State can claim FFP for excess cost. Note, that this requires that principles of OMB Circular A–87 be properly applied and that total fees collected serve as an applicable credit to the Medicaid program.

Comment: One commenter requested that CMS confirm whether the application fee is intended to cover both State and Federal share of the costs.

Response: The application fees collected by the State must be used to offset the total cost, both State and Federal share, of the screening program. As stated in the proposed rule, if the fees collected by a State agency exceed the cost of the State's screening program, the State agency must return that portion of the fees to the Federal Government.

Comment: One commenter asked if States would be eligible for enhanced Federal match for changes to provider enrollment and claims processing systems that implement reporting and screening requirements.

Response: If the changes are to the MMIS for purposes of Medicaid provider enrollment and Medicaid claims processing, then States may be eligible for the enhanced match rate (either 90 percent for enhancements/new functionality or 75 percent for ongoing maintenance and operations). States must contact their CMS Regional Office to determine whether an advance planning document (APD) is required.

Comment: One commenter requested clarification on how the state should record expenditures on necessary MMIS changes to implement the rule, prior to collecting the application fee.

Response: All State share costs including those involving the enhancement and operation of the MMIS in addition to administrative costs related to provider screening and reporting as specified in the proposed regulation (§ 455.460) are to be included in the screening program costs and offset by the application fees collected by the State. We understand that the MMIS costs may be matched at higher rates (90 percent for development and 75 percent for operation). States will be required to report the 10 percent and 25 percent State share of the MMIS costs associated with the screening program and offset the application fee against such costs. In the event that the application fees are greater than the costs for the screening program for any reporting period, the State will refund the difference to CMS. Please refer to OMB Circular A–87, "Cost Principles for State, Local, and Indian Tribal Governments" for guidance in the reporting of the application fees as an applicable credit.

Comment: One commenter asked if the application fee is an allowable cost report expense for Medicaid and CHIP providers.

Response: If a Medicaid-only or CHIP-only institutional provider is subject to the application fee, this could be considered an allowable cost report expense. This determination would be governed by the State's approved reimbursement methodology within its State plan.

Comment: One commenter asked if the amount of the fee could be included in determining a government provider's cost based rates.

Response: Yes, if the application fee is imposed on a government institutional provider, then the amount of the fee could be included in determining the government provider's cost-based rates.

Comment: A few commenters asked if a State is permitted to have the applicant/provider pay the fees associated with fingerprinting and conducting criminal history checks.

Response: The application fee is intended to cover the costs associated with the State's Medicaid or CHIP provider screening program. It is permissible for the State to require the provider to pay the costs associated with capturing fingerprints. However, we expect that the amount of funds collected by imposition of the application fee should be used by the State to fund the costs incurred by the State associated with processing the fingerprints and conducting the criminal background checks.

Comment: A number of commenters stated that local education agencies (that is, public schools) should be exempt from having to pay the application fee.

Response: To the extent that a State determines, consistent with the approved State plan, that a local education agency is an institutional provider for purposes of this provision, then it would be subject to the application fee.

Comment: A few commenters requested that CMS clarify whether the application fee applies to institutional providers only under Medicaid and/or CHIP, and what types of Medicaid and CHIP providers are considered institutional.

Response: We will clarify in the regulation that the application fee does not apply to physicians or other individual non-physician practitioners such as nurse practitioners under Medicaid and/or CHIP. Medicaid-only and CHIP-only institutional providers that would be subject to the application fee include: Medicaid-only nursing facilities, intermediate care facilities for persons with mental retardation (ICF/MR), and psychiatric residential treatment facilities. Additionally, a State may impose the application fee on other types of Medicaid-only or CHIP-only institutional providers, consistent with their approved State plan.

Comment: One commenter asked if pharmacies are considered institutional providers for purposes of the application fee.

Response: In the Medicare program, pharmacies are generally enrolled as DMEPOS suppliers, and thus are considered institutional providers for the purposes of the application fee. Therefore, pharmacies would be subject to the application fee, and it would likely be imposed at the time of Medicare enrollment or revalidation.

Comment: One commenter suggested that the application fee requirement should provide an exception for providers that are required to pay a pre-existing State-level application or certification fee to enroll in the Medicaid program.

Response: The enrollment screening activities are distinct from State-licensing and certification activities that seek to address conditions of participation or structures, processes and outcomes to support quality of care for the beneficiaries. The application fee is intended to support provider screening activities as part of enrollment.

Comment: A number of commenters requested that CMS provide further guidance regarding the manner in which States will be expected to report the costs associated with screening. One commenter specifically requested whether CMS will want screening costs detailed per screening, per provider (for example, detailed travel expenses for site visits) or if a more generic reporting of screening cost is expected.

Response: We anticipate that a State will be required to report the costs associated with its provider screening program on a semi-annual or annual

basis. Although we do not anticipate requiring States to routinely report very detailed information such as detailed travel expenses for a site visit, this information should be maintained by the State and be made available upon request if necessary for conducting an audit or other oversight activities. Additional guidance for States will be forthcoming regarding the specific form and manner of reporting.

Comments: One commenter requested that CMS clarify whether the application fee be designed to include current program integrity activities, or whether the State will be expected to track the increased expenditures of PI activities resulting from this regulation separate from historic PI activities.

Response: The application fee may only be used by the State to offset the cost of the provider screening program. It is not permissible for a State to design the fee in any manner that would include current program integrity activities. If the fees collected by a State agency exceed the cost of the screening program, the State agency must return that portion of fees to the Federal Government.

Comment: One commenter recommended that CMS provide a comprehensive exception for out-of-State providers providing emergency services to managed care members, stating that such an exception would allow for timely access to critical services for managed care enrollees.

Response: After considering the comment, we are not inclined to provide a comprehensive exception to the application fee in this circumstance. We believe that the overwhelming majority of providers that provide emergency services to out-of-State MCO members are dually-participating providers, and would thus be subject to the application fee at the time of Medicare enrollment. Furthermore, there are additional Federal laws that exist to safeguard beneficiary well-being in emergency situations, such as, the Emergency Medical Treatment and Active Labor Act (EMTALA).

Comment: A few commenters stated that each State should have the flexibility to waive the application fee, for particular providers or a class of providers, if it determines that this would help assure access to services for beneficiaries.

Response: We agree and will clarify that a State, in consultation with the Secretary, may waive the application fee for Medicaid-only or CHIP-only providers if the State demonstrates that imposition of such a fee will impede beneficiary access to care.

Comment: One commenter stated that providers who have already paid the fee to their own State's Medicaid or CHIP program should also be exempt, if the provider is already enrolled in one and applies to the other.

Response: We agree that providers enrolled in more than one program, be it Medicare, Medicaid, and CHIP, including Medicaid and CHIP in multiple States must only be required to pay the application fee once.

Comment: One commenter urged CMS to expand the exemption provisions to allow an exemption for providers in medically underserved areas as well as those whose patient population are overwhelmingly Medicaid beneficiaries.

Response: We are committed to assuring access to care and services for program beneficiaries and will clarify that a State, in consultation with the Secretary, may waive the application fee for Medicaid-only or CHIP-only providers if the State demonstrates that imposition of such a fee will impede beneficiary access to care.

Comment: A few commenters expressed concern that requiring providers to pay a non-refundable application fee to participate in the Medicaid program will decrease the likelihood that providers will choose to participate.

Response: We are committed to assuring access to care and services for program beneficiaries and will clarify that a State, in consultation with the Secretary, may waive the application fee for Medicaid-only or CHIP-only providers if the State demonstrates that imposition of such a fee will impede beneficiary access to care.

Comment: A number of commenters requested clarification as to the process that a Medicaid agency would use to determine if a provider has paid an application fee to Medicare or another State. One commenter specifically requested clarification on whether the Medicare revalidation fee is applicable to payments made in one calendar year only when considered for Medicaid program(s). Will waiver programs honor fees made to Medicare? How will Medicaid honor a Medicare fee when the revalidation is a different time period?

Response: The basic concept of the screening and enrollment provisions included in this regulation is that Medicaid will accept Medicare screening for providers that receive payments from both Medicare and Medicaid. For dually-participating providers, the application fee is imposed at the time of Medicare enrollment and no additional screening fee is imposed by the State regardless of the time period or revalidation cycle. For institutional providers that participate only in Medicaid, the State Agency is responsible for assuring that the provisions of the regulation are met. Institutional providers will be required to submit the application fee to only one program. We believe these operational logistics are more appropriately addressed in subregulatory guidance. We will be issuing subregulatory guidance to assist States with the operational aspect of implementing this provision in the near future.

Comment: One commenter supported the proposal that for dually participating providers, the application fee would be imposed at the time of Medicare enrollment.

Response: We agree and are finalizing this provision accordingly.

Comment: One commenter encouraged CMS to consider establishing a lower price point or expedited review for providers in the lower risk group.

Response: The amount of the application fee is derived from a statutorily-mandated formula. Neither CMS nor the States have discretion to change the amount of the fee that is collected from Medicaid-only or CHIP-only institutional providers.

Comment: One commenter requested clarification that ongoing resubmissions do not trigger the application fee and that the fee will merely be levied through the actual recertification process.

Response: The ACA authorizes fees for new enrollment and revalidation of enrollment. Simple changes to the provider enrollment information, that is, new phone numbers, new bank account information, new billing address, change in name of provider or other such updates are not subject to the fee. They will apply to newly-enrolling providers, revalidating providers and creation of new practice locations.

Comment: A commenter noted that the application fee and other provisions are effective on March 23, 2011. The commenter stated, however, that CMS must first complete the notice and comment rulemaking process. The commenter recommended that CMS implement the application fee only after a final regulation has been issued and the public has been given at least 60 days notice.

Response: We agree with the commenter and we are finalizing the regulation in regard to the application fee. It will be displayed for 60 days prior to the effective date on March 25, 2011.

Comment: A commenter stated that some of the provider types listed under

the definition of "institutional provider" do not bill Medicare on a fee-for-service basis. For example, RHCs and FQHCs bill Medicare on a cost-based, all-inclusive rate basis. The commenter believes this distinction is significant because on past occasions when the Congress authorized certain incentive payments and linked those payments to the "fee-for-service" payment, RHCs and FQHCs were excluded from those incentive payment programs. The commenter believes it was unfair to deny certain providers from participating in programs because they are not "fee-for-service," but then mandate their inclusion in other initiatives reserved for "fee-for-service" providers. Moreover, the commenter stated that RHCs and FQHCs are by definition located in areas designated as underserved or serving populations with a demonstrated problem accessing the healthcare delivery system. Imposing an application fee on these providers will only serve as a further barrier to access to care. The commenter believes that the term "institutional providers" should exclude new entities seeking designation as RHCs and FQHCs and include only those providers that bill Medicare on a fee-for-service basis. Another commenter believes that the term "institutional provider" refers to providers whose beneficiaries are institutionalized; the proposed rule's envisioned use of the term is therefore inappropriate. The commenter suggested using the term "non-institutional provider."

Response: In the NPRM, we proposed a definition of institutional provider that does not distinguish among providers or suppliers based on which version of the form 855 they submit, or whether they submit the form electronically. We are finalizing this definition. The distinction on payment methods the commenter suggests is not related to the definition of institutional provider used in this rule. Physician and practitioner organizations are exempt from the application fee by statute; the exemption is not affected by how they are reimbursed. In addition, the inpatient status of patients has no bearing on whether a provider or supplier is considered an institutional provider in this rule. For example, hospitals are institutional providers as are home health agencies and DMEPOS suppliers.

If certain institutional providers and suppliers such as FQHCs and RHCs may face financial obstacles to paying the application fee, they can seek a waiver of the fee based upon a request for a hardship exception for Medicare or a request for a hardship waiver for Medicaid. Newly enrolling institutional providers and suppliers that are seeking such a waiver must submit a request for the hardship exception at the time of filing a Medicare enrollment application on or after March 25, 2011.

Comment: A commenter stated that the proposed rule indicates that the fee will be applied only to those providers that bill "Medicare, Medicaid, or CHIP on a fee-for-service basis." The commenter stated that most Indian and tribal providers are reimbursed either on the encounter rates established annually by CMS and IHS for Indian health programs or on FQHC encounter rates. The commenter requested clarification as to whether Indian and tribal providers will therefore be exempt from the application fee. The commenter added that the proposed rate of increase in the fee has often exceeded the increase in funding for Indian and tribal programs. Finally, the commenter stated that CMS failed to seek an exchange of views, information, or advice from the Tribal Technical Advisory Group (TTAG) or to consult directly with Tribes or confer with urban Indian organizations. Unless Indian and tribal health programs are exempt from these rules, the commenter believes that the effective date should be delayed, discussions with the TTAG and consultation with Tribes held, after which the proposed rules with any changes that result from the advice and consultation be published with a new comment period.

Response: We are statutorily unable to exempt IHS, Tribal, and Urban (I/T/U) Indian health programs from these rules or to delay the effective date. Moreover, we do understand Tribal concerns about not having the opportunity to provide advice on this regulation. All I/T/U's are eligible to apply for the hardship exception to the application fee and CMS is committed to working with Tribes, the TTAG and I/T/Us in implementing requests for hardship exceptions.

4. Final Application Fee Provisions—Medicare, Medicaid, and CHIP

This final rule with comment period finalizes the provision of the proposed rule in regards to the application fees with the following exceptions:

In § 424.514, we modified our proposal as follows:

- Added language to clarify that a provider or supplier may submit both an application fee and hardship exception waiver to avoid delays in the processing of the application if the hardship exception is not approved at § 424.514(a) and (b).
- Added language at § 424.514(d)(2) clarifying that the application fee is non-refundable except in the circumstance where the provider or supplier opts to submit both an application fee and a hardship waiver request and the waiver request is subsequently approved.
- Added language to clarify that if a provider submits a hardship exception request without an application fee, and CMS does not approve the hardship exception request, CMS will notify the provider or supplier and allow the provider or supplier thirty (30) days from the date of notification to submit the application fee at § 424.514(h).
- Added language that specifies that States must collect the applicable application fee from Medicaid-only and CHIP-only providers and suppliers at § 455.460.

C. Temporary Moratoria on Enrollment of Medicare Providers and Suppliers, Medicaid and CHIP Providers

1. Statutory Changes

Section 6401(a) of the ACA amended section 1866(j) of the Act by adding a new section 1866(j)(7) of the Act, which provides that the Secretary may impose temporary moratoria on the enrollment of new Medicare, Medicaid, or CHIP providers and suppliers, including categories of providers and suppliers, if the Secretary determines such moratoria are necessary to prevent or combat fraud, waste, or abuse under the programs.

Section 6401(b)(1) of the Act adds specific moratorium language applicable to Medicaid at section 1902(kk)(4) of the Act, requiring States to comply with any temporary moratorium imposed by the Secretary unless the State determines that the imposition of such moratorium would adversely affect Medicaid beneficiaries' access to care. Section 1902(kk)(4)(B) of the Act further permits States to impose temporary enrollment moratoria, numerical caps, or other limits, for providers identified by the Secretary as being at high risk for fraud, waste, or abuse, if the State determines that the imposition of such moratorium, cap, or other limits would not adversely impact Medicaid beneficiaries' access to care.

Section 1866(j)(7) of the Act uses the term "providers of services and suppliers." Although, as noted previously, the Medicaid program does not use the term "suppliers," section 1902(kk)(4) of the Act refers to "providers and suppliers." In this regulation, for uniformity with sections II A. and B. of this final rule with comment period, we are using the term

"providers and suppliers" in lieu of the term "provider of services and suppliers." We are using the term "provider" or "Medicaid provider" or "CHIP provider" in lieu of the term "provider or supplier" when referring to all Medicaid or CHIP health care providers, including, but not limited to, providers and suppliers of Medicaid items or services, individual practitioners, and institutional providers.

2. Proposed Temporary Moratoria Provisions

a. Medicare

We proposed at § 424.570(a) that we may impose a temporary moratorium on the enrollment of new Medicare providers and suppliers in 6 month increments in situations where—(1) CMS, based on its review of existing data, without limitation, identifies a trend that appears to be associated with a high risk of fraud, waste or abuse, such as highly disproportionate number of providers or suppliers in a category relative to the number of beneficiaries or a rapid increase in enrollment applications within a category suggests that there is a significant potential for fraud, waste or abuse with respect to a particular provider or supplier type or particular geographic area or both; (2) a State has imposed a moratorium on enrollment in a particular geographic area or on a particular provider of supplier type or both; or (3) CMS, in consultation with the HHS OIG or the Department of Justice (DOJ) or both and with the approval of the CMS Administrator identifies either or both of the following as having a significant potential for fraud, waste or abuse in the Medicare program:

- A particular provider or supplier type.
- Any particular geographic area.

As part of the CMS decision making process, we will consider any recommendation from the DOJ, HHS OIG, or the GAO to impose a temporary moratorium for a specific provider or supplier type in a specific geographic area.

We believe that imposing moratoria will, among other things, allow us to review and consider additional programmatic initiatives, including the development of additional regulatory and sub regulatory provisions to ensure that Medicare providers and suppliers are meeting program requirements, beneficiaries receive quality care, and that an adequate number of providers of suppliers exists to furnish services to Medicare beneficiaries.

We also proposed that enrollment moratoria be limited to: (1) Newly enrolling providers and suppliers (that is, initial enrollment applications); and (2) the establishment of new practice locations, not to a change of practice locations. The temporary moratoria will not apply to existing providers or suppliers of services unless they were attempting to expand operations to new practice locations where a temporary moratorium was imposed. Moreover, the temporary moratoria would not apply in situations involving changes in ownership of existing providers or suppliers, mergers, or consolidations.

We also proposed at § 424.570(b) that a temporary enrollment moratorium would be imposed for a period of 6 months, and such moratorium could be extended by CMS in 6 month increments if we continue to believe that a moratorium is needed to prevent or combat fraud, waste, or abuse. The Secretary will re-evaluate whether a moratorium should continue prior to each 6 month expiration date.

We also proposed at § 424.570(c) that we will deny enrollment applications received from providers or suppliers covered by an existing moratorium. We noted that denial of Medicare billing privileges is subject to the administrative review process established in § 405.874. Accordingly, we believe that a provider or supplier also is afforded the right to appeal a Medicare contractor determination to deny enrollment into the Medicare program.

In § 424.530(a)(10), we proposed adding a new reason why we can deny Medicare billing privileges. Specifically, we proposed a new § 424.530(a)(10) to state, "A provider or supplier submits an enrollment application for a practice location in a geographic area where CMS has imposed a temporary moratorium." Further, in § 498.5(l)(4), we proposed that the scope of review for appeals of denials under § 424.530(a)(10) based upon a provider or supplier being subject to a temporary moratorium will be limited to whether the temporary moratoria applies to that particular provider or supplier.

We noted that section 1866(j)(7) of the Act provides that there shall be no judicial review of a temporary moratorium. Accordingly, we proposed that a provider or supplier may administratively appeal an adverse determination based on the imposition of a temporary moratorium up to and including the Department Appeal Board (DAB) level of review.

Finally, we proposed at § 424.570(d) that we may lift a moratorium in the following circumstances: (1) In the case of a Presidentially declared disaster under the Robert T. Stafford Disaster Relief and Emergency Assistance Act, 42 U.S.C. 5121 through 5206 (Stafford Act); (2) circumstances warranting the imposition of a moratorium have abated or CMS has implemented program safeguards to address any program vulnerability that was the basis for the moratorium; or (3) in the judgment of the Secretary, the moratorium is no longer needed.

We also recognized that in a limited number of circumstances a State Medicaid agency may enroll a provider or supplier into Medicaid during the temporary moratorium period established by Medicare. If this occurs and the prospective Medicare provider or supplier applies to enroll in the Medicare program after the temporary moratorium is lifted, we would use the screening tools described in section II.A. of this final rule with comment period.

We also solicited public comment on specific exemptions to the temporary moratoria criteria proposed previously. Prior to imposing a moratorium, we would assess Medicare beneficiary access to the type(s) of services that are furnished by the provider or supplier type and/or within the geographic area to which the moratorium would apply.

We would announce the implementation of a moratorium at any time when it is being imposed. The announcement would be made in the **Federal Register** and we would also address it in other methods or forums, such as Press Releases, at CMS Provider Open Door Forums, in CMS provider listservs, and on the CMS Provider/Supplier Enrollment web page (*http://www.cms.gov/MedicareProviderSupEnroll*). We would also require our Medicare contractors to post the moratorium announcement or note the expiration of a moratorium on their Web sites. Our **Federal Register** announcement would explain in detail the rationale for the moratorium and the rationale for the geographic area(s) in which it would apply.

b. Medicaid and CHIP

Pursuant to section 1902(kk)(4)(A) of the Act, we proposed at § 455.470(a)(2) and (3) that a State Medicaid agency will comply with a temporary moratorium imposed by the Secretary unless it determines that the imposition of such a moratorium would adversely affect beneficiaries' access to medical assistance.

Where the Secretary has imposed a temporary moratorium in accordance with § 424.570, and the State has determined that compliance with such a moratorium would adversely impact Medicaid beneficiaries', or CHIP participants', as the case may be, access

to medical assistance, section 1902(kk)(4)(A)(ii) of the Act creates an exception for the State from complying with the moratorium. We proposed that the State provide the Secretary with written details of the moratorium's adverse impact on Medicaid beneficiaries. Prior to the Secretary imposing such a moratorium in any State, we proposed at § 455.470(a)(1) that the Secretary consult with the State, so that the State may have an opportunity to seek an exception from the moratorium.

Pursuant to section 1902(kk)(4)(B) of the Act, States have authority to impose moratoria, numerical caps, or other limits for providers that are identified by the Secretary as being at "high" risk for fraud, waste, or abuse. We proposed, at § 455.470(b) that where the State identifies a category of providers as posing a significant risk of fraud, waste, or abuse, the State must seek our concurrence with that determination and provide us with written details of the proposed moratorium, including the anticipated duration, and with a substantial justification explaining why disallowing newly enrolling providers would reduce the risk of fraud. We proposed at § 455.470(c) that States' moratoria would be imposed for a period of 6 months and may be extended in 6 month increments.

Section 2107(e)(1) of the Act provides that all provisions that apply to Medicaid under sections 1902(a)(77) and 1902(kk) of the Act apply to CHIP. Accordingly, we proposed in new regulation § 457.990 that all the provider screening, provider application, and moratorium regulations that apply to Medicaid providers also apply in providers that participate in CHIP.

3. Analysis of and Responses to Public Comment

Below is a summary of the comments we received regarding the temporary enrollment moratoria.

Comment: A commenter expressed support for our proposal to establish a moratorium on new providers or new practice locations only when it is believes through the agency's review that a risk of fraud and abuse is detected. The commenter, however, requested CMS to: (1) To review the proposed 6-month timeframe for the moratoria, (2) add more flexibility to the standard if it is determined that 6 months is too long, and (3) give the provider community an opportunity to comment prior to its effective date. Another commenter stated that a moratorium is a drastic remedy that should only be used when CMS can clearly articulate the basis for imposing such an extreme measure. CMS must, in such cases, publish: (1) The data it used to determine a moratorium was necessary, (2) the steps it will take to resolve the issues that gave rise to the need for the moratorium, and (3) when it expects to lift the suspension in new enrollments.

Response: We believe that the rule as proposed directly addressed the timeframe, standards, and process for imposing, explaining the rationale for, and lifting an enrollment moratorium; because we received multiple related comments, this response should be read in conjunction with the discussion of those comments. The ACA gives the Secretary broad authority to impose a temporary moratorium on the enrollment of new providers and suppliers if the Secretary determines that a moratorium is necessary to prevent fraud, waste or abuse in Medicare, Medicaid or CHIP. After considerable discussion within CMS and HHS, the proposed rule was published proposing that an initial temporary enrollment moratorium would be imposed for a period of 6 months, with possible extensions in 6-month increments should the Secretary determine that the moratorium was still needed. The 6-month duration was proposed in the NPRM because it was sufficiently long to enable an assessment of its impact on the circumstances that the moratorium was designed to address. The proposed rule also included criteria for when the Secretary would consider imposition of a temporary enrollment moratorium, and the circumstances under which such a temporary enrollment moratorium would be lifted. The proposed rule also indicated that we would announce the implementation of a moratorium at any time, that the announcement would be made in the **Federal Register**, and that the announcement would explain in detail the rationale for the moratorium and the rationale for the geographic area(s) in which it would apply.

Comment: A commenter stated that advance public notice in the **Federal Register** of a moratorium should be given. The commenter recognized that this may lead to a rush to apply prior to the effective date, but stated that this could be fixed by limiting the length of time for the advance notice to 30–60 days.

Response: A temporary moratorium on enrollment is an action that will only be used if necessary to fight fraud, waste or abuse in Medicare, Medicaid, or CHIP. Moratoria will be imposed only if based on detailed information indicating a problem that can be addressed through a temporary enrollment moratorium. Although not required by the ACA to do so, we will announce the imposition of a moratorium in the **Federal Register**. The announcement would explain in detail the rationale for the moratorium and the rationale for the geographic area(s) in which it would apply. We will not be providing advance notice of any planned moratorium as such a notice would likely cause a rush of enrollments of the type posing the problem that would be addressed by the moratorium.

Comment: Several commenters stated that applying a moratorium to providers whose enrollment applications are pending would be unfair and could—in light of the efforts and cost the provider incurred in attempting to enroll—prove financially harmful. They requested that CMS limit moratoria to new applications, not those already submitted. Another commenter requested that the moratorium not apply to applications submitted prior to public notice of the moratorium being given in the **Federal Register**. Another commenter recommended that CMS explain: (1) What will happen to an application submitted by a new provider when CMS imposes a temporary moratorium, and (2) whether pending applications will be processed when a temporary moratorium is imposed or whether the application will be automatically denied using § 424.530(a)(10).

Response: In the NPRM, we indicated both in the preamble and the proposed regulations that an application to enroll in Medicare from a provider or supplier that is subject to a temporary enrollment moratorium would be denied. With regard to pending applications, we interpret the ACA as applying to pending applications. If a temporary enrollment moratorium is deemed necessary for any provider or supplier type, or for any geographic area, then all enrollment applications from unenrolled providers and suppliers of the type subject to the temporary enrollment moratorium or in the geographic area subject to the moratorium would be denied. However, we will not deny any enrollment for which the Medicare enrollment contractor has completed review of the application and has determined that the provider or supplier meets all the requirements for enrollment and all that remains is to assign appropriate billing number(s) and enter the provider or supplier into PECOS.

Comment: A commenter stated that in CMS's manual instructions, it describes

a provider enrollment fraud detection program for high-risk areas, but that this process is not discussed in the proposed rule. The commenter requested that CMS explain the nexus, if any, between this fraud detection program and the policy described in the temporary moratorium provisions contained in this proposed rule. The commenter also requested that CMS explain whether it will use data submitted or obtained from its contractors in determining whether to impose a temporary moratorium.

Response: We plan to revise our manuals to be consistent with the provisions of the final rule with comment period. We plan to use data from many sources in making a decision about imposing a temporary moratorium—including data from our contractors.

Comment: One commenter recommended that CMS: (1) Explain why it is not using section 1866(j)(3) of the Act, related to a provisional period of enhanced oversight for new providers and suppliers, in the process of establishing a temporary moratorium, and (2) publish a **Federal Register** Notice explaining its reasons and rationale for establishing a temporary moratorium for a provider or supplier.

Response: Section 1866(j)(3) of the Act is not a part of this final rule with comment period. Moreover, its provisions can be implemented by subregulatory instructions. We plan to implement the provisions in that fashion and in concert with the provisions of this rule and other CMS regulations governing program integrity. As stated in a response to a previous comment, we will publish a notice of imposition of a temporary enrollment moratorium in the **Federal Register**.

Comment: One commenter expressed concern that the language associated with the temporary moratoria provision: (1) Is vague, (2) does not provide sufficient information on the specific triggers that would cause CMS to suspect that a provider or group of providers is committing fraud, and (3) does not identify the situations in which the moratoria would be applied. The commenter feared that certain providers or suppliers could be prevented from providing services in a particular area without sufficient grounds and that patient access to care could be hindered in the process. The commenter recommended that CMS specifically define the parameters and triggers that CMS intends to use in imposing or enforcing a moratorium on the enrollment of new Medicare providers or suppliers. Another commenter expressed concern with the general nature of the proposed temporary moratoria provisions because it could lead to an abuse of discretion or arbitrary and capricious decision-making with little recourse beyond the internal review process. The commenter was also concerned with the proposed length of the moratorium, stating that a 6 month period: (1) Cannot be reasonably inferred from the Congress having authorized "temporary" moratoria, (2) cannot be considered "temporary," (3) would have significant consequences for new physicians interested in enrolling in the Medicare program, and (4) should not be extended because there is no congressional authority to do so.

Response: As stated previously, the Affordable Care Act gives the Secretary broad authority to impose a temporary moratorium. After considerable discussion within CMS and HHS, the proposed rule was published proposing that an initial temporary enrollment moratorium would be imposed for a period of 6 months, with possible extensions in six month increments should the Secretary determine that the moratorium was still needed. The 6 month duration was proposed in the NPRM because it was sufficiently long to enable an assessment of its impact on the circumstances that the moratorium was designed to address, and would afford us the opportunity to determine whether the circumstances warranting the imposition of a temporary enrollment moratorium have abated or we have implemented program safeguards to address program vulnerabilities. With regard to the temporary nature of a moratorium, we would note that the NPRM explicitly indicated that an initial moratorium would be for a 6 month period, not an indefinite period. Regarding the impact a temporary enrollment moratorium would have on beneficiary access to care, we stated in the NPRM that we will assess Medicare and Medicaid beneficiaries' and CHIP participants access' to the types of services that are furnished by the provider or supplier type and/or within the geographic area to which the moratorium would apply. We take seriously our responsibility to assure that all Medicare beneficiaries have access to the services and supplies they need. With regard to extending moratoria, we would note that, as stated previously, the Secretary has broad authority to impose a moratorium. The statute confers on the Secretary the responsibility and authority to make the judgment about the need for moratoria—whether initial or an extension—if the circumstances requiring the moratorium are still present.

Comment: A commenter stated that CMS failed to outline the criteria it will use to make the determination that a moratorium is to be extended.

Response: We would not impose a temporary enrollment moratorium without an adequate rationale. Should it be necessary to impose a temporary enrollment moratorium on any provider or supplier type, we will discuss the issues associated with the decision to impose a temporary enrollment moratorium in a public notice in the **Federal Register**.

In the NPRM, we listed some examples of circumstances that could lead to the imposition of a temporary enrollment moratorium in situations where: (1) CMS, based on its review of existing data, identifies a trend that appears to be associated with a high risk of fraud, waste or abuse, such as highly disproportionate number of providers or suppliers in a category relative to the number of beneficiaries or a rapid increase in enrollment applications within a category determines that there is a significant potential for fraud, waste or abuse with respect to a particular provider or supplier type or particular geographic area or both, (2) a State has imposed a temporary enrollment moratorium, or (3) CMS in consultation with the Department of HHS Office of Inspector General or the Department of Justice or both identifies either or both a particular provider or supplier type or a particular geographic area as having significant potential for fraud, waste, or abuse. We also included in the NPRM the reasons a temporary enrollment moratorium could be lifted. The decision to extend a moratorium would be based on the proposals in the NPRM and would take into account the extent to which the conditions necessitating the moratorium were still present.

Comment: A commenter requested clarification regarding the term "geographic area" as it is used in proposed § 424.530(a)(10).

Response: The geographic area referred to in § 424.530(a)(10) is the region that is under a temporary enrollment moratorium. For example, this may constitute a county, a number of counties, state, a number of states, regions, or MSAs.

Comment: A commenter expressed support for CMS's proposal to impose a temporary moratorium on the enrollment of new providers or provider types in a geographic location to prevent fraud and abuse. However, the commenter urged CMS to ensure that such moratoria do not prevent health care providers in the geographic

location from enrolling as an ordering/referring provider, as a moratorium may impair these practitioners from providing Medicare beneficiaries with needed care.

Response: We take seriously our responsibility to assure that all Medicare beneficiaries have access to the services and supplies they need. As a part of this assurance, we would consider the implications of a temporary enrollment moratorium for physicians and other eligible professionals who order and refer services for Medicare. However, enrollment moratoria imposed on provider types will not distinguish between the enrollment purpose, that is, enrollment for the right to bill Medicare versus enrollment solely to order and refer, unless otherwise specified in the **Federal Register**. As stated previously, the notice in the **Federal Register** will both discuss the issues associated such the decision, and identify the provider types subject to the temporary enrollment moratoria. We believe the rationale that supports a decision to put a temporary enrollment moratorium in place for those who bill Medicare should extend to those same types of providers who seek to enroll to order and refer. In addition, the enrollment process solely to order and refer was established by us for those provider types that do not typically enroll in Medicare, such as dentists, other government agency employees (such as the Department of Veterans Affairs), and pediatricians. Therefore, it will be highly unlikely that those who were seeking to enroll in order to bill Medicare will similarly seek to enroll solely to order and refer. Regarding the impact a temporary enrollment moratorium may have on beneficiary access to needed care, we stated in the NPRM that we will assess Medicare beneficiary access to the types of services that are furnished by the provider or supplier type and/or within the geographic area to which the moratorium would apply.

Comment: A commenter supported CMS's statement in the preamble to the proposed rule that a moratorium shall not apply to a change of practice location or to changes of ownership of existing providers or suppliers.

Response: We agree and plan to finalize these provisions.

Comment: A commenter recommended that CMS establish a temporary moratorium on the enrollment of slide preparation Facilities, since these organizations are not authorized by the Congress to enroll in or bill the Medicare program.

Response: It would be premature to identify in this rule any provider or supplier type that might be subject to imposition of a temporary enrollment moratorium. Should it be necessary to impose a temporary enrollment moratorium on any provider or supplier type, we will explain the reasons for the temporary enrollment moratorium in a public notice in the **Federal Register**.

Comment: A commenter recommended that CMS develop and implement a regulatory-defined process to utilize when determining whether or not to mandate a moratorium. The process should effectively prevent any negative impact in quality of and access to care for Medicare beneficiaries or Medicaid program enrollees.

Response: We would consider a number of factors in deciding whether to impose a temporary enrollment moratorium. These are spelled out in the proposed rule and include: situations where: (1) CMS, based on its review of existing data, identifies a trend that appears to be associated with a high risk of fraud, waste or abuse, such as highly disproportionate number of providers or suppliers in a category relative to the number of beneficiaries or a rapid increase in enrollment applications within a category determines that there is a significant potential for fraud, waste or abuse with respect to a particular provider or supplier type or particular geographic area or both, (2) a State has imposed a temporary enrollment moratorium, or (3) CMS in consultation with the Department of HHS Office of Inspector General or the Department of Justice or both identifies either or both a particular provider or supplier type or a particular geographic area as having significant potential for fraud, waste, or abuse.

As mentioned elsewhere, we indicated in the NPRM that prior to imposing a temporary enrollment moratorium we would assess Medicare beneficiary access to the type(s) of services that are furnished by the provider or supplier type and/or within the geographic area to which the moratorium would apply. We also indicated that if a State has determined that compliance with a Medicare imposed moratorium would adversely impact Medicaid beneficiaries' or CHIP participants' access to care, the State would not be required to comply with the moratorium. We and the States take the assurance of adequate access seriously.

Comment: A commenter requested clarification as to the mechanism—for instance, via the **Federal Register**—by which it will announce the lifting of a temporary moratorium.

Response: We will announce the imposition of any temporary enrollment moratorium via a notice published in the **Federal Register**. We would also provide notice on our Web sites, listservs, and through open door forums. Similarly, we would provide notice of the lifting of a moratorium in the **Federal Register**. We would also provide notice on our Web sites, listservs, and through open door forums.

Comment: A commenter mentioned that while the preamble of the proposed rule states that CMS will announce a moratorium in the **Federal Register**, the regulation text does not include a reference to **Federal Register**. The commenter recommended that the regulation text match the preamble language.

Response: We agree. We will ensure that the regulation text matches the preamble and other portions of this document.

Comments: A commenter urged CMS to immediately impose the proposed 6 month moratorium on the new certification of HHAs and hospices in its final rule with comment period, stating that there is a clear relationship between rapid development of new home health and hospice providers and the growth in fraud, abuse and waste. The commenter added that this will allow some time for other initiatives and proposals in the proposed rule to reduce fraud and abuse before hundreds of more providers enter the already saturated home health and hospice programs. For home health, the commenter stated that the moratorium should be maintained until new home health conditions of participation (CoPs) are implemented by CMS and other protections against referral abuse can be implemented by the OIG. For hospices, the commenter recommended that the moratorium be maintained until standardized hospice quality measures and payment system reforms are implemented by CMS.

Response: It would be premature to identify any provider or supplier type that might be subject to imposition of a temporary enrollment moratorium, or the circumstances necessitating such an action. Should it be necessary to impose a temporary enrollment moratorium on any provider or supplier type, we will explain the reasons for the temporary enrollment moratorium in a public notice in the **Federal Register**. We specified in the NPRM examples of why a moratorium would be imposed. "Revisions to the HHA Conditions of Participation" is not among the examples we cited for the reason that moratoria are focused on specific kinds of problems or areas, and are to be temporary.

Comments: A commenter requested that CMS clarify the process for timely notifying the State Medicaid agency of a moratorium imposition, and whether the process will include advance notice.

Response: We will be issuing subregulatory guidance to assist States with the operational aspect of implementing this provision in the near future.

Comments: A commenter stated that while a temporary moratorium might be reasonable in some limited situations, CMS should make such decisions based on specialty, not on provider type; for instance, it would be inappropriate for all DMEPOS suppliers to be put under such a moratorium when fraud concerns do not include orthotists and prosthetists.

Response: The ACA gives the Secretary broad authority to impose a temporary enrollment moratorium. We believe that circumstances could justify imposing a temporary enrollment moratorium on a category of providers or suppliers and not a subset within a provider or supplier type. As stated previously, the Secretary would explain the reasons for the moratorium in a **Federal Register** notice.

Comment: A commenter stated that the proposed policies need to be modified to accommodate newly enrolling physicians (and physicians establishing new practice locations) in cases where a moratorium relates to DMEPOS suppliers. In other words, if CMS or a State imposes a moratorium on DMEPOS suppliers, the moratorium should not apply to newly enrolling physicians (or physicians establishing a new practice location) who are now also required to enroll as DMEPOS suppliers if they wish to furnish DMEPOS to their own patients.

Response: In the example cited by the commenter, physicians enrolled as physicians to provide medical care would not be subject to a moratorium on DMEPOS suppliers. Only the new DMEPOS suppliers would be subject to the temporary enrollment moratorium. Physicians would be able to enroll in Medicare as physicians for the purpose of providing medical care (or ordering or referring medical care or services). The moratorium would only apply to the physician if he or she were newly applying to be a DMEPOS supplier in the geographic area covered by the moratorium.

Comment: A commenter suggested that CMS specify that a moratorium will not be imposed unless: (1) There is significant risk of widespread fraud, waste, or abuse in a specified and discrete geographic region, and (2) clear and documented agency analysis showing that the moratorium will not exacerbate health disparities or create additional barriers for underserved communities. Also, CMS should include greater specificity as to what conditions would warrant the imposition of a moratorium and what factors would be considered to ensure that the harm does not outweigh the benefit and will not have a disparate adverse impact on racially and ethnically diverse beneficiaries and physicians.

Response: We appreciate the concerns expressed by the commenter and we are also concerned about the issues of access and disparities. As mentioned previously, we indicated in the proposed rule that prior to imposing a temporary enrollment moratorium we will assess Medicare beneficiary access to the type(s) of services that are furnished by the provider or supplier type and/or within the geographic area to which a moratorium would apply. We also indicated that if a State has determined that compliance with a Medicare imposed moratorium would adversely impact Medicaid beneficiaries' or CHIP participants' access to care, the State would not be required to comply with the moratorium. CMS and the States take the assurance of adequate access seriously. We do not intend to impose a moratorium that would impede access to needed services.

Comment: A commenter expressed concern that CMS's proposed standards for implementing a temporary moratorium on new enrollment of potentially high risk providers and suppliers is too broad, and that CMS could impose a moratorium on new enrollment of all DMEPOS suppliers, even though only a subset of suppliers or a particular region or State poses a high risk of fraud. CMS should specify that it will narrowly limit the moratoria to those provider types or those narrow geographic regions that generate the fraud concerns. In particular, the commenter stated that community pharmacies face the danger that, in the midst of preparing to open up, CMS will impose a moratorium. The commenter urged that the expansion of an existing community pharmacy DMEPOS supplier does not pose a fraud risk and such an expansion should not be subject to a possible moratorium. Another commenter stated that CMS should adopt a more targeted approach to moratoria that takes other relevant factors into consideration, such as the history or trend in proven fraud and/or abusive practices for specific types or categories of providers or suppliers. The commenter believes that painting all providers and suppliers in a particular geographic area with the same broad brush is too extreme a measure, and that CMS should not use geography, by itself, as a determining factor in imposing a temporary enrollment moratorium on all providers and suppliers.

Response: As stated elsewhere in this document, we will publish a notice in the **Federal Register** announcing imposition of a temporary enrollment moratorium. This notice would contain a discussion of the factors associated with the moratorium. Although there are clear differences in the levels of fraud in different geographic areas of the United States, geography by itself without any indication of a risk of fraud, waste or abuse would not be a cause for a moratorium. Community pharmacies generally enroll in Medicare as roster billers for purposes of immunizations, and as such are listed in the limited risk level. DMEPOS suppliers that are owned by a community pharmacy are enrolled in Medicare as DMEPOS suppliers and are subject to the supplier standards for DMEPOS suppliers (except accreditation under certain circumstances). If we, on behalf of the Secretary, determine that a moratorium is needed for any particular provider or supplier type or geographic area or both, we would publish our rationale for the moratorium in our **Federal Register** notice. Decisions to impose a temporary enrollment moratorium would be made based on presenting circumstances. It would not be appropriate to exclude any provider or supplier category, for example, DMEPOS suppliers owned by community pharmacies, from being subject to a moratorium if the circumstances warrant the imposition of a temporary enrollment moratorium.

Comment: Several commenters recommended that CMS also be permitted to lift a moratorium if the Secretary of HHS declares a public health emergency in an area.

Response: The ACA gives the Secretary broad authority to impose temporary enrollment moratoria as a means to combat fraud, waste or abuse. The Secretary has considerable discretion to consider all aspects of the impact of a possible temporary moratorium. In the NPRM we proposed that the Secretary may lift a moratorium in the following three circumstances: (1) The President declares an area a disaster under the Robert T. Stafford Disaster Relief and Emergency Assistance Act, (2) circumstances warranting imposition of moratorium have abated or we have implemented safeguards to address the issue that was the cause of such moratorium, or (3) in the judgment of the Secretary, the moratorium is no

longer needed. Based on the comments received in response to the NPRM, and consistent with the broad authority provided to the Secretary in the Affordable Care Act, we have decided to add a public health emergency declared by the Secretary under section 319 of the Public Health Service Act to the list of circumstances the Secretary could cite in lifting a moratorium. We would closely evaluate these circumstances in the decision to continue a temporary enrollment moratorium.

Comment: A commenter suggested that CMS include the restrictions listed in the preamble regarding temporary moratoria in the regulation text at § 424.570.

Response: It is unclear which provisions included in the preamble of the NPRM are of concern to the commenter. However, we will include any provisions dealing with imposition of temporary enrollment moratoria at § 424.570.

Comment: A commenter asserted that new § 424.570 is inconsistent with the DMEPOS competitive bidding program. Under competitive bidding, a company might win a contract in a competitive bidding area (CBA) where a moratorium exists. If so, the company could not alter its geographic locations to best serve the CBA. The commenter requested that CMS in the final rule with comment period carefully delineate how the competitive bidding program and the proposed temporary moratoria requirements will intersect.

Response: All winners of DMEPOS competitive bidding contracts are required to be enrolled in Medicare as a condition of their contract. As a result, these suppliers would not likely be subject to a moratorium on enrollment after they were awarded a contract, as they would already be enrolled. However, in a situation where a competitive bid winner applied to expand to a new practice location, the new location would need to be enrolled in Medicare. If a moratorium were imposed on DMEPOS suppliers in the area where the competitive bid winner was attempting to enroll a new practice location, the application would in all likelihood be denied based on the existence of a moratorium.

Comment: The same commenter also suggested that: (1) Suppliers with 10 or more provider transaction account numbers (PTANs) be exempt from § 424.570 and (2) CMS allow exceptions for bona fide acquisitions of assets belonging to an existing provider in the area for the protection of the beneficiaries served by the selling provider.

Response: We will be applying the provisions of this rule to all enrolled physicians, individual practitioners, providers and suppliers regardless of the number of PTANs. In addition, as stated in the NPRM, changes in ownership are not subject to moratoria. Moreover, the provisions of this rule do not address the conditions under which a provider or supplier can complete a bona fide acquisition of assets.

Comment: Several commenters stated that new locations of enrolled suppliers should not be subject to a moratorium. Existing suppliers with no history of fraud should not be constrained in their ability to adjust their businesses to best meet the needs of beneficiaries; indeed, beneficiary access could be impaired if new locations were affected by a moratorium. Another commenter stated that applying a moratorium to a new location should only occur when the supplier has an objectively demonstrated history of fraud or for whom CMS has credible evidence of fraud.

Response: As mentioned elsewhere in this document, a temporary enrollment moratorium would not be imposed without adequate rationale. The decision to impose a temporary enrollment moratorium would not be made lightly and would only be pursued should one or more of the conditions for imposing a temporary moratoria exist—as described in the proposed rule. One factor for imposing a moratorium could be that—as stated in the NPRM—there are a disproportionate number of providers or suppliers relative to the number of beneficiaries. For example, currently enrolled providers and suppliers that are trying to enroll in or establish new practice locations in areas subject to a moratorium that has been imposed because there is a disproportionate number of a particular provider category relative to beneficiaries, should not be exempt from the moratorium.

Comment: A commenter stated that given that the intensity of a Certificate of Need program is designed to limit the number of providers to match beneficiary need, an exception to a temporary moratorium should be granted in the presence of such a program. Another commenter agreed that an exemption to the moratorium should be given if the State has a Certificate of Need program and the State determines that there is a need for additional providers. Several commenters also recommended exceptions to a moratorium when a provider is establishing a branch location within its geographic service area. Branch locations are subject to the oversight of the established parent location and operate under the same Medicare provider number. Another commenter stated that the addition of a branch office to an HHA is not the equivalent of "establishing a new practice location."

Response: We have decided not to provide a link to State CON programs because these programs vary in effectiveness and are subject to different standards, coverage and regulations and are not focused on fraud, waste or abuse prevention as would be a temporary enrollment moratorium that is authorized in the ACA. To provide an exemption in States with CON programs would require considerable effort to assure that all provider types are afforded due process and equal treatment. Accordingly, we did not propose an exemption from temporary enrollment moratoria in States with CON programs. We plan to take into account the impact a CON has on provider supply and beneficiary access when deciding to impose a moratorium. Regarding the HHA branch offices, we note that the extent to which the branch office is subject to a moratorium depends on whether the branch office is to be enrolled separately.

Comment: A commenter stated that the proposal to allow unlimited 6 month extensions without thorough documentation of supporting data hardly makes the moratoria temporary and could pose a significant risk to access to quality care for Medicare beneficiaries.

Response: The ACA gives the Secretary broad authority to impose a temporary moratorium on the enrollment of new providers and suppliers if the Secretary determines that a moratorium is necessary to prevent fraud, waste or abuse in Medicare, Medicaid or CHIP. The statute did not provide a specific time period for the duration of a moratorium. After considerable discussion within CMS and HHS, the proposed rule was published proposing that an initial temporary enrollment moratorium would be imposed for a period of 6 months, with possible extensions in 6 month increments should the Secretary determine that the moratorium was still needed. We proposed the 6 month duration because it would be sufficiently long to enable an assessment of its impact on the circumstances that the moratorium was designed to address, and would afford us the opportunity to determine whether the circumstances warranting the imposition of a temporary enrollment moratorium have abated or whether we have implemented program

safeguards to address program vulnerabilities. The 6 month period would also afford the Secretary reasonable opportunity to determine whether the moratorium was no longer needed. With regard to the temporary nature of a moratorium, we would note that the NPRM explicitly indicated that an initial moratorium would be for a 6 month period, not an indefinite period. Regarding the impact a temporary enrollment moratorium would have on beneficiary access to needed care, we stated in the NPRM that we will assess Medicare beneficiary access to the types of services that are furnished by the provider or supplier type and/or within the geographic area to which the moratorium would apply. We take seriously our responsibility to assure that all Medicare beneficiaries have access to the services and supplies they need. With regard to extending moratoria, the statute confers on the Secretary the responsibility and authority to make the judgment about the need for moratoria—whether initial or an extension—if the circumstances requiring the moratorium are still present.

Comment: A commenter stated that as part of the implementation of a temporary moratorium and any extension thereof, CMS should publish data and research that support their decision to impose the moratorium. The data should be thorough and indicate the "actual increased" risk rather than perceived risk for fraud and abuse, in addition to supportive material data. Another commenter added that CMS should ensure that beneficiary access is not curtailed in an area where a moratorium is imposed.

Response: As stated earlier, the ACA gives the Secretary broad authority to impose temporary enrollment moratoria when necessary to prevent or combat fraud, waste or abuse. We will announce any temporary enrollment moratoria in the **Federal Register**, including a discussion of the issues associated with the decision to impose a temporary enrollment moratorium. We are concerned about the effect imposition of a temporary enrollment moratorium would have on beneficiary access, and would consider access to care as one possible factor related to imposition of a moratorium. The ACA specifically mentions access to Medicaid services as a reason that States should consider in making decisions to implement moratoria.

Comment: A commenter stated that the proposed rule should be amended to state that a moratorium does not apply to instances where the new provider is a result of a merger, change of ownership, or consolidation. Also, the fact that the moratorium would not apply where there is a change in practice location should be stated directly in the rule.

Response: We agree. All of these instances are addressed in the final rule with comment period.

Comment: A commenter requested that FQHCs be exempt from any geographical moratoria established by CMS. FQHCs are required to contract with State Medicaid and CHIP programs within certain specified locations. Inclusion in a moratorium would force these FQHCs to provide services without compensation.

Response: The ACA gives the Secretary authority to impose a moratorium when necessary to combat fraud waste and abuse in Medicare, Medicaid, or CHIP. Should there ever be a reason to impose a temporary enrollment moratorium on FQHCs, we would need to be able to do so. As mentioned previously, we indicated in the NPRM that prior to imposing a temporary enrollment moratorium we would assess Medicare beneficiary access to the type(s) of services that are furnished by the provider or supplier type and/or within the geographic area to which the moratorium would apply. We also indicated that if a State has determined that compliance with a Medicare imposed moratorium would adversely impact Medicaid beneficiaries' or CHIP participants' access to care, the State would not be required to comply with the moratorium. We and the States take the assurance of adequate access seriously.

Comment: The commenter also stated that Indian and Tribal providers should be exempt from the temporary moratoria provisions, as their programs are not viable without third-party revenue (especially Medicare and Medicaid) and that a moratorium could impede the programs and harm access to care.

Response: The ACA gives the Secretary authority to impose a temporary enrollment moratorium when necessary to combat fraud, waste and abuse in Medicare, Medicaid, or CHIP. Should there ever be a reason to impose a temporary enrollment moratorium on Indian or Tribal providers, we would need to be able to do so. As mentioned previously, we indicated in the NPRM that prior to imposing a temporary enrollment moratorium we would assess Medicare beneficiary access to the type(s) of services that are furnished by the provider or supplier type and/or within the geographic area to which the moratorium would apply. We also indicated that if a State has determined that compliance with a Medicare imposed moratorium would adversely impact Medicaid beneficiaries' or CHIP participants' access to care, the State would not be required to comply with the moratorium. We and the States take the assurance of adequate access seriously.

Comment: A commenter stated that the moratorium exceptions should be very limited. The commenter agreed with CMS's proposal for an exemption for health crisis situations related to, for example, a natural disaster. The commenter also recommended that exceptions should be granted in areas: (1) With active CON programs, (2) not being served by any provider or (3) where the provider(s) (other than the applicant for the exception) attest that they lack the capacity to meet current demand. Still, the commenter stated that exemptions should only be granted in such exceptional circumstances and not become a vehicle for routine circumvention of the moratorium.

Response: We agree with the intent of these comments. Temporary enrollment moratoria must be considered carefully and the reasons for their imposition must be clear. Prior to imposing a moratorium, we will consider a number of factors, such as, any potential effect on access to care for beneficiaries. CON programs are not factored in to CMS decisions regarding exceptions.

Comment: A commenter requested clarification as to whether the temporary moratoria provisions apply to managed care organizations.

Response: This provision does not apply to Medicaid managed care entities. Medicaid risk based managed care is subject to contracts between States and the managed care entities, and the States rely upon those contracts to ensure that Medicaid beneficiaries have access to providers and a choice of networks within the managed care programs the State maintains. We would not impose moratoria on managed care programs that could restrict the ability of States to ensure beneficiary access and choice.

Comment: A commenter stated that an enrollment moratorium should not apply to publicly traded companies, since CMS can look to the board of directors and similar organizational structures to provide appropriate oversight and accountability. Moreover, after a moratorium is lifted, publicly traded providers and suppliers that were subject to the moratorium should not be lifted to a high screening level; to do so would be inconsistent with CMS's own statements in the preamble that publicly traded providers and suppliers pose a limited risk.

Response: It would be inappropriate for us to identify any one provider or supplier characteristic, such as being publicly traded, as a basis for not being subject to a temporary enrollment moratorium. In addition, as noted below, in the screening portion of this final rule with comment period, we have decided not to draw a distinction between publicly traded and other providers and suppliers. Should there ever be a reason to impose a temporary enrollment moratorium in a geographic area or on a particular provider or supplier category; we would need to be able to do so. We cannot state that there will never be circumstances that warrant imposition of a temporary enrollment moratorium that will affect providers and suppliers that are publicly traded or that these providers and suppliers will never be subject to a temporary enrollment moratorium. We have in response to many comments on this issue, has decided to eliminate the distinction between publicly traded and non-publicly traded status as a determinant of assignment of provider or supplier types to risk levels. Temporary enrollment moratoria will not be imposed without adequate rationale for how the moratorium would address fraud, waste and abuse in Medicare, Medicaid and CHIP. Such moratoria would be imposed based on careful analysis and assessment of circumstances that are present.

Comment: CMS, according to one commenter, states repeatedly that the application of the temporary moratoria could be to either a particular provider or supplier type or a particular geographic area. The commenter urged CMS to reconsider whether it is appropriate to ever apply moratoria on particular geographic areas for all provider and supplier types—such as physicians, whom CMS assigns to the limited level of screening. The commenter believes that physicians should be exempt from geographic provider/supplier enrollment moratoria.

Response: We would not likely impose a temporary enrollment moratorium on all provider and supplier types in a particular geographic area particularly given the potential impact on beneficiary access. However, if circumstances were to be such that a temporary enrollment moratorium in a particular geographic area should apply to all provider and supplier types in that area, we would need to be able to impose such a moratorium. As stated elsewhere in this document, we would publish notice of any moratorium and would include in the notice the rationale for the imposition of a temporary enrollment moratorium. Also, as stated earlier, we would consider access issues as well.

Comment: A commenter urged that the final rule with comment period be revised to clarify that it is only to be used as an option of last resort, when less onerous enforcement efforts have failed to reduce program abuse by a significant number of providers or suppliers of the same type. The commenter also stated that it should be imposed only if there is irrefutable evidence of fraud, waste or program abuse by a significant portion of the population of providers that are targeted by the moratorium.

Response: The ACA gives the Secretary broad authority to impose temporary enrollment moratoria in instances where the Secretary has determined that the moratorium is necessary to combat fraud, waste or abuse in Medicare, Medicaid or CHIP. A moratorium would not be imposed without adequate justification. We would announce in the **Federal Register** the imposition of any temporary enrollment moratorium and would include a discussion of the issues associated with the decision to impose the temporary enrollment moratorium.

In the NPRM, we did list circumstances that could lead to the imposition of a temporary enrollment moratorium in situations where: (1) Based on our review of existing data, identifies a trend that appears to be associated with a high risk of fraud, waste or abuse, such as when a highly disproportionate number of providers or suppliers in a category relative to the number of beneficiaries or a rapid increase in enrollment applications within a category is associated with a significant potential for fraud, waste or abuse with respect to a particular provider or supplier type or particular geographic area or both, (2) a State has imposed a temporary enrollment moratorium, or (3) CMS in consultation with the Department of HHS Office of Inspector General or the Department of Justice or both identifies either or both a particular provider or supplier type or a particular geographic area as having significant potential for fraud, waste, or abuse. We also included in the NPRM the reasons a temporary enrollment moratorium could be lifted. The decision to extend a moratorium would be based on the proposals in the NPRM and would take into account the extent to which the conditions necessitating the moratorium were still present.

Comment: A commenter stated that CMS and Medicaid should be permitted to extend a temporary moratorium by a maximum of one additional 6 month period. Twelve months is more than a sufficient amount of time for CMS to consider additional programmatic initiatives. The commenter added that CMS's statement in the preamble that it "would assess Medicare beneficiary access to the type(s) of services that are furnished by the provider or supplier type and/or within the geographic area to which the moratorium would apply" before imposing a moratorium, should be included in the regulatory text.

Response: We reserve the option to extend a temporary moratorium if circumstances warrant the continuation. We do not want to limit our ability to keep a temporary enrollment moratorium in place if necessary. Conversely, if the Secretary determines that a moratorium is no longer needed, consistent with the provisions of the proposed rule, the moratorium could be lifted at any time. We have modified the regulation text to make this clarification. We will consider safeguards for beneficiary access related to the imposition of an enrollment moratorium at § 424.570.

Comment: A commenter stated that CMS should exempt new practice locations from the moratoria and should limit the moratorium to newly-enrolling providers and suppliers.

Response: Currently enrolled providers and suppliers that are trying to establish additional new practice locations as a means to enroll in areas that are subject to a moratorium, and the provider is of the type for which the temporary enrollment moratorium is imposed, should not be exempt from the moratorium. However, if an enrolled provider or supplier is merely changing its practice location from a current location to a new location—not an additional new location—then that new location would not be subject to a temporary enrollment moratorium.

Comment: A commenter stated that CMS should establish an administrative appeals mechanism to address adverse determinations based on the imposition of a temporary moratorium that would also permit providers and suppliers to question whether CMS has an appropriate statutory or evidentiary basis for imposing a temporary moratorium.

Response: The ACA specifies that there is no judicial review under sections 1869 and 1878 of the Act, or otherwise of the decision to impose a temporary enrollment moratorium

However, as stated in the NPRM, we note that a provider or supplier may use the existing appeal procedures at 42 CFR part 498 to administratively appeal a denial of billing privileges based on the imposition of a temporary moratorium.

Comment: One commenter stated that CMS should allow exceptions to the moratorium, such as: (1) A low ratio of the provider or supplier type to the number of beneficiaries in the targeted area, (2) pandemics and other threats to beneficiary health that would be served by the provider or supplier type, and (3) other circumstances as the Secretary or the State Medicaid director determine are in the best interests of the program.

Response: As discussed previously, the ACA gives the Secretary broad authority to impose temporary enrollment moratoria. We also stated earlier that we listed in the NPRM circumstances that could lead to the imposition of a temporary enrollment moratorium in situations. We also indicated in the NPRM that prior to imposing a temporary enrollment moratorium we would assess Medicare beneficiary access issues. And we indicated that if a State has determined that compliance with a Medicare imposed temporary enrollment moratorium would adversely impact Medicaid beneficiaries', or CHIP participants' access to care, the State would not be required to comply with the temporary enrollment moratorium. We and the States take the assurance of adequate access seriously.

Comment: A commenter believes that CMS moratoria authority was open-ended to the point where CMS could, towards the end of a fiscal year, announce the suspension of provider enrollment in a variety of categories not to stem fraud and abuse, but rather to achieve some budgetary goal of reducing Medicare expenditures. The commenter requested that CMS clarify: (1) Who will decide what constitutes a highly disproportionate number of providers relative to the number of beneficiaries, (2) the standards that will be used to determine the number of providers necessary relative to the number of beneficiaries, and (3) whether this is a de facto return of the certificate of need process.

Response: We proposed and sought comments on factors that would have to be in place to impose a temporary enrollment moratorium, including identifiable trends in CMS data, State imposition of a moratoria, or consultation with the Office of Inspector General or the Department of Justice. The ACA requires that any moratorium imposed be implemented to reduce fraud, waste and abuse in the Medicare, Medicaid and CHIP programs. Additionally, we will not deny any enrollment for which the Medicare enrollment contractor has completed review of the application and has determined that the provider or supplier meets all the requirements for enrollment and all that remains is to assign appropriate billing number(s) and enter the provider or supplier into PECOS. Actively enrolled providers and suppliers will still be reimbursed for claims for services that are provided, and reimbursement would be at levels preceding the moratoria. The process for imposing a moratorium in this rule provides no opportunity for us to use the temporary enrollment moratoria to stop payments to enrolled providers and suppliers, and there is no intention for us to use temporary moratoria for purposes other than the ones authorized under the ACA.

Additionally, as stated previously, we would provide notice in the **Federal Register** of the imposition of a temporary enrollment moratorium and would include a discussion of the issues associated with the decision to impose a temporary enrollment moratorium. We will decide what constitutes a disproportionate number of providers relative to beneficiaries. We indicated in the NPRM that prior to imposing a temporary enrollment moratorium we would assess Medicare beneficiary access to the type(s) of services that are furnished by the provider or supplier type and/or within the geographic area to which the temporary enrollment moratorium would apply. As a part of this process, we would examine the levels of providers in a given area and make a judgment about whether any temporary enrollment moratorium would adversely affect the delivery of needed services to beneficiaries. Regarding Certificate of Need processes, we would note that a number of States use the CON process. We have stated elsewhere in this document that we have not linked this proposed rule to the CON process. The CON programs vary in effectiveness and coverage and are subject to different standards and regulations. If there were a need to impose a temporary enrollment moratorium in any part of a State that has a CON requirement, we would impose the temporary enrollment moratorium in that part of the State, as needed.

Comment: A commenter stated that CMS should exclude from any moratoria those providers and suppliers: (1) Assigned to the limited level of screening, and (2) that have completed and passed a State licensure process. Another commenter urged that a moratorium be applied only to providers included within the moderate or high screening levels, and then only after: (1) Appropriate appeals measures have been established, and (2) CMS has addressed any beneficiary access to care issues.

Response: The ACA provides that the Secretary can impose a moratorium if she decides that it is necessary to combat fraud, waste or abuse. Accordingly the decision to impose a temporary enrollment moratorium will be based on a variety of factors, including the potential risk of fraud in the Medicare program that could be posed by a particular category of provider or supplier in a specific geographic area. The ACA gives the Secretary authority to impose a moratorium when necessary to combat fraud waste and abuse in Medicare, Medicaid, or CHIP. Should there ever be a reason to impose a temporary enrollment moratorium on any category of providers or suppliers, we would need to be able to do so—regardless of the screening level to which they were assigned as part of the provider and supplier screening process described in this regulation. We cannot state that providers and suppliers in the "limited" screening level will never be subject to a temporary enrollment moratorium. Nor are we prepared to state that providers or suppliers that are licensed would never be subject to a temporary enrollment moratorium. With regard to access to care, we indicated in the NPRM that prior to imposing a temporary enrollment moratorium we would assess Medicare beneficiary access to the type(s) of services that are furnished by the provider or supplier type and/or within the geographic area to which the temporary enrollment moratorium would apply. We also indicated that if a State has determined that compliance with a Medicare imposed temporary enrollment moratorium would adversely impact Medicaid beneficiaries', or CHIP participants' access to care, the State would not be required to comply with the temporary enrollment moratorium. We and the States take the assurance of adequate access seriously.

Comment: A commenter stated that while the preamble mentions that advanced notice of a moratorium will be given, this is not specified in the regulation text. The commenter stated that the text should be amended to reflect the advanced notice requirement.

Response: The preamble to the proposed rule says that we will announce the imposition of a temporary enrollment moratorium in the **Federal Register**. The preamble does not say we will give advance notice. We have stated in response to other comments that we do not think we should provide advance notice as this may foster an increase in applications for enrollment in an

attempt to circumvent the intent of the temporary enrollment moratorium. Accordingly, we did not include any language about advance notice in the regulation text.

Comment: A commenter requested clarification as to what the term "significant potential for fraud" means in the context of the moratorium and the datasets that will be used to determine whether such a trend exists.

Response: We offered examples in the NPRM of the kinds of circumstances that might warrant imposition of a temporary enrollment moratorium. We plan to draw on data and information from many sources in coming to a decision about imposition of temporary enrollment moratoria—including existing CMS claims and enrollment data as well as other public data as well as data from our contractors or from law enforcement entities.

Comment: A commenter noted that CMS proposes to allow a Medicare enrollment moratorium where a State Medicaid program has imposed a moratorium on a group of providers who are also eligible to enroll in Medicare. The commenter stated that the proposal does not clarify whether CMS intends for such a moratorium to apply only to those providers within the affected State or whether that moratorium could apply nationwide in the event that the moratorium pertains to provider type. The commenter believes that for a State-imposed moratorium to have such a drastic effect across the country without evidence of a nationwide problem would be an overly broad and unnecessary imposition of CMS authority, and urged CMS to craft this provision more narrowly.

Response: We agree that imposing a moratorium on a national level based on one State's action in its State would be an unnecessarily broad action for us to take. The intent of that provision in the NPRM was to afford Medicare the option to adopt a State moratorium in a State or part of a State if appropriate.

Comment: A commenter stated that in the case of a moratorium, CMS and the States should explain their actions and provide an opportunity for notice and comment.

Response: We have said that we plan to provide notice of imposition of a temporary enrollment moratorium in the **Federal Register**, explaining the rationale for the imposition. We will not be providing an opportunity for comment prior to the imposition of a temporary enrollment moratorium, because it is not a rulemaking effort. Moreover, we think that providing advance notice of a temporary enrollment moratorium might foster a spike in enrollment applications from providers or suppliers that would be subject to the moratorium. If we determine that a temporary enrollment moratorium is needed, we would not want to provide opportunities for providers and suppliers to circumvent the moratorium's purpose.

Comment: A commenter recommended that CMS impose a temporary moratorium nationally on any Medicare-certified HHAs. As an alternative, the commenter suggested a moratorium in any State without either HHA licensure or a certificate of need, or in any State where the growth in new HHAs in the most recent 4 years has exceeded 15 percent.

Response: At this time, we are not contemplating the imposition of national moratoria. Moreover, it would be premature to identify any provider or supplier type that might be subject to imposition of a temporary enrollment moratorium. Should it be necessary to impose a temporary enrollment moratorium on any provider or supplier type, we will explain the reasons for the temporary enrollment moratorium in a public notice in the **Federal Register**.

Comment: One commenter stated that while they are in agreement with the proposal that State Medicaid agencies should have the authority to impose temporary moratoria on the enrollment of new providers or impose numerical caps or other limits on the providers assigned to the high screening level by the Secretary, the State Medicaid agency should also be allowed the discretion to identify providers that are high risk by State standards.

Response: We agree that the State Medicaid agency has the discretion to identify providers that are high risk by State standards. However, section 1902(kk)(4)(B) of the Act explicitly states that the designation of "high risk" providers for purposes of this provision must be made by the Secretary. Thus, we are finalizing the requirement that when a State Medicaid agency identifies a category of providers that are high risk of fraud, waste or abuse by State standards, the State must seek our concurrence with that assignment prior to imposing any type of moratoria, numerical caps or other limits on the enrollment of these providers.

Comment: One commenter requested that the rule be clarified to allow a State to complete any provider enrollment initiated prior to a Federally imposed moratorium.

Response: If a moratorium is deemed necessary, then we believe that all unenrolled providers should be subject to the moratorium. However, we would not require the State to deny any enrollment for which the State has completed its review of the enrollment application and has made a determination that the provider meets all requirements for enrollment.

Comment: A few commenters requested additional information regarding the process that should be used by State Medicaid agencies to notify CMS that imposition of a temporary moratorium would adversely impact beneficiaries' access to medical assistance, including the documentation that will be required and the standards CMS will use for its review.

Response: We believe that additional information regarding the operational processes that should be used by States regarding temporary moratorium are more appropriately addressed in subregulatory guidance. We will be issuing subregulatory guidance to assist States with the operational impact of implementing this provision in the near future.

Comment: Regarding State "identification" of providers with a "significant potential for fraud, waste or abuse," one commenter asked that documentation of the significant risk be required, as well as a description of the rationale used to arrive at numerical caps or other limits on enrollment of that provider type.

Response: Consistent with section 1902(kk)(4)(B) of the Act, when a State Medicaid agency identifies a category of providers that is high risk by State standards, the State must seek our concurrence with that designation prior to imposing any type of moratorium, numerical cap or other limit on the enrollment of these providers. We will expect the State to provide rationale and justification for assigning providers to the high screening level when seeking our concurrence. We will be issuing subregulatory guidance to assist States with the operational aspect of implementing this provision in the near future. We agree a temporary enrollment moratorium should be imposed only with adequate rationale. A temporary enrollment moratorium on any category of provider that a State identifies as posing a significant potential for fraud, waste, or abuse, should be supported by adequate rationale to justify the imposition of a temporary moratorium, numerical caps or other limits on enrollment of that provider type.

Comment: One commenter requested that CMS add an exception where the State has other measures in place that adequately control for the potential fraud, waste, and abuse that is the basis for the proposed moratorium.

Response: The ACA does not allow us to grant such an exception to States even when the State has other fraud controls in place. Additionally, we believe this additional program integrity safeguard is necessary to prevent loss to Medicare, Medicaid and CHIP programs when existing safeguards have not prevented an emergent trend in fraudulent, *wasteful,* or abusive practices. We believe the authority to impose temporary enrollment moratorium when appropriate will be a useful tool for both CMS and the States.

Comment: Several commenters requested clarification regarding whether this requirement applies to Medicaid managed care. These commenters specifically asked CMS to provide an explicit exception to temporary moratoria for Medicaid managed care entities so to ensure that the adequacy of these plans' provider networks is not compromised and in turn, impede beneficiary access to care.

Response: As stated previously, this provision does not apply to Medicaid managed care entities. Medicaid risk based managed care is subject to contracts between States and the managed care entities, and the States rely upon those contracts to ensure that Medicaid beneficiaries have access to providers and a choice of networks within the managed care programs the State maintains. We would not impose moratoria on managed care programs that could restrict the ability of States to ensure beneficiary access and choice.

Comment: One commenter requested the development of a process for an individual provider exemption from a moratorium or, in the alternative, the establishment of a more focused process for imposing any necessary moratoria.

Response: As mentioned previously, we will take action to impose a temporary moratorium only if justified. Accordingly, the decision to impose a temporary enrollment moratorium will be based on the potential risk of fraud, waste or abuse in the Medicare or Medicaid programs.

Comment: A commenter stated that CMS, should it proceed with this proposed rule, must introduce much better controls to limit over-reaching and to assure providers due process rights. The commenter cited CMS's proposed ability to impose a temporary enrollment moratorium on potentially high risk providers and suppliers with no rights of judicial review of the agency's decision. The commenter stated that the absence of defined rights for orthotic and prosthetic suppliers in the proposed rule could, in some instances, appear to be a Federal "taking" without due process.

Response: As stated previously, we will provide a discussion of the factors for imposing a moratorium on a case by case basis when the notice of such a moratorium is published in the **Federal Register**. If a provider or supplier's billing privileges are denied due to the imposition of a temporary enrollment moratorium, the denial of billing privileges can be challenged administratively through the existing enrollment appeal procedures at 42 CFR part 498. Further, we disagree with the commenter's characterization of a temporary moratoria of newly-enrolling providers and suppliers as a Federal "taking."

4. Final Temporary Moratoria on Enrollment of Medicare Providers and Suppliers, Medicaid and CHIP Provisions

This final rule with comment period finalizes the provision of the proposed rule in regards to the temporary enrollment moratoria with the following exceptions:

In § 424.570, we modified our proposal as follows:

- Added language to clarify that we will fully assess the impact of a temporary enrollment moratorium would have on beneficiary access to services that will be subject to the temporary enrollment moratorium at § 424.570(a).
- Added language that specifies we will announce any temporary enrollment moratorium in a notice in the **Federal Register** that will include the rational for the imposition of the moratorium, the particular provider or supplier type or the establishment of new practice locations of a particular type in a particular geographic area at § 424.570(a).
- Added language to clarify that Medicare contractor will deny enrollment applications from a provider or supplier subject to a moratorium specified in paragraph (a) including providers and suppliers with pending enrollment applications, EXCEPT such applications that have been approved by the enrollment contractor before the imposition of a moratorium at § 424.530(a)(10).
- Added language that adopts a public commenter's proposal that the Secretary may lift a temporary enrollment moratorium in the event of a public health emergency in the affected geographic area at § 424.570(d).
- Added language that specifies we will publish notice of lifting the moratorium in the **Federal Register** at § 424.570(d).

D. Suspension of Payments

1. Medicare

a. Background

In section 6402(h) of the ACA, the Congress amended section 1862 of the Act by adding a new paragraph (o), under which the Secretary may suspend payments to a provider or supplier pending an investigation of a credible allegation of fraud unless the Secretary determines that there is good cause not to suspend payments. This section requires that the Secretary consult with the HHS OIG in determining whether there is a credible allegation of fraud against a provider or supplier. For purposes of this Medicare payment suspension regulation, we will refer to providers and suppliers collectively as "providers".

b. Previous Medicare Regulations

We have long been authorized to suspend payments in cases of suspected fraudulent activity. On December 2, 1996, we finalized regulations § 405.370 through § 405.379 that provides for suspension of payments to providers for several scenarios, including when we possess reliable information that fraud or willful misrepresentation exists. The rule provides that we may suspend payments to a provider in whole or in part based upon possession of reliable information that an overpayment or fraud or willful misrepresentation exists or that the payments to be made may not be correct, although additional evidence may be needed for a determination.

The existing rule provides that a suspension of payments is limited to 180 days, unless it meets one of several exceptions. A Medicare contractor may request a one-time only extension of the suspension period for up to 180 additional days if it is unable to complete its examination of the information that serves as the basis for the suspension. Also, OIG or a law enforcement agency may request a one-time only extension for up to 180 additional days to complete its investigation in cases of fraud and willful misrepresentation. The rule provides that these time limits do not apply if the case has been referred to and is being considered by the OIG for administrative action, such as civil monetary penalties. We may also grant an extension beyond the 180 additional days if DOJ requests that the suspension of payments be continued based on the ongoing investigation and anticipated filing of criminal or civil actions. The DOJ extension is limited to the amount

of time needed to implement the criminal or civil proceedings.

c. Proposed Medicare Suspension of Payments Requirements

Section 6402(h) of the ACA requires that the Secretary consult with the OIG in determining whether there is a credible allegation of fraud against a provider. If a credible allegation of fraud exists, the Secretary may impose a suspension of payments pending an investigation of the allegations, unless the Secretary determines that there is good cause not to suspend payments. We proposed to revise § 405.370 to add a definition of what constitutes a "credible allegation of fraud," to include an allegation from any source, including but not limited to fraud hotline complaints, claims data mining, patterns identified through provider audits, civil False Claims Act, and law enforcement investigations. Allegations are considered to be credible when they have indicia of reliability. Many issues related to this definition will need to be determined on a case-by-case basis by looking at all the factors, circumstances and issues at hand. We continue to believe that CMS or its contractors must review all allegations, facts, and information carefully and act judiciously on a case-by-case basis when contemplating a payment suspension, mindful of the impact that payment suspension may have upon a provider.

We received the following comments:

Comment: We received numerous comments suggesting that the proposed definition of "credible allegation of fraud" was ambiguous and fails to detail a precise evidentiary standard that CMS and OIG will employ in determining if a payment suspension is warranted. Commenters were also concerned that including fraud hotline complaints as a source of allegations would inevitably lead to disingenuous allegations from competitors and/or disgruntled former employees that would lead to unjustified payment suspensions.

Response: We did not intend to detail a precise evidentiary standard in this definition; rather we intended to give examples of the typical sources of allegations of fraud and explain that assessing the reliability of an allegation is a process that will occur on a case-by-case basis. CMS and OIG fully understand the need to act judiciously when corroborating information and investigating allegations of fraud, especially when the source of the allegation is an anonymous fraud hotline complaint. The statutorily required consultation between CMS and the OIG prior to implementing a payment suspension will provide ample opportunity for the credibility of an allegation to be assessed and for a preliminary investigation into the allegation of fraud to occur sufficient to meet a reasonable evidentiary standard.

We additionally proposed modifying the existing § 405.370 to add a definition for "resolution of an investigation." The ACA provides for the suspension of payments pending the investigation of a credible allegation of fraud, and we believe that this provision necessitates defining when an investigation has concluded and the basis for the suspension of payments no longer exists. The definition proposed in the proposed rule and finalized here is that a resolution of an investigation occurs when legal action is terminated by settlement, judgment, or dismissal, or when the case is closed or dropped because of insufficient evidence. We solicited comments on an alternative definition of the term "resolution of an investigation" which is that it occurs when a legal action is initiated or the case is closed or dropped because of insufficient evidence to support the allegations of fraud. We did not receive any comments that specifically addressed a preference for either of these definitions.

We proposed modifying the existing § 405.371(a) to differentiate between suspensions based on either reliable information that an overpayment exists or that payments to be made may not be correct, and suspensions based upon a credible allegation of fraud. As required by the ACA, we proposed in this section that CMS or its contractor must consult with the OIG, and as appropriate, the Department of Justice (DOJ) in determining whether a credible allegation of fraud exists prior to suspending payments on the basis of alleged fraud.

We also proposed in accordance with the ACA that we retain discretion regarding whether or not to impose a suspension or continue a suspension, as there may be good cause not to suspend payments or not to continue to suspend payments to providers or suppliers in certain circumstances. We proposed to add a new § 405.371(b) to describe circumstances that may qualify as good cause not to suspend payments or not to continue to suspend payments despite credible allegations of fraud.

In paragraph (b)(1), we proposed a good cause exception based upon specific requests by law enforcement that CMS not suspend payments. There are numerous reasons for which law enforcement personnel might make such a request, including that imposing a payment suspension might alert a potential perpetrator to an investigation at an inopportune or particularly sensitive time, jeopardize an undercover investigation, or potentially expose whistleblowers or confidential sources.

In paragraph (b)(2), we proposed a good cause exception not to suspend payments if we determine that beneficiary access to necessary items or services may be jeopardized. We envision there may be scenarios in which a payment suspension to a provider might jeopardize a provider's ability to continue rendering services to Medicare beneficiaries whose access to items or services would be so jeopardized as to cause a danger to life or health.

In paragraph (b)(3) of the proposed rule, we proposed a good cause exception not to suspend payments if CMS determines that other available remedies implemented by or on behalf of CMS more effectively or quickly protect Medicare funds than would implementing a payment suspension. For example, law enforcement personnel might request that a court immediately enjoin potentially unlawful conduct or prevent the withdrawal, removal, transfer, disposal, or dissipation of assets, either or both of which might protect Medicare funds more fully or quickly than would imposition of a payment suspension.

More generally, in paragraph (b)(4) of the proposed rule, we proposed a good cause exception based upon a determination by us that a payment suspension or continuation of a payment suspension is not in the best interests of the Medicare program. We further proposed that we will conduct an evaluation of whether there is good cause not to continue a suspension every 180 days after the initiation of a suspension based on credible allegations of fraud. We believe that circumstances surrounding a specific case may change as an investigation progresses, and it may become in the best of interests of the Medicare program to terminate a payment suspension prior to the resolution of an investigation. As part of this ongoing evaluation, we will request a certification from the OIG or other law enforcement agency as to whether that agency continues to investigate the matter.

We considered additional specific circumstances and scenarios that may qualify as good cause not to continue a payment suspension prior to the resolution of an investigation, and solicited comments on this approach. For example, one scenario that we considered as additional good cause not to continue a suspension is when a

suspension has been in place for a specific length of time, such as 2 years or 3 years, and the investigation has not been resolved. We anticipated that on a case by case basis, we would evaluate the status of a particular investigation and the nature of the alleged fraud in determining whether keeping a payment suspension in effect beyond a certain length of time may not be in the best interests of the Medicare program. We chose not to propose specific language on duration in the regulatory text. However, we solicited comment on this approach.

Comment: Numerous commenters supported an additional good cause exception not to continue a payment suspension when the accompanying investigation continued beyond a certain length of time. Several commenters supported this exception, however most believe that 2 years or 3 years was much too long for a suspension to be in effect and the length of time associated with this good cause exception should be much shorter.

Response: We agree with the commenters who support the additional good cause exception not to continue a payment suspension when an investigation has continued beyond a certain length of time, in certain cases. We believe that 18 months is the appropriate timeframe for a good cause-based exception beyond which a payment suspension ought not continue except under certain limited circumstances. Therefore, good cause not to continue a payment suspension beyond 18 months shall be deemed to exist unless one of two specific criteria is met. The first of these criteria is if the case has been referred to, and is being considered by, the OIG for administrative action (for example, civil money penalties) or such administrative action is pending. The second of these criteria is if the Department of Justice submits a written request to CMS that the suspension of payments be continued based on the ongoing investigation and anticipated filing of criminal and/or civil actions or based on a pending criminal and/or civil action. We are adopting these two law enforcement specific scenarios that will serve as the criteria for extending a payment suspension beyond 18 months and are based upon the longstanding criteria for extending suspensions found in the Medicare payment suspension regulations.

We proposed modifying the existing § 405.372 to reflect the changes made in § 405.371 which divides the payment suspension authority into situations involving overpayments and situations involving allegations of fraud. In § 405.372(c) we clarify the subsequent action requirements to distinguish between suspensions based on credible allegations of fraud and those that are based on other factors, such as overpayments. For suspensions that are not based on credible allegations of fraud, CMS and its contractors will continue to take timely action to obtain additional information needed to make an overpayment determination and make all reasonable efforts to expedite the determination. Once the determination is made, notice of the determination will be given to the provider or supplier and the payment suspension will be terminated. If the payment suspension is based on credible allegations of fraud, CMS and its contractors will take subsequent action to determine if an overpayment exists or if the payments may be made, however the termination of the suspension and the issuance of a final determination notice to the provider or supplier may be delayed until resolution of the investigation. At the end of the fraud investigation, it is possible that the Medicare contractor will not have completed its overpayment determination, but will have reliable evidence of an overpayment or will have evidence that the payments to be made may not be correct. This typically occurs when a law enforcement investigation results in civil or criminal resolution prior to the Medicare contractor having had sufficient time to complete its overpayment determination. In such a situation, we would allow the suspension to continue as an overpayment suspension.

We proposed modifying the existing § 405.372(d) concerning the duration of suspension of payment. In § 405.372(d)(3) we except suspensions based on credible allegations of fraud from the established time limits specified in paragraphs (d)(1) and (d)(2). We believe the strict time constraints found in paragraphs (d)(1) and (d)(2) should only be applied to suspensions based on reliable information of an overpayment or where payments to be made may not be correct, both of which require a speedy overpayment determination. When credible allegations of fraud are present, we believe we should have the flexibility to maintain a suspension beyond these established time limits in order for an investigation to be completed or the matter to be resolved. However, we noted that by excepting suspensions based on credible allegations of fraud from these previously established timeframes, we do not intend to suspend payments to providers and suppliers indefinitely. We will be actively evaluating the progress of any investigation to determine if good cause exists to no longer continue the suspension of payments, as suspensions are designed to be a temporary measure. As part of this recurring evaluation, we will request a certification from the OIG or other law enforcement agency that the matter continues to be under investigation.

We also proposed eliminating the two other existing scenarios in paragraph (d)(3) for extending payment suspensions beyond the time limits in paragraphs (d)(1) and (d)(2), which are when the OIG is considering administrative action such as civil monetary penalties and also when the DOJ requests an extension based on an ongoing investigation and the anticipated filing of criminal and/or civil actions. We have removed these two scenarios from the existing duration provisions in § 405.372(d), however we have added similar criteria for extending suspensions to the good cause criteria at § 405.371 (b)(3), based on these law enforcement scenarios.

Comment: We received numerous comments raising concern over the perceived lack of due process afforded to the provider community in this proposed rule and numerous comments suggesting that more attention needs to be paid to establishing clear criteria for suspensions and basic due process rights before implementing this provision. Commenters also pointed out that the ACA does not mandate a deadline for implementing this policy and commenters recommend we withdraw the suspension provision from the final rule with comment period and work to develop defined standards with meaningful due process protections.

Response: We believe that the proposed rule affords providers who have had their payments suspended based on credible allegations of fraud ample opportunity to submit information to us in the established rebuttal statement process to demonstrate their case for why a suspension is unjustified. We believe that the criteria for suspension of payments are clear. We reiterate that this authority will be exercised judiciously by CMS, in consultation with the OIG, and that only in the most egregious cases will payment suspensions last longer than the previously established timeframes for payment suspensions. We will not withdraw the suspension provision from the final rule with comment period as we believe the due process

protections are more than adequate and the evidentiary standards for payment suspensions cannot be more precisely defined.

Comment: A commenter suggested that the proposed rule lacks specificity around the required consultation between CMS and the OIG and the DOJ and asked which entity ultimately decides whether an allegation is credible and whether a unanimous determination is required.

Response: We retain the ultimate authority regarding whether or not a payment suspension will be implemented in a given case. The mechanics of the consultation between CMS and our law enforcement partners to determine the credibility of allegations will be detailed in a Memorandum of Understanding between the respective agencies and we do not believe it is appropriate to detail this process in the final rule with comment period.

Comment: A commenter questions why there is no defined time requirement for CMS to provide written notice of a suspension that was imposed without prior notice, similar to the time limits required of States in the Medicaid payment suspension rule.

Response: The Medicare and Medicaid payment suspension rules need not mirror each other in every respect. We have long suspended payments without prior notice to providers in cases of suspected fraud and have an established track record for providing written notice to providers as soon as is practicable after implementing a suspension. We do not believe it is necessary to impose a strictly defined time period for providing notice to providers who were suspended without prior notice based on credible allegations of fraud, and we do not believe that a 30, 60, or 90 day limit is necessary as in nearly all historical cases we have provided notice to providers well within these suggested time limits.

Comment: One commenter expressed concern over CMS treatment of payment suspensions in the cases of overpayments without credible allegations of fraud and pointed out that there are a multitude of scenarios under which physicians might be overpaid due to inadvertent billing errors or Medicare contractor claims processing errors that are no fault of the provider.

Response: We believe that we must retain the ability to suspend payments in both cases of potential fraud and cases that do not involve potential fraud but are based solely on potential overpayments. We have long had the authority to suspend payments without evidence of fraud but historically have not often used the suspension tool in these cases. We will determine on a case-by-case basis whether a suspension of payments is appropriate in cases that do not involve fraud, and factors such as Medicare contractor claims processing errors and provider billing history are certainly considered.

Comment: One commenter requested that CMS provide clarification on whether the proposed rule's suspension provisions apply to the Medicare Part D program and suggested that the proposed rule seems to conflict with legislation and CMS promulgated rules regarding prompt payment of Medicare Part D claims.

Response: The Medicare payment suspension authority is applicable to providers under both the Part A and Part B programs. Separate authorities are available to address potential fraud by plans participating in the Part C and D programs.

Comment: One commenter believes that Federally Qualified Health Centers (FQHCs) should be exempted from the potential application of the suspension of payments because payment to FQHCs is premised on reimbursement of reasonable costs and FQHCs are subject to an annual reconciliation process under which surplus payments in excess of reasonable Medicare costs are returned to the CMS contractor.

Response: All providers in Medicare Part A and Part B are subject to the payment suspension provisions, regardless of the method of reimbursement. The annual reconciliation process under which surplus payments are returned does not necessarily account for credible allegations of fraud and we reserve the right to impose a payment suspension on any provider for whom there is a credible allegation of fraud.

We are adopting the provisions of the proposed rule, with one exception. In § 405.371(b)(3), we state that good cause shall be deemed to exist to not continue to suspend payments if a payment suspension has been in effect for a period of 18 months unless certain conditions are met.

2. Medicaid

a. Background

In section 6402(h) of the ACA, the Congress amended section 1903(i)(2) of the Act to provide that Federal Financial Participation (FFP) in the Medicaid program shall not be made with respect to any amount expended for items or services (other than an emergency item or service, not including items or services furnished in an emergency room of a hospital) furnished by an individual or entity to whom a State has failed to suspend payments under the plan during any period when there is pending an investigation of a credible allegation of fraud against the individual or entity as determined by the State in accordance with these regulations, unless the State determines in accordance with these regulations that good cause exists not to suspend such payments.

b. Previous Medicaid Regulations

State Medicaid agencies have long been authorized to withhold payments in cases of fraud or willful misrepresentation. On December 28, 1987, DHHS finalized regulations at § 455.23 that they described as specifically encouraging State Medicaid agencies to withhold program payments to providers without first granting administrative review where the State agency has reliable evidence of fraudulent activity by the provider. The regulations were issued by the HHS OIG based on a concern that State administrative hearings could interfere with investigations conducted by HHS OIG's Office of Investigations or by the State's Medicaid fraud control unit (MFCU). The requirements of an administrative hearing could jeopardize criminal cases and investigators were reluctant to agree to a State's withholding payment, thus risking additional overpayments. (*See* the December 28, 1987 final rule (52 FR 48814)). The December 28, 1987 final rule remains in effect and has remained unchanged since it was promulgated.

At the time the rule was proposed, the Department was in the process of reorganizing its fraud and abuse regulations to reflect authorities transferred to HHS OIG in 1983, as well as those retained by CMS. HHS OIG authorities were transferred to a new 42 CFR chapter V, while CMS' Medicaid program integrity authorities were retained at 42 CFR part 455. (*See* the September 30, 1986 final rule (51 FR 34764)).

This current rule provides that a State Medicaid agency may withhold payments to a provider in whole or in part based upon receipt of reliable evidence that the need for withholding payments involves fraud or willful misrepresentation under the Medicaid program. At the time this rule was published, commenters questioned what constituted "reliable evidence of fraud." The HHS OIG declined to provide a specific definition, noting that what constitutes "reliable evidence" is not easily and readily definable. The HHS OIG noted that while the existence of an

ongoing criminal or civil investigation against a provider may be a factor in determining whether reliable evidence exists, that reliable evidence should be determined on a case-by-case basis with the State agency looking at all the factors, circumstances, and issues at hand, and acting judiciously on this information.

The 1987 regulations also permitted payments to be suspended in whole or in part. Commenters had suggested that "clean claims" continue to be processed without delay, and that any withholding ought to be targeted to only the type of Medicaid claims under investigation. The HHS OIG responded that it is usually difficult to determine which claims are "clean" until after an investigation has been completed, but noted that where an investigation is solely and definitively centered upon a specific type of claim that a State could, at its discretion, withhold payments on just those types of claims. The HHS OIG also agreed to commenters' requests to clarify that the withholding provisions apply only to alleged fraud or willful misrepresentation related to improperly received Medicaid payments and not to ancillary unrelated matters such as deceptive advertising.

c. Proposed Medicaid Suspension of Payments Requirements

The current regulation at § 455.23 formed the framework for these final regulations. State Medicaid agencies have long had the authority to withhold payments in cases of alleged fraud or willful misrepresentation. Section 6402(h)(2) of the ACA now mandates that States not receive FFP in cases where they fail to suspend Medicaid payments during any period when there is pending an investigation of a credible allegation of fraud against an individual or entity as determined by the State in accordance with these proposed regulations unless the State determines that good cause exists for a State not to suspend such payments. To conform the existing regulation to the terminology of the ACA, we proposed to change the phrase "withhold payments" to "suspend payments," a change we believe is merely semantic.

We proposed to implement section 6402(h)(2) of the ACA by modifying the existing § 455.23(a) to make payment suspensions mandatory where an investigation of a credible allegation of fraud under the Medicaid program exists. Based on the ACA's use of just the term "fraud," we did not propose to retain the existing term "willful misrepresentation." We believe that fraud encompasses willful misrepresentation as well as other acts that may constitute civil or criminal fraud; thus we do not believe this proposal represents a substantive change nor do we intend it to have a substantive effect insofar as reducing or limiting a State's authority to suspend Medicaid payments. We solicited comments on this approach.

To conform the proposed regulation to the requirements of the ACA, we proposed to modify terminology in the existing § 455.23(a) that now refers to "receipt of reliable evidence" to instead refer to a "pending investigation of a credible allegation of fraud." In contrast to the semantic change from "withhold payments" to "suspend payments," in this case we believe that there is a substantive difference between the threshold level of certainty or proof necessary to identify a "credible allegation" versus the heightened requirement of "reliable evidence" in the current regulation.

We do not believe that the phrase "when there is pending an investigation of a credible allegation of fraud" necessarily demands that an investigation originate in or with a law enforcement agency. Rather, State Medicaid agencies have program integrity units that, in the normal course of business, receive, and conduct investigations based upon, tips alleging fraud, and which also conduct proactive investigations based upon internal data analyses and other fraud detection techniques. We believe that State agency investigations, though they may be preliminary in the sense that they lead to a referral to a law enforcement agency for continued investigation, are adequate vehicles by which it may be determined that a credible allegation of fraud exists sufficient to trigger a payment suspension to protect Medicaid funds.

This threshold by which a State agency investigation may give rise to a payment suspension is a somewhat lesser threshold than that in the current regulation. The preamble to the current regulation specified that it was anticipated the State agency would confer with, and receive the concurrence of, investigative or prosecuting authorities prior to imposing a withholding action. However, that preamble also stated that it was establishing mere minimum requirements, and that States could exercise broader power where State law or regulation so provided. Most States have availed themselves of the existing Federal authority (or broader state authority) to withhold payments, and we believe that experience over the past 20 years offers no indication this authority has been misused against providers. Moreover, we believe this proposed threshold is consistent with the phrase "pending investigation of a credible allegation of fraud" of the ACA. We do anticipate that payment suspension authority will be used more frequently because the ACA dictates that where there is a pending investigation of credible allegations of fraud against a provider, a State that fails to suspend payments to that provider will not receive FFP with respect to such payments unless good cause exists not to suspend them.

We proposed to adopt at § 455.2 the same broad definition of "credible allegation" proposed previously in the context of the Medicare program. In many cases, what constitutes a "credible allegation" must be determined on a case-by-case basis with the State agency looking at all the factors, circumstances, and issues at hand. Guided by the experience of more than 20 years, we are aware that States have been able to identify "reliable evidence" through a variety of means including, but not limited to, fraud hotline complaints, Medicaid claims data mining, and patterns identified through provider audits, along with the appropriate level of additional investigation that accompanies each of these. Moreover, States have received referrals from State MFCUs, other law enforcement agencies, and other State benefits program investigative units. We continue to believe that State agencies must review all allegations, facts, and evidence carefully and act judiciously on a case-by-case basis when contemplating a payment suspension, mindful of the impact that payment suspension may have upon a provider.

We proposed at § 455.23(b) that the State agency notify a provider of a payment suspension in a way very similar to the mechanism currently specified in regulation, by which the State agency is required to notify a provider, specifying certain details, within 5 days of taking such action. However, we did propose to provide for a 30-day period, renewable in writing up to twice for a total not to exceed 90 days, by which law enforcement may, in writing, request the State agency to delay notification to a provider. We proposed this because we believe that occasionally an investigation may be at a sensitive stage, perhaps involving undercover personnel or a confidential informant, where required notification to the provider at a particular time might jeopardize the investigation. We do not believe we should extend the delay notification beyond 90 days out of fairness to a provider and, in any event, a provider deriving any significant

revenue stream from Medicaid is likely to itself discern the fact of a payment suspension well in advance of 90 days.

We proposed only minor changes to the current provisions in § 455.23(c) on the duration of a suspension. To comport with the ACA, we change the term "withholding" to "suspension"; this is a semantic change that, as noted previously, has been made throughout. In the new § 455.23(c)(2), we propose to require a State to notify a provider of the termination of a payment suspension and, where applicable, to specify the availability to a provider of any appeal rights under State law and regulation.

Substantively, we did not propose significant change to the existing duration provisions, which specify that withholding (now, suspension) will be temporary and will not continue after: (1) Authorities discern that there is insufficient evidence of fraud upon which to base a legal action; or (2) legal proceedings related to the alleged fraud are completed.

We believe that maintaining the existing duration provisions is consistent with the ACA that requires that FFP not be made when a State fails to suspend payments "during any period when there is pending an investigation of a credible allegation of fraud against an individual or entity." We further recognized that the Act applies a very similar standard to the Medicare program. We solicited comments on our proposal to maintain the existing duration provisions.

In § 455.23(d) of the proposed rule, we proposed to require a State to make a formal, written suspected fraud referral to its MFCU or, where a State does not have a MFCU to an appropriate law enforcement agency, for each instance of payment suspension as the result of a State agency's preliminary investigation of a credible allegation of fraud. This will ensure that an appropriate full investigation by a law enforcement agency timely ensues. If the MFCU or other law enforcement agency declines to accept the referral, we proposed to require the State to immediately release the payment suspension unless the State refers the matter to another law enforcement entity or unless the State has alternative Federal or State authority by which it may impose a suspension. In the latter case, the requirements of that alternative authority, including any notice and due process or other safeguards, will be applicable.

We proposed to require that a State's formal, written suspected fraud referral meets fraud referral performance standards issued by the Secretary. The currently applicable fraud referral performance standards were issued by CMS on September 30, 2008.

In § 455.23(d)(3), we proposed that on a quarterly basis a State must request a certification from the MFCU or other law enforcement agency that any matter accepted on the basis of a referral continues to be under investigation or in the course of enforcement proceedings warranting continuation of the payment suspension. We recognized that due to various constraints, law enforcement agencies may not be able to provide specific updates on matters under investigation. In recognition of the fact that payment suspensions are only temporary, however, we proposed to require such quarterly certifications to ensure, for example, that a suspension will not be continued long after a law enforcement agency has closed an investigation but neglected to alert a State agency of that fact. To maximize State flexibility to implement this requirement, we are not prescribing the precise format such certifications must take.

Consistent with the new ACA provision, we also proposed to create several "good cause" exceptions by which States may determine good cause exists not to suspend payments or to suspend payments only in part. In new § 455.23(e) we included several circumstances that we believe constitute "good cause" for a State to determine not to suspend payments, or not to continue a payment suspension previously imposed, to an individual or entity despite a pending investigation of a credible allegation of fraud. In § 455.23(e)(1), we proposed a good cause exception based upon specific requests by law enforcement that State officials not suspend (or continue to suspend) payment. There are numerous reasons for which law enforcement personnel might make such a request, including that imposing a payment suspension might alert a potential perpetrator to an investigation at an inopportune or particularly sensitive time, jeopardize an undercover investigation, or potentially expose whistleblowers or confidential sources.

In § 455.23(e)(2), we proposed a good cause exception if a State determines that other available remedies implemented by the State could more effectively or quickly protect Medicaid funds than would implementing (or continuing) a payment suspension. For example, law enforcement personnel might request that a court immediately enjoin potentially unlawful conduct or prevent the withdrawal, removal, transfer, disposal, or dissipation of assets, either or both of which might protect Medicaid funds more fully or quickly than would imposition of a payment suspension.

Paragraph (e)(3) proposed a good cause exception based upon a determination by the State agency that a payment suspension is not in the best interests of the Medicaid program. It is conceivable that a State may, in rare situations, face exigent circumstances with respect to a suspension situation not addressed by the other good cause exceptions specified here but where it otherwise determines suspension would not be in the State Medicaid program's best interests. This broad standard is intended to reflect that payment suspension is a very serious action that can potentially lead to dire consequences, but that it is impossible to specify detailed contingencies with respect to every possible scenario that might arise. We did not anticipate that States will frequently make use of this exception; however where this exception is utilized we do require that States document their use of this exception, and will closely monitor its implementation to determine whether further regulation is necessary. We solicited comments on this approach.

In paragraph (e)(4), we proposed a good cause exception based upon a determination by the State of an adverse effect of the suspension on beneficiary access to necessary items or services. We envision there may be scenarios in which a payment suspension to a provider might jeopardize a provider's ability to continue rendering services to Medicaid beneficiaries, thus threatening Medicaid beneficiaries' access to care. Utilizing a standard identical to that which CMS and the HHS OIG apply in assessing requests for waivers of exclusion at Parts 402 and 1001 of Title 42, for example, we posit one basis for a good cause exception from payment suspension is if a provider under investigation is a sole community physician or the sole source of specialized services available in a community. Likewise, in Federally-designated medically underserved areas the potential impact of a payment suspension upon a large provider might equally threaten recipient access, thus this underlies a second access exception. We welcomed comments on this approach, including comments with respect to other metrics by which to assess potential beneficiary jeopardy in terms of access to necessary items or services.

Finally, in paragraph (e)(5) we proposed a good cause exception that would permit (but not require) a State to discontinue an existing suspension to the extent law enforcement declines to cooperate in certifying under the

requirements of paragraph (d)(3) that a matter continues to be under investigation and therefore warrants continuing the suspension.

We do not interpret the new provision in the ACA as mandating that a State must always suspend all payments to a provider in cases of an investigation of a credible allegation of fraud. In general, we continue to believe a payment suspension should apply to all of a provider's claims consistent with the HHS OIG's responses to comments in the 1987 regulations that it is usually difficult to determine which claims are clean claims until after an investigation is completed, and one purpose of payment suspension is to build a type of escrow account out of which any overpayments can be deducted when an investigation is concluded.

With certain new constraints, however, we have chosen to continue to allow States the flexibility to suspend payments in part. For example, as stated in the preamble to the current regulation, there may be times where an investigation is solely and definitively centered on only a specific type of claim in which case a State may determine it is appropriate to impose a payment suspension on only that type of claim. Likewise, a State might determine that an investigation of a credible allegation of fraud is limited to a particular business unit or component of a provider such that a suspension need not apply to certain business units or components of a provider.

Balancing these approaches, we proposed to allow States to implement a partial payment suspension, or, where appropriate, to convert a previously imposed full payment suspension to a partial payment suspension, if justified via a good cause exception. The good cause exceptions for partial suspension at paragraphs (f)(1) and (2) mirror those at paragraphs (e)(4) and (3), respectively, and allow the State to adopt a partial payment suspension where suspension in whole would so jeopardize a recipient's access to items or services as to endanger the recipient's life or health, or where the State deems it in the best interests of the Medicaid program. At paragraph (f)(3), we proposed that a State may avail itself of the good cause exception to suspend payments only in part if the nature of the credible allegation is focused solely and definitively on only a specific type of claim or arises from only a specific business unit of a provider, and the State determines and documents in writing that a payment suspension in part would effectively ensure that potentially fraudulent claims were not continuing to be paid. Many such cases will still demand suspension in full, but this provision, which we anticipate States would exercise sparingly, gives States flexibility to act otherwise in those limited circumstances where appropriate. Finally, at paragraph (f)(4), we proposed that a State may avail itself of the good cause exception to convert a payment suspension in whole to one only in part to the extent law enforcement declines to cooperate in certifying under the requirements of paragraph (d)(3) that a matter continues to be under investigation. We solicited comment on these proposed approaches.

We proposed in new paragraph (g) to add several reporting and document retention guidelines to § 455.23. Payment suspension authority is critically important to protect Medicaid funds, but payment suspension can have dire consequences to a provider. Payment suspension authority, including a State's exercise of a good cause exception to otherwise address a suspension situation, must be exercised responsibly by a State at all stages, from the inception to the termination of the suspension. Through, among other things, our State Program Integrity Reviews, we expect to maintain close oversight of State utilization of suspension authority. However, to be clear, we expressly and explicitly do not expect State compliance (or noncompliance) with these documentation or retention provisions to give rise to any enforceable right of a provider aggrieved by any real or perceived failures with respect to these requirements to seek any form of redress (administratively, judicially, or otherwise).

Under these final reporting and retention guidelines, States are required to maintain for a minimum of 5 years from the date of issuance all materials documenting the life cycle of a payment suspension that is imposed, including: (1) All notices of suspension of payment in whole or part; (2) all fraud referrals to MFCUs or other law enforcement agencies; (3) all quarterly certifications by law enforcement that a matter continues to be under investigation; and (4) all notices documenting the termination of a suspension. Likewise, we proposed to require States to maintain for the same period all documentation justifying the exercise of the good cause exceptions. Finally, we proposed to require States to annually report to the Secretary information regarding the life cycle of each payment suspension imposed and any determinations to exercise the good cause exceptions not to suspend payment, to suspend payment only in part, or to discontinue a payment suspension.

To effectuate section 6402(h)(2) of the ACA's prohibition on expenditure of FFP where a State fails to suspend payments that should, by virtue of the ACA standard and this proposed rule, have been suspended, we proposed to add a new § 447.90. Paragraph (a) of proposed § 447.90 specifies the basis and purpose for the new provision, while paragraph (b) specifies the general rule that FFP would not be available with respect to items or services furnished by an individual or entity to whom the State has failed to suspend Medicaid payments during any period where there is pending an investigation of a credible allegation of fraud against the individual or entity except in specified circumstances that include certain emergency circumstances, or if good cause exists as specified at § 455.23(e) or (f).

As mentioned, we anticipate that CMS' enforcement and monitoring of these provisions will largely be accomplished through measures such as State Program Integrity reviews conducted by CMS. Such reviews will, among other things, evaluate States' complaint intake and investigation efforts, and assess whether States have an effective process to move matters where there are found to be credible allegations of fraud to the point where they are evaluated for payment suspension. However, we do not believe it is viable to require States to report and document to CMS every instance of where any allegation of fraud arises and further qualify which ones rise to the level of credible allegation. We want to foster effective and efficient State program integrity efforts with respect to which payment suspension is an integral component, but we do not want to create a system so procedurally onerous that it overwhelms a State's ability to substantively perform this critical work. Nevertheless, we will thoroughly investigate and act by, among other things, deferring and/or disallowing FFP in accordance with § 430.40 and § 430.42, if program integrity reviews or other methods of ensuring State compliance with Medicaid program requirements reveal a State is failing to suspend payments (or inappropriately applying a good cause exception) where pending investigations of credible allegations of fraud do exist. A State may not claim (on its Form CMS–64) FFP for payments that are suspended. Any State that does not suspend payments, or that suspends payments but continues to claim FFP with respect to what would have been paid had no suspension been in place,

puts that FFP at risk. In such cases, we would pursue a deferral and/or disallowance to reclaim the Federal portion of such payment. We solicited comments on CMS' proposed oversight approach.

Finally, three provisions were proposed to be added to the regulations at § 1007.9 that specify the State MFCU's relationship to, and agreement with, the State Medicaid agency. These proposed revisions were necessary to effectuate the proposed revisions under § 455.23. The regulations at 42 CFR part 1007 are enforced by HHS OIG as part of its delegated authority to certify and fund the State MFCUs. (*See* August 15, 1979 final rule (44 FR 47811). However, we are including amendments to part 1007 here to ensure a comprehensive regulatory package that sets forth in one location the Department's implementation of the suspension provisions of section 6402(h) of the ACA.

The first of these provisions proposes to add a new paragraph (e) to § 1007.9 that specifies that the MFCU may refer to the State agency any provider against which there is pending an investigation of a credible allegation of fraud for purposes of payment suspension in accord with § 455.23. Allegations of potential fraud may first be identified by the MFCU rather than by the State agency, so this provision merely formalizes a path from the MFCU to the State agency so a payment suspension may be implemented where appropriate. This provision also proposed that any referral to the State agency for consideration of a payment suspension be in writing. The written referral need not be extensive, but must include information adequate to enable the State agency to identify the provider and a brief explanation of the credible allegations forming the grounds for the payment suspension. The second proposed addition to § 1007.9 proposed to add a new paragraph (f) providing that any request by the unit to the State agency to delay notification of suspension to a provider pursuant to the provisions of the proposed § 455.23(b)(1)(ii) come in writing. Requiring that such requests be made in writing (which could take the form of an email) provides for an audit trail to ensure that proper procedures are followed. However, we expressly do not intend for this requirement to create any substantive right upon which a provider might lodge objection or other legal challenge to the extent the proper procedures were not followed. Last, a new paragraph (g) was proposed to require the unit to notify the State agency in writing when it has accepted or declined a case referred by the State agency. Aside from also creating an audit trail, this proposed provision is important in that it would alert the State agency as to the status of a referral, which would shape how the State agency would handle a suspension under the proposed revisions to § 455.23.

We received the following comments:

Comment: Several commenters expressed concern regarding the definition of "credible allegation of fraud." Specifically, several commenters requested that CMS provide an exact definition of "credible allegation of fraud" as well as specific standards and guidelines for providers to follow to make a determination regarding what is a credible allegation of fraud. One commenter suggested removing the word "fraud" from the term. Other commenters indicated that the definition of what is credible or reliable under the proposed rule is circular, that is, an allegation is credible if it has "indicia of reliability." In addition, several commenters have suggested that the new evidentiary threshold is too low.

Response: The term "credible allegation of fraud" is a statutory term as reflected in section 6402(h) of the ACA. Accordingly, we do not have the authority to change the term. We have considered these comments but decline to provide a more exact definition, recognizing that different States may have different considerations in determining what may be a "credible allegation of fraud." Accordingly, we believe that States should have the flexibility to determine what constitutes a "credible allegation of fraud" consistent with individual State law. We will neither seek to limit what States may determine qualifies as a "credible allegation of fraud" nor will we require States to consult with HHS in making such a determination.

Comment: One commenter suggested that CMS should update its policies and procedures and develop consistent and standard guidance to State Medicaid programs regarding the determination of credible allegations of fraud.

Response: We will review our current policies and procedures in light of the regulatory changes contained in this rule, and will provide updated guidance to States as necessary.

Comment: Several commenters expressed concern that the evidentiary standard is too low and urged CMS to retain the current standard, by which they suggested defining a "credible allegation of fraud" as "reliable information that fraud or willful misrepresentation exists" as a component of the basis for suspension of payments under § 455.23(a).

Response: In the proposed rule, we acknowledged that the proposed threshold for triggering a payment suspension is lower than what is contemplated in current regulations, but we also indicated that we believe this result is dictated by the ACA. However, in this final rule with comment period, we are amending the definition of "credible allegation of fraud" at § 455.2, which in the proposed rule read, in pertinent part, "[a]llegations are considered to be credible when they have indicia of reliability" to include the following: "and the State Medicaid agency has reviewed all allegations, facts, and evidence carefully and acts judiciously on a case-by-case basis." Due to use of just the word "fraud" in section 6402(h)(2) of the ACA, we proposed to remove the term "willful misrepresentation" from existing regulation, though as we noted in the proposed rule, we take the position that "fraud" includes "willful misrepresentation."

Comment: A few commenters suggested that the final regulation should include a requirement and a discussion to provide technical guidance to State Medicaid programs that clarifies the term "fraud" as a legal term and one that carries evidence of a willful intent to deceive.

Response: The definition of fraud, for purposes of Medicaid program integrity, is reflected in existing regulations at § 455.2 and reads as follows: "an intentional deception or misrepresentation made by a person with the knowledge that the deception could result in some unauthorized benefit to himself or some other person. It includes any act that constitutes fraud under applicable Federal or State law." Medicaid fraud is addressed through, for example, civil remedies imposed under Federal and State false claims acts, as well as through criminal prosecutions.

Comment: Numerous commenters expressed concerns regarding the list of potential sources of credible allegations of fraud. Specifically, several commenters expressed concern about false reports of fraud that may be generated by competitors or disgruntled employees. In addition, there were numerous comments that expressed concern over allegations received through a fraud hotline and whether such allegations could be considered to be reliable. Another commenter suggested that anonymous hotlines should refer to State-operated Medicaid fraud hotlines as well as specify to

whom or what entity the fraud hotline complaints are being made.

Response: First, we will not seek to limit the potential sources from which States may derive credible allegations of fraud. We provided examples of sources for States to consider and will clarify in the final regulation that we are not limiting such sources. We recognize that credible allegations may come from a variety of sources. Second, with respect to identifying fraud hotlines as a potential source of a credible allegation of fraud, we recognize that there may be irrelevant or false reports made through hotlines. Due to the potential for not just false allegations, but also the equal possibility of honest mistakes and the like, we encourage States to not solely rely on a singular allegation without considering the total facts and circumstances surrounding such allegations. In the proposed rule, we indicated that States "must review all allegations, facts, and evidence carefully and act judiciously on a case-by-case basis * * *". As noted previously, we are including this language in the final rule with comment period in the definition of "credible allegation of fraud" at § 455.2. We take the position that States should have the flexibility to determine what they deem to be reliable sources for credible allegations of fraud. Finally, we will not identify which specific fraud hotlines States may use. We are aware that there may be a variety of hotlines. For example, States may have different components within their respective agencies that utilize hotlines or State law enforcement agencies may also utilize hotlines from which credible allegations may be generated. Accordingly, we will not seek to limit the type of hotline States use as sources for credible allegations of fraud.

Comment: Commenters indicated that discussions of investigations and credible allegations of fraud need to defer to State and Federal legal definitions of "fraud." In addition, commenters suggested that existing Federal regulations indicate that investigating fraud is the responsibility of State Medicaid Fraud Control Units (MFCU). Accordingly, MFCUs should be the designated investigators of allegations of fraud.

Response: First, as noted previously, "fraud" is defined in existing regulations at § 455.2. Second, we disagree that only the MFCU may investigate allegations of fraud. While MFCUs clearly play a key role in investigating and prosecuting Medicaid fraud, most, if not all, States have program integrity units that, in the normal course of business, receive hotline and other tips about potential fraud, and conduct proactive investigations based upon internal data analyses and other fraud detection techniques. Program integrity units have the responsibility under existing Federal regulations at § 455.14 and § 455.15(a)(1) and the proposed regulation at § 455.23(d) of determining whether allegations constitute fraud, and if they do, referring the matter to the MFCU or an appropriate law enforcement agency for further investigations. Thus, we do not believe MFCUs are the sole investigators of fraud.

Comment: Several commenters requested that CMS clarify whether a finding of billing errors during an audit that are not related to allegations of fraud would trigger a payment suspension.

Response: Irrespective of the circumstances, absent pending investigations of credible allegations of fraud, payment suspensions would not be triggered under these regulations, although that does not preclude the possibility that a State may exercise its own broader suspension authority in other circumstances.

Comment: Several commenters requested clarification regarding whether States should determine the credibility of an allegation of fraud prior to initiating a suspension action.

Response: Due to the potential for not just false allegations, but also for good faith mistakes, misunderstandings, and misinterpretations regarding reports of alleged fraud as well as data analysis errors, we encourage States not to rely on any singular allegation or data run but rather States should review all allegations, facts, and data carefully and act judiciously on a case-by-case basis, mindful of the potential impact a payment suspension may have on a provider.

Comment: One commenter suggested that we include the term "abuse" as a basis for payment suspension and not limit such suspensions to investigations of "credible allegations of fraud."

Response: We decline to add the term "abuse" to Federal regulations in the context of payment suspensions, as the phrase we have adopted, "credible allegation of fraud" has a statutory basis reflected in section 6402(h) of the ACA. As a practical matter, however, conduct that constitutes abuse as opposed to fraud (we note that both terms are defined at § 455.2) may be indistinguishable not just at the outset of an investigation but even through the course of an investigation and enforcement proceedings and may hinge on fine factual distinctions or legal points including knowledge and intent, and this regulation would not preclude the imposition of a suspension in such a circumstance so long as there is a credible allegation of fraud. Moreover, this regulation presents a floor for protection of Medicaid funds and does not bar a State from setting a higher bar allowing for imposition of suspensions in other circumstances.

Comment: One commenter expressed concern regarding Federal oversight and whether such oversight will amount to second-guessing a State's determination of what constitutes a credible allegation of fraud.

Response: We do not intend to second-guess State determinations regarding credible allegations of fraud. We intend to work collaboratively with States to prevent critical Medicaid funds. The purpose of Federal oversight is to ensure that States have effective processes in place in order to make determinations regarding credible allegations of fraud.

Comment: Several commenters expressed concern regarding the lack of a definition for the phrase "indicia of reliability" and requested CMS to provide one.

Response: We have considered the concerns of commenters, but decline in this final rule with comment period to define "indicia of reliability." We recognize the possibility that there may be differing standards among States with respect to what may be considered "indicia of reliability," but also, as we have noted several times in these responses, we expect States to gauge the credibility of allegations through a lens after reviewing all allegations, facts, data, and evidence carefully and that State action will be exercised judiciously on a case-by-case basis.

Comment: Several commenters want CMS to define "investigation" of a credible allegation of fraud. One commenter inquired whether a State may rely on its MFCU to determine if an allegation of fraud is credible. Other commenters suggested that the State and its investigators are in the best position to determine when credible allegations of fraud should lead to a payment suspension, such that CMS should rely on the judgment of these individuals in deciding whether to withhold FFP. Certain commenters also wanted to know if the process of determining whether an allegation of fraud is credible is sufficient to trigger a payment suspension.

Response: We recognize that the process to determine whether an allegation of fraud is credible may vary among States, and we defer to States—applying the principles of careful review and judicious action to which we refer several times in these responses

and which we now include in the final rule with comment period—to determine whether an allegation or complaint rises to the level of a credible allegation of fraud. We do not want to limit a State's due diligence process or preliminary investigations with respect to its assessment of credibility. Nor do the proposed regulations specify or limit who, or what other agency, may assist the State agency with the investigation or validation of credible allegations of fraud. Nevertheless, if it is determined that an allegation is credible, a State must still submit a formal written referral to its MFCU irrespective of whether the MFCU assisted in validating an allegation's credibility. Finally, the mere fact of an investigation to assess the credibility of a fraud allegation is insufficient to trigger a payment suspension. Rather, a payment suspension is triggered when that there is, in fact, a pending investigation of a credible allegation of fraud. We will clarify this in the regulation.

Comment: One commenter suggested that the notice of suspension to providers should be sent by certified mail, set forth the specific (not general) allegations and inform the providers of the State's administrative review process and provide appropriate citation. Another commenter suggested revising the language in § 455.23(b)(2)(v) regarding notice of suspension to include information about any administrative appeal procedures that are available under State law. Other commenters suggested that notice be furnished to providers prior to the implementation of an adverse action such as payment suspensions. One commenter suggested giving States more discretion regarding when notices of suspension should be furnished to providers. One commenter in particular indicated that bi-weekly remittance advisories are issued to providers that would, in effect, disclose the State's actions.

Response: We believe that we should afford States the flexibility to determine the best method of delivery of notices of suspension so we decline to take an overly prescriptive approach in this regulation. However, we agree that a notice of suspension furnished to a provider should appropriately reference the general allegations upon which a suspension is based as well as any existing State appeals process. Accordingly, we will revise the proposed language to reflect the inclusion of State administrative appeal procedures in the notice of suspension to providers. We do not agree that providers should be given notice of a payment suspension prior to such action being taken. We recognize the sensitive nature of a fraud investigation which may be jeopardized by such notice, and expect that State agencies will act appropriately so as not to jeopardize any investigation.

Comment: Commenters suggested that if a provider or supplier who is subject to a payment suspension submits an acceptable written rebuttal statement as to why the suspension should be removed, then this should qualify as "good cause" as currently permitted under § 405.372(b). In other words, a rebuttal could establish a good cause exception to end a payment suspension. Several other commenters suggested that in cases of economic hardship, a provider should be able to submit evidence of this fact for consideration by the State in determining whether to terminate a payment suspension, and requested that CMS create an expedited review process. Commenters also suggested that the regulations should acknowledge the severe financial impact of a payment suspension and should limit the scope of the suspension to the services under review.

Response: We believe that the proposed regulation as written allows a State to account for a provider's rebuttal statement. Specifically, as proposed at § 455.23(e), States have the flexibility to make a determination that a payment suspension is not in the best interests of the Medicaid program. States also have the option to suspend payments only in part if there is good cause. Therefore, we do not believe that an additional good cause exception is necessary. Moreover, as the existing Medicaid suspension has for more than 20 years, we continue to defer to any State administrative (or judicial) review processes, and therefore decline to require States to adopt an expedited review process. Nevertheless, we are including new good cause exceptions in this final rule with comment period at § 455.23(e)(3) and (f)(2) to allow a State to terminate a whole payment suspension or impose a payment suspension only in part if a provider furnishes written evidence that persuades the State that a payment suspension should be terminated or imposed only in part. Furthermore, the preamble acknowledges and requests States to be mindful of the impact that suspensions may have upon providers.

Comment: One commenter inquired whether "good cause" is established if the items or services are furnished as an emergency.

Response: Section 1903(i)(2) of the Act provides for a limited exception for payment to be made with respect to emergency items or services, though not including items or services furnished in the emergency room of a hospital. We believe this statutory exception speaks for itself and we do not need to otherwise address or expand upon it in these regulations.

Comment: Commenters have suggested that the proposed "good cause" regulatory provisions should include the language contained in the preamble acknowledging that "reliable evidence should be determined on a case-by-case basis with the State agency looking at all the factors, circumstances, and issues at hand * * * " (75 FR 58224).

Response: We disagree that this language belongs in the "good cause" regulatory provisions. Instead, we have revised the definition of "credible allegation of fraud" to reflect that States must carefully review all allegations, facts and evidence on a case-by-case basis. Accordingly, we do not see the need to include this language in the "good cause" regulatory provisions.

Comment: One commenter suggested that CMS consider placing the catchall of "not in the best interests of the Medicaid program" reflected in § 455.23(e)(3) and similarly the catchall reflected at subparagraph (f)(2) of "* * * payment suspension in part is in the best interests of the Medicaid program" at the end of the respective subparagraphs.

Response: We agree and will make such changes in the final regulation.

Comment: One of the good cause exceptions not to suspend payments to Medicaid providers is when "an individual or entity is the sole community physician or the sole source of essential specialized services *in a community.*" (emphasis added) One commenter suggested replacing "in a community" with "for a particular beneficiary population."

Response: We disagree. We are concerned about negatively impacting beneficiary access to care so this exception does not turn on whether a provider serves a particular beneficiary population, but on whether a beneficiary's access to necessary care is impeded. Thus, the good cause exception may be applied when a beneficiary's access to care is jeopardized because he/she cannot obtain necessary services from a particular provider type.

Comment: Several commenters questioned whether the requirements of this section would apply to Medicaid managed care, including whether the term "provider" includes managed care entities, whether managed care capitation payments are included in suspensions when an individual network provider is under investigation;

and what would be the process for notifying a managed care entity of a credible allegation of fraud.

Response: The rules governing payment suspensions based upon pending investigations of credible allegations of fraud apply to Medicaid managed care entities. If there is a pending investigation of a credible allegation of fraud against a Medicaid managed care organization (MCO), prepaid inpatient health plan (PIHP), prepaid ambulatory health plan (PAHP), or health insuring organization (HIO) at the plan level, the State should address the issue either through imposing a payment suspension or through other authorities that may be available to them under State law or as part of the State's negotiated agreement with the Medicaid MCO, PIHP, PAHP, or HIO. The same would hold true for pending investigations of credible allegations of fraud regarding individual network providers. Managed care capitation payments may be included in a suspension when an individual network provider is under investigation based upon credible allegations of fraud, depending on the allegations at issue. We would expect the process regarding the notice of suspension to a Medicaid MCO, PIHP, PAHP, or HIO to follow the criteria as outlined in this final rule with comment period.

Comment: Some commenters requested clarification regarding whether FFP extends to managed care entities' capitation payment.

Response: FFP extends to Medicaid MCOs', PIHPs', PAHPs', and HIOs' capitation payments. Accordingly, if a State fails to suspend payments to such an entity for which there is a pending investigation of a credible allegation of fraud, without good cause, FFP may be disallowed with regard to such payments to the managed care entity.

Comment: Several commenters requested that CMS clarify whether interest accrued on suspended payments to providers is eligible for FFP.

Response: FFP is not available for interest accrued on suspended payments to providers.

Comment: Commenters asked how CMS will notify a State that FFP is to be suspended as a result of payment to an entity for items or services for which the State has received a credible allegation of fraud. Will the State receive advanced notice of the FFP suspension and be given the opportunity to correct or will the suspension be immediate?

Response: The process for deferring and disallowing FFP is governed by § 430.40 and § 430.42, respectively. Generally, we take action to defer the claim (by excluding the claimed amount from the grant award) within 60 days after the receipt of a Quarterly Statement of Expenditures (prepared in accordance with our instructions) that includes that claim. The notice of deferral to the State is provided by CMS within 15 days of such deferral. The notice should identify the type and amount of the deferred claim and specify the reason for deferral. The State is also requested to make available all the documents and materials that CMS believes are necessary to determine the allow-ability of the claim. However, prior to taking action to defer or disallow FFP, we may engage States to request that impermissible claims for FFP are removed from the Quarterly Medicaid Statement of Expenditures for the Medicaid Assistance Program (Form CMS–64).

Comment: One commenter asked, if CMS suspends a State's FFP, and the allegations of fraud are cleared after the fact, what the process will be to restore FFP.

Response: When we determine claims associated with deferred or disallowed FFP are permissible, we will release the deferred or disallowed funds to the State by providing FFP for the subject claims.

Comment: One commenter expressed concern regarding what the commenter saw as a "shift in evaluation of the appropriateness of suspensions away from the Medicaid agency and entities investigating the allegations of fraud to the exclusive and unilateral discretion of CMS" as well as a broad and sweeping increase in CMS's ability to impose a deferral of FFP.

Response: We have long had the authority to withhold FFP and the payment suspension rule is not an attempt to inappropriately withhold FFP from States. Instead, the rule is intended to protect precious Medicaid dollars from fraudulent providers, an effort in which we view the States as partners. Generally, we will withhold FFP only where a State has unreasonably or repeatedly failed to suspend payments or otherwise terminate a payment suspension where there are credible allegations of fraud.

Comment: One commenter suggested that the proposed rule regarding suspension of payments to Medicaid providers gives Medicaid agencies an improper incentive to aggressively deny payments to providers or risk losing FFP.

Response: We disagree. As we explained in the proposed rule, State Medicaid agencies have long had the authority to suspend payments to providers based upon suspected fraudulent conduct. Our goal is to ensure that State agencies appropriately suspend payments from potentially fraudulent providers, in order to protect critical Medicaid dollars from falling into the hands of such providers. In this rule we encourage State agencies to suspend payment based upon pending investigations of credible allegations of fraud only after reviewing all of the facts and circumstances surrounding a particular case and making a determination that such suspension is in fact warranted.

Comment: One commenter suggested that the suspension of payments could be interpreted to have retroactive application to providers who have already been referred to MFCUs or other law enforcement agencies:

Response: We will not require States to retroactively apply the law regarding suspension of payments based on pending investigations of credible allegations of fraud. However, upon the effective date of this final rule with comment period, we expect States; to the extent they have not already done so, to suspend payments to providers against whom there exist pending investigations of credible allegations of fraud.

Comment: Commenters have sought clarification regarding whether the proposed rule applies to individual providers who are employed or contracted by institutional providers.

Response: The payment suspension rule applies to institutional providers as well as enrolled providers who are employed or contracted by such institutional providers.

Comment: One commenter wanted CMS to clarify whether the "individual or entity" under investigation is the same "individual or entity" subject to the payment suspension.

Response: Yes, the "individual or entity" under investigation is the same "individual or entity" that is subject to the payment suspension.

Comment: Several commenters expressed concern with States' compliance dates with the Medicaid payment suspension rule because some States may require State law or regulatory changes in order to be able to implement the rule. Certain commenters also expressed similar concerns that the proposed document retention requirements exceed time frames currently required by their State laws.

Response: We encourage the State Medicaid or program integrity director of any State that faces State legislative, regulatory, or administrative implementation obstacles to contact us

in order to work out a plan of resolution.

Comment: One commenter suggested that the process for quarterly reporting and certification at § 455.23(d) is onerous to the State and the MFCU. The commenter further indicated that reporting is already addressed in Memoranda of Understanding between the States and the MFCUs, and therefore, additional reporting requirements would be burdensome on the State.

Response: We disagree, and in the proposed rule stated that we would not prescribe the format that such certifications must take to maximize State flexibility. The Memoranda of Understanding between the States and the MFCUs routinely do not address reporting and documentation to the degree that will be required by § 455.23(d). Moreover, in the proposed rule we emphasized that payment suspensions should be temporary and we noted the profound impact that a payment suspension can have upon a provider. We believe that the quarterly reporting and certification process is an important protection for providers to ensure that suspensions do not continue after law enforcement has concluded its investigation but did not report this information to the State Medicaid agency.

Comment: Some commenters suggested that documentation and record retention in instances regarding the decision to not suspend payments is expensive and unnecessary given the high volume of unfounded allegations. These commenters also suggested that the requirement to report summary information to the Secretary is duplicative given that CMS will be reviewing State actions on suspension of payment during periodic on-site program integrity reviews.

Response: We disagree. As we generally discuss in both these responses and in the proposed rule, we are balancing a number of interests including: (1) A statutory directive from the ACA that FFP not be paid in certain circumstances; (2) a payment suspension provision that, if not rigorously and carefully administered, can detrimentally impact honest providers; and (3) CMS' intent to maintain its appropriate oversight role but at the same time not to arbitrarily or unreasonably second-guess State decision-making. As such, we believe rigorous documentation requirements that go beyond what may be reviewed during on-site program integrity reviews actually serve to protect everyone's interests. Moreover, we believe it is particularly important that States carefully document those processes that require special judgment calls, such as with respect to exercising the various good cause exceptions, so that, upon CMS review, FFP is not inappropriately withheld.

Comment: One commenter recommended that Medicaid State agencies should be allowed to share potentially helpful information with their MFCUs without following the requirements in the proposed rule regarding documentation and timing of the referral of a credible allegation of fraud.

Response: We fully agree with the notion that States may share information or otherwise consult with their MFCUs, recognizing that States may need to consult and/or exchange information with their respective MFCUs prior to making a formal referral, and do not seek to limit or otherwise define the circumstances by which States make such communications. We disagree, however, with the proposition that States should not need to follow our proposed MFCU documentation/referral requirements, which we believe are important for reasons similar to those addressed in the previous response, thus we will not alter the proposed documentation and timing requirements.

Comment: Certain commenters have suggested that it will be cumbersome to require the State to obtain a written certification from the MFCU or other law enforcement agency that any matter that is accepted on the basis of a referral continues to be under investigation or in the course of enforcement proceedings warranting continuation of the payment suspension every 90 days. In addition, these commenters expressed concern that this requirement will result in a substantial increase in workload and could result in increased staffing levels. Commenters also suggested that existing methods of communication regarding caseload and referrals between the States and the MFCUs should be sufficient.

Response: We disagree with the proposition that the quarterly law enforcement certification requirement is overly cumbersome or that the documentation requirements finalized here will result in substantial increases in workload. As we have indicated previously in these responses and in the proposed rule, we believe rigorous documentation requirements are in everyone's interest. Moreover, to maintain State flexibility, we are not prescriptive with respect to the format of the quarterly certification. States have long had authority to implement payment suspensions and, though we formalize certain documentation and referral requirements here, we believe that most States that have used suspension authority likely have rigorous documentation requirements already in place to ensure they are able to adequately justify suspension actions and withstand any provider challenges.

Comment: With regard to formal fraud referrals issued by the State to the MFCU or other law enforcement agency, one commenter suggested combining the relevant NPIs of the affected providers into one referral instead of referring individual cases.

Response: This is outside the scope of the proposed rule and therefore we will not address this issue at this time.

Comment: One commenter suggested that the regulation at § 455.23(g) proposing to require States to annually report to the Secretary information regarding the life cycle of each payment suspension imposed and any determinations to exercise the good cause exceptions not to suspend payment, to suspend payment only in part, or to discontinue a payment suspension, be modified. Specifically, the commenter suggested that such annual report be filed only if such information is shared by law enforcement.

Response: We disagree with the commenter's proposition for two reasons. First, a number of the elements the commenter points out are not contingent on any response from law enforcement. Second, we certainly appreciate that States can only report on the information that is in their possession, but believe that annual reporting should not be contingent on whether law enforcement has shared such information. Importantly, to the extent that annual reporting reveals gaps where law enforcement has neglected or refused to share information it will illustrate where CMS may have to exercise additional oversight authority to attempt to close such gaps. Likewise, law enforcement's "failure to communicate" may be a significant factor in a State's decision to exercise certain of the rule's good cause exception authorities.

Comment: One commenter suggested that CMS include in the final regulation at § 455.23(d)(4), as reflected in the preamble to the proposed rule, a requirement for States to immediately release the payment suspension "unless the State has alternative Federal or State authority by which it may impose a suspension." (75 FR 58225). The proposed regulation does not reflect this additional language governing the immediate release of a payment suspension when MFCU or law

enforcement declines to accept the fraud referral.

Response: We agree, and are including this language in the final rule with comment period.

Comment: Certain commenters suggested revising the proposed language to include a 180 day time limit for the duration of a suspension of payment in the Medicaid program, similar to the proposed process under Medicare.

Response: Aside from the general constraints and protections built in to the rule around the notion that suspensions are intended to be temporary, we believe that States need the flexibility to decide the duration of payment suspensions in order to accommodate State laws and legal processes. Because Medicare is a national program there is more uniformity surrounding the disposition of Medicare program suspensions. So while a specific time limit may be adequate there, we believe a more flexible approach, nearly identical to the approach used with respect to Medicaid payment suspensions for more than 20 years, is necessary to address the needs of 50 plus States and territories.

Comment: One commenter suggested that the duration of a payment suspension by States should be permanent where the provider is later convicted of the offense.

Response: Payment suspensions are intended to stem the flow of Medicaid dollars to providers against whom there are credible allegations of fraud, during the pendency of the investigation, which includes any related proceedings. Separate authorities, some administered by other agencies, including possible exclusion from participation in Federal health care programs, may be implemented upon a provider's conviction.

Comment: One commenter indicated that while the proposed rule gives States authority to immediately release payment suspensions if a timely investigation by law enforcement does not ensue, that "timely," is not clearly defined.

Response: We believe that when a State learns that law enforcement has declined to investigate a fraud referral from the State in connection with a payment suspension or otherwise discontinues a pending investigation, the State should immediately take steps to terminate a payment suspension. As discussed several times in these responses, we proposed a requirement for States to obtain quarterly certifications from law enforcement to help address this type of scenario so that providers are not subject to a continuing payment suspension based upon a fraud referral that was declined by law enforcement or an investigation that has been concluded without the State's knowledge.

Comment: Certain commenters requested clarification regarding the resolution of an investigation for purposes of terminating a payment suspension.

Response: Generally, a payment suspension is temporary and will not continue after the State Medicaid agency or the prosecuting authorities determine that there is insufficient evidence of fraud by the provider or legal proceedings related to the alleged fraud are completed.

Comment: One commenter suggested that the proposed rule be changed to defer to State law to dictate how long and under what circumstances a payment suspension can be imposed.

Response: As we noted in an earlier response, this rule presents a floor for protection of Medicaid funds and does not bar a State from setting a higher bar allowing for imposition of suspensions with other conditions or in other circumstances.

Comment: Several commenters suggested that the proposed rule does not provide adequate due process for providers facing suspension of payments. Certain commenters also suggested that the proposed rule could result in a de facto termination from the Medicaid program without any meaningful due process. Commenters expressed concern that non-fraudulent providers may effectively be terminated by lengthy suspensions. Commenters also suggested shortening the length of suspensions or in the alternative, maintaining the current permitted duration without extension. Another commenter indicated that the proposed rule does not create a right to challenge the ongoing validity of a payment suspension.

Response: Under the proposed rule, providers have an opportunity to submit written evidence for consideration by the Medicaid agency regarding payment suspensions. Based upon this written evidence, a State may determine whether there is good cause to terminate a suspension of payment. Accordingly, we believe there are adequate due process protections in place pursuant to which a provider may establish good cause to terminate a payment suspension. In addition, this process was already accounted for in existing Medicaid regulations and we did not change the process. We are not aware of any issues associated with this process which has been in existence for more than 20 years. Moreover, we expressed in the proposed rule that suspensions, because of their significant impact upon providers, are only temporary. We provided in the rule several protections (such as the quarterly law enforcement certification and State documentation requirements) and also various "good cause" exceptions. Moreover, the duration of suspension provisions of the proposed rule, finalized here, are essentially the same as have been in place for more than 20 years with the existing Medicaid payment suspension rule. We believe that the significant built-in protections, in conjunction with the fact that we are not aware that the current Medicaid suspension process has caused significant undue hardship with providers having payments wrongly suspended, lend adequate safeguards to the process. CMS will also monitor States' implementation of the Medicaid payment suspension rule through the various documentation requirements and State program integrity reviews, to ensure that there are no marked shortcomings with regard to States' processes.

Comment: One commenter suggested that the final regulation should require State Medicaid programs to establish and codify a Medicaid administrative review process with regard to the review of payment suspensions.

Response: We recognize that individual State laws vary with regard to their respective administrative review processes, and believe that most or all States have established such processes. As previously stated, we will revise the proposed language in the regulations to reflect the inclusion of State administrative appeal procedures in the notice of suspension furnished to providers. In addition, we believe the notice should also include relevant citations to State law, where applicable.

Comment: A couple of commenters suggested that CMS develop a system or process for exposing and penalizing those who make false fraud complaints.

Response: This is outside the scope of the proposed rule and therefore we will not consider this suggestion at this time.

Comment: One commenter requested clarification regarding the fraud referral standards established by CMS as a result of an OIG January 2007 report entitled "Suspected Medicaid Fraud Referrals" (OEI 07–04–00181).

Response: We issued fraud referral standards on September 30, 2008. The link to CMS' Web site where the fraud referral standards may be found is: *http://www.cms.gov/FraudAbuseforProfs/downloads/fraudreferralperformancestandardsstateagencytomfcu.pdf.*

Comment: One commenter suggested that the content of a fraud referral should be left to the discretion of each State. This commenter suggested that a continuing collaborative environment will fulfill the regulatory provisions regarding content of fraud referrals.

Response: We encourage States to collaborate with their MFCU. A fraud referral must contain, at a minimum, the elements as outlined in the proposed regulation and finalized here, but it is within a State's discretion to the extent it wishes to add additional information.

Comment: One commenter suggested that FQHCs should be exempted from the application of payment suspensions.

Response: We disagree. There is no statutory requirement to carve out an exception for any particular category of provider. We believe that payment suspensions apply to fraudulent conduct regardless of provider type.

Comment: One commenter suggested that payment suspensions should only apply to providers in the limited screening level, as that term is defined and used in connection with the provider screening rules, under only the most extraordinary circumstances.

Response: We decline to carve out an exception for providers in the limited screening level in the context of a payment suspension. This assignment to the limited level applies in the context of provider screening, not for suspension of payments. The determination regarding whether to impose a payment suspension is driven by credible allegations of fraudulent conduct and not whether a provider is assigned to a certain level for purposes of screening.

Comment: One commenter requested clarification regarding the application of payment suspensions to billing providers as opposed to prescribing providers. Another commenter requested a guarantee that payment suspensions will not be imposed against a billing provider.

Response: We understand that there are circumstances in which the prescribing provider may be different from the furnishing provider and/or billing provider. Generally, we believe that payment suspension is not the appropriate mechanism to recover Medicaid funds from one provider who inescapably, but innocently, happens to be associated with the fraudulent conduct of another provider. Because payment suspensions only apply based upon credible allegations of fraud, payment suspensions are generally not the appropriate vehicle by which to recover reimbursement for items and/or services furnished by a provider against whom there are no allegations of fraud. Nevertheless, there is no guarantee that a payment suspension will only be imposed against the billing provider as, particularly at the outset of an investigation of a credible allegation of fraud, it may be impossible to precisely determine the locus of the fraud or whether it involved collusion or conspiracy.

Comment: One commenter requested clarification regarding whether States with authority under existing State law may impose suspensions for reasons other than where there is a credible allegation of fraud. This commenter suggested that where such authority exists, the requirements proposed under § 455.23, including those concerning referrals to the MFCU and the duration of suspension should not apply.

Response: The requirements for payment suspensions under the proposed rule are based upon credible allegations of fraud. As we have noted several times in both these responses and in the proposed rule, nothing in these rules bar a State from exercising other broader authorities to suspend payments to providers.

We are adopting the provisions of the proposed rule with the exception of the following changes:

- In § 455.2, we have revised the definition of "credible allegation of fraud" to address the issue of the State's verification of the allegation.
- In § 455.23(a)(1), we have added the verbiage "after the agency determines there is a credible allegation of fraud for which" after the term "provider."
- In § 455.23(b)(2), we have added a new subsection (vi) that reads: "Set forth the applicable State administrative appeals process and corresponding citations to State law."
- In § 455.23(d), we have added the verbiage "has alternative Federal or State authority by which it may impose a suspension or" before "makes a fraud referral to another law enforcement agency."
- In § 455.23(e), we have revised subsection (3) to state: "The State determines, based upon the submission of written evidence by the individual or entity that is the subject of the payment suspension, that the suspension should be removed."
- In § 455.23(e), we have added a new subsection (6) that states: "The State determines that payment suspension is not in the best interests of the Medicaid program."
- In § 455.23(f), we have revised subsection (2) to read: "The State determines, based upon the submission of written evidence by the individual or entity that is the subject of a whole payment suspension, that such suspension should be imposed only in part."
- In § 455.23(f), we have added a new subsection (5) that states: "The State determines that payment suspension only in part is in the best interests of the Medicaid program."

E. Proposed Approach and Solicitation of Comments for Sections 6102 and 6401(a) of the Affordable Care Act —Ethics and Compliance Program

1. Statutory Changes

Under section 6102 of the ACA which established new section 1128I of the Act, a nursing facility (NF) or SNF shall have in operation a compliance and ethics program that is effective in preventing and detecting criminal, civil, and administrative violations and in promoting quality of care, consistent with regulations developed by the Secretary, working jointly with the HHS OIG. The regulations to establish the compliance and ethics program for operating organizations may include a model compliance program. The statute requires that in the case of an organization that has five or more facilities, the formality or specific elements of the program vary with the size of the organization. The statute also requires that not later than 3 years after the effective date of the regulations, the Secretary shall complete an evaluation of the programs to determine if such programs led to changes in deficiency citations, changes in quality performance, or changes in the quality of resident care. The Secretary shall submit to the Congress a report on such evaluation with recommendations for changes in the requirements, as the Secretary deems appropriate.

Similarly, under section 6401(a) of the ACA, which established a new section 1866(j)(8) of the Act, a provider of medical or other items or services or a supplier shall, as a condition of enrollment in Medicare, Medicaid or CHIP, establish a compliance program that contains certain "core elements." The statute requires the Secretary, in consultation with the HHS OIG, to establish the core elements for providers or suppliers within a particular industry or category. The statute allows the Secretary to determine the date that providers and suppliers need to establish the required core elements as a condition of enrollment in Medicare, Medicaid, and CHIP. The statute requires the Secretary to consider the extent to which the adoption of compliance programs by providers or suppliers is widespread in a particular industry sector or particular provider or supplier category. Please note, NFs and

SNFs are subject to both compliance plan requirements under sections 6102 and 6401(a) since section 6401(a) of the ACA includes all providers and suppliers enrolling into Medicare, Medicaid and CHIP. We intend to establish compliance program core elements per section 6401(a) of the ACA for NFs and SNFs that closely match the required components of a compliance program per section 6102 of the ACA.

2. Proposed Ethics and Compliance Program Provisions

In order to consider the views of industry stakeholders, we solicited comments on compliance program requirements included in the ACA. We do not intend to finalize compliance plan requirements in this final rule with comment period; rather, we intend to do further rulemaking on compliance plan requirements and will advance specific proposals at some point in the future. We were most interested in receiving comments on the following:

The use of the seven elements of an effective compliance and ethics program as described in Chapter 8 of the U.S. Federal Sentencing Guidelines Manual (*http://www.ussc.gov/2010guid/20100503_Reader_Friendly_Proposed_Amendments.pdf,* pp. 31–35) as the basis for the core elements of the required compliance programs for Medicare, Medicaid and CHIP enrollment. These elements instill a commitment to prevent, detect and correct inappropriate behavior and ensure compliance with all applicable laws, regulations and requirements, and include:

- The development and distribution of written policies, procedures and standards of conduct to prevent and detect inappropriate behavior;
- The designation of a chief compliance officer and other appropriate bodies (for example a corporate compliance committee) charged with the responsibility of operating and monitoring the compliance program and who report directly to high-level personnel and the governing body;
- The use of reasonable efforts not to include any individual in the substantial authority personnel whom the organization knew, or should have known, has engaged in illegal activities or other conduct inconsistent with an effective compliance and ethics program;
- The development and implementation of regular, effective education and training programs for the governing body, all employees, including high-level personnel, and, as appropriate, the organization's agents;
- The maintenance of a process, such as a hotline, to receive complaints and the adoption of procedures to protect the anonymity of complainants and to protect whistleblowers from retaliation;
- The development of a system to respond to allegations of improper conduct and the enforcement of appropriate disciplinary action against employees who have violated internal compliance policies, applicable statutes, regulations or Federal health care program requirements;
- The use of audits and/or other evaluation techniques to monitor compliance and assist in the reduction of identified problem areas; and
- The investigation and remediation of identified systemic problems including making any necessary modifications to the organization's compliance and ethics program.

In addition, we are particularly interested in comments about the following:

- The extent to which, and the manner in which, providers and suppliers already incorporate each of the seven U.S. Federal Sentencing Guidelines elements into their compliance programs or business operations. We are interested in how and to what degree each element has been incorporated effectively into the compliance programs of different types of providers and suppliers considering their risk areas, business model and industry sector or particular provider or supplier category.
- Any other suggestions for compliance program elements beyond, or related to, the seven elements referenced previously considering provider or supplier risk areas, business model and industry sector or particular provider or supplier category including whether external and/or internal quality monitoring should be a required for hospitals and long-term care facilities.
- The costs and benefits of compliance programs or operations including aggregate or component costs and benefits of implementing particular elements and how these costs and benefits were measured.
- The types of systems necessary for effective compliance, the costs associated with these systems and the degree to which providers and suppliers already have these systems including, but not limited to, tracking systems, data capturing systems and electronic claims submission systems. We anticipate having providers and suppliers evaluate the effectiveness of their compliance plans using electronic data.
- The existence of and experience with State or other compliance requirements for various providers and suppliers and foreseeable conflicts or duplication from multiple requirements.
- The criteria we should consider when determining whether, and if so, how to divide providers and suppliers into groupings that would be subject to similar compliance requirements including whether individuals should have different compliance obligations from corporations.
- Available research or individual experience regarding the current rate of adoption and level of sophistication of compliance programs for providers or suppliers based on their business model and industry sector or particular provider or supplier category.
- How effective compliance programs have been for varied providers and suppliers and how the level of effectiveness was measured.
- The extent to which providers and suppliers currently use third party resources, such as consultants, review organizations, and auditors, in their compliance efforts.
- The extent to which providers and suppliers have already identified staff responsible for compliance and, for those who already have staff responsible for compliance, the positions of these staff.
- A reasonable timeline for establishment of a required compliance program for various types and sizes of providers and suppliers, assuming the compliance program core elements were based on the aforementioned U.S. Federal Sentencing Guidelines' seven elements of an effective compliance and ethics program, considering business model and industry sector or particular provider or supplier category.

We welcomed any information concerning how the industry views compliance program elements and how we can establish required compliance program elements to protect Medicare, Medicaid, and CHIP from fraud and abuse.

3. Analysis of and Responses to Public Comment

We received numerous comments on compliance program elements in response to this request. Though we will not respond to those comments within this final rule with comment period, these will be considered for further rulemaking on compliance plan requirements.

4. Final Provisions—Ethics and Compliance Program

We are not finalizing these provisions in this final regulation. We are in the process of developing a new Notice of Proposed Rule Making incorporating the

compliance plan provisions and comments received that will be published at a later date. The proposed rule will also have an opportunity for further public comment.

F. Termination of Provider Participation Under the Medicaid Program and CHIP if Terminated Under the Medicare Program or Another State Medicaid Program or CHIP

1. Statutory Change

Section 6501 of the ACA amends section 1902(a)(39) of the Act to require a State Medicaid program to terminate any provider, be it an individual or entity, participating in that program, subject to the limitations on exclusions in sections 1128(c)(3)(B) and 1128(d)(3)(B) of the Act, if the provider's participation has been terminated under title XVIII of the Act or another State's Medicaid program. Effective provider screening prevents excluded providers from enrolling in government health care programs and being paid with Federal and State funds. Effective screening of providers barred from participation can reduce the risk of fraud, waste, and abuse in the Medicare and Medicaid programs and CHIP

When a State terminates a provider but does not share that information with any other State, all other States become vulnerable to potential fraud, waste, and abuse committed by that provider. Similarly, a provider, supplier, or eligible professional that has been terminated from Medicare or has had Medicare billing privileges revoked may enroll with a State Medicaid program or with CHIP when a State is not aware of the Medicare termination or revocation. We may terminate or revoke the billing privileges of a provider, supplier, or eligible professional under Medicare for a number of reasons, as set forth at § 424.535, including exclusion from health care programs, government-wide debarment, and conviction of certain violent felonies and financial crimes.

Section 6501 of the ACA requires a State's Medicaid program to terminate an individual or entity's participation in the program (subject to certain limitations on exclusions in sections 1128(c)(3)(B) and 1128(d)(3)(B) of the Act), if the individual or entity has been terminated under Medicare or another State's Medicaid program. Although the term "termination" only applies to providers under Medicare whose billing privileges have been revoked (and does not apply to Medicare suppliers or eligible professionals), we believe it was the intent of the Congress that this requirement also be applicable to suppliers and eligible professionals that have had their billing privileges under Medicare revoked as well. Therefore, we proposed that "termination" be inclusive of situations where an individual's or entity's billing privileges have been revoked. The requirement for States to terminate would only apply in cases where providers, suppliers, or eligible professionals were terminated or had their billing privileges revoked for cause. "For cause" may include fraud, integrity or quality, but not cases where the providers, suppliers, or eligible professionals were terminated or had their billing privileges revoked based upon voluntary action taken by the provider to end its participation in the program, except where that voluntary action is taken to avoid a sanction, or where a State removes inactive providers from its enrollment files.

In addition, State Medicaid programs would terminate a provider only after the provider had exhausted all available appeal rights in the Medicare program or in the State that originally terminated the provider or the timeline for such appeal has expired.

Section 6501 of the ACA builds upon the requirements in section 6401(b)(2) of the ACA, which requires that we establish a process to make available Medicare provider, supplier, and eligible professional and CHIP provider termination information to State Medicaid programs. Section 1902(kk)(6) of the Act also requires States to report adverse provider actions to CMS, including criminal convictions, sanctions, and negative licensure actions.

When States are apprised of the terminations or revocations of billing privileges, as the case may be, of providers, suppliers, and eligible professionals that have occurred in other State Medicaid programs, CHIP, or in Medicare, States have the information they need to protect their programs.

2. Proposed Provisions for Termination of Provider Participation Under the Medicaid Program and CHIP if Terminated Under the Medicare Program or Another State Medicaid Program or CHIP

We proposed at § 455.416(c) that a State Medicaid program must deny enrollment or terminate the enrollment of a provider that is terminated on or after January 1, 2011 under Medicare, or has had its billing privileges revoked, or is terminated on or after January 1, 2011 under any other State's Medicaid program or CHIP.

While section 6501 of the ACA does not expressly require that individuals or entities that have been terminated under Medicare or Medicaid also be terminated from CHIP, we also proposed, under our general rulemaking authority pursuant to section 1102 of the Act, to require in CHIP regulations that CHIP take similar action to terminate a provider terminated or revoked under Medicare, or terminated under any other State's Medicaid program or CHIP.

We also proposed to add a definition at § 455.101 for termination for purposes of this section. That definition distinguishes between Medicaid providers and Medicare providers, suppliers, and eligible professionals and specifies that termination means a State Medicaid program or the Medicare program has taken action to revoke the Medicaid provider's or Medicare provider, supplier or eligible professional's billing privileges and the provider, supplier or eligible professional has exhausted all applicable appeal rights. There is no expectation on the part of the provider, supplier, or eligible professional or the State or Medicare program that the termination or revocation is temporary. The provider, supplier or eligible professional would be required to reenroll with the applicable program if they wish billing privileges to be reinstated.

3. Analysis of and Responses to Public Comment

We received the following comments:

Comment: One commenter stated that while there is value to the States to have additional authority under which to deny or terminate Medicaid providers, it will be necessary to amend current statute and regulations to include new reasons for denials and terminations, and additional time will be required.

Response: In accordance with section 6508(b) of the ACA, a State may delay implementation of this provision if the Secretary determines that State legislation is required.

Comment: Commenters asked for clarification regarding ACA section 6401(b)(2) that requires CMS to establish a process to make available Medicare provider, supplier, and eligible professional and CHIP termination information to State Medicaid programs. Commenters asked if a mechanism was in place for States to check for terminated providers starting January 1, 2011. One commenter requested clarification as to how State Medicaid programs would communicate with Medicare contractors when the States had revoked or suspended a Medicaid enrollment. Another commenter asked if the Provider Enrollment, Chain, and Ownership System (PECOS) would be

used. Another commenter stated it would be "next to impossible" to carry out this provision without an effective way to obtain information from Medicare regarding terminated providers. One commenter urged CMS to establish a national database that contains Medicare, CHIP termination and exclusion information as well as information on terminations from all State Medicaid programs.

Response: We are in the process of establishing a secure web-based portal that will allow States to share information regarding terminated providers. Using this web-based portal, a State will be able to upload as well as download information regarding its terminated providers and download information regarding terminated providers in other States and Medicare. States will not be required to report those providers who were terminated prior to January 1, 2011. Access to the information-sharing portal is limited to users that we have approved.

Comment: Some commenters requested that CMS clarify the timeframes for State reporting of terminations.

Response: States should report terminations on a monthly basis in order to assist other States and the Medicare program in protecting themselves from providers who pose an increased risk to government health care programs.

Comment: One commenter requested that States be granted real time access to the exclusion database. Another commenter suggested that CMS consider leveraging existing Federal databases such as the NPI and NPPES.

Response: We are in the process of exploring potential opportunities to leverage existing databases and infrastructure that would enable timely access to provider enrollment data across programs. We are currently examining to what extent we can support such a centralized information sharing solution.

Comment: One commenter requested clarification that Medicaid termination should only last as long as the Medicare termination, especially in States where "terminate" means "permanent exclusion."

Response: When a State terminates a provider based on the fact that the provider was terminated by Medicare, the duration of the State's termination action should be consistent with State law, and not necessarily driven by the length of the Medicare termination. The same would hold true when a State terminates a provider based on a termination action in another State. We do not wish to dictate to States the duration of their terminations.

Comment: One commenter contended that the proposed rule did not detail the parameters of the termination process. Specifically, it did not state what would happen if a provider is wrongfully terminated from participation in Medicare or another public benefit, or the different termination scenarios—such as the effect on a group practice if a provider in that group is suspected of fraud. The commenter also requested further explanation and clarification regarding the timeline and parameters for termination of provider participation in Medicare, Medicaid, and CHIP.

Response: For purposes of the Medicaid program, the parameters of the termination process would be governed by the terminating State's administrative appeals processes. Accordingly, the timeline and parameters for termination will vary depending on the State in which the termination occurs. State Medicaid agencies and CHIP must deny enrollment or terminate the enrollment of any provider that is terminated by Medicare or another State's Medicaid program or CHIP on or after January 1, 2011. If a provider is wrongfully terminated from Medicare or another State's Medicaid program or CHIP, and a subsequent State has already terminated such provider from its Medicaid program or CHIP, the subsequent State should reinstate the provider once the subsequent State has evidence demonstrating that the provider was wrongfully terminated.

When an individual provider is terminated by a State Medicaid program or CHIP, the effect on a group practice would be that the individual provider who is terminated may not participate in the Medicaid or CHIP programs until that provider is eligible to, and does re-enroll. Therefore, neither the individual provider, nor the group practice would be able to bill Medicaid or CHIP for care and/or services provided by the individual provider that has been terminated.

Comment: One commenter stated that termination is defined to be inclusive of situations where an individual or entity's billing privileges have been revoked. The commenter requested clarification because not all providers have billing privileges. For example, a particular pharmacist may be denied participation in a State's Medicaid program; however, because the pharmacist does not have direct billing privileges, another State would not have to also terminate that provider.

Response: The requirement for termination is not limited to situations in which a provider is billing the Medicaid program. The requirement for termination applies to enrolled providers generally, not just billing providers. An enrolled provider that has had its billing privileges revoked by Medicare must be terminated by the States' Medicaid programs, regardless of whether the provider is submitting claims.

Comment: One commenter requested clarification for States regarding termination when a provider has more than one NPI or Medicare ID number. A commenter inquired if CMS will terminate a provider's NPI, Medicare legacy number or both. This commenter also asked if a provider has multiple NPIs and/or Medicare numbers, does Medicare terminate a provider under one number but allow them to continue to participate under other NPI/Medicare numbers. This commenter indicated that if the response is yes, would a State be expected to follow suit, that is, terminate only the NPI that Medicare has terminated. Finally, the commenter asked what States should do in cases where providers have multiple legacy Medicaid numbers that crosswalk to a single NPI.

Response: It is the provider, not the provider's identifiers, which are to be terminated under this provision. Thus, to the extent that Medicare terminated one or multiple NPIs/Medicare legacy numbers for cause that are tied to one provider we generally expect that State Medicaid agencies will follow suit. Accordingly, if one provider has multiple Medicaid identification numbers, then the State would be required to terminate such provider numbers if the State determines there is cause for such termination and the provider has exhausted its appeal rights.

Comment: Several commenters expressed concern over the potential for terminations of affiliated providers when one provider had been terminated in another State. One commenter asked if other State Medicaid agencies will be compelled to terminate affiliates that have a common corporate parent. A commenter asked if terminations for a corporation apply to any branches or franchises of that corporation.

Response: Section 6501 of the ACA does not require the termination of affiliates of terminated entities. Accordingly, we are not requiring States at this time to terminate affiliates of those individuals or entities that have been terminated by another Medicaid program or had their billing privileges revoked by the Medicare program.

Comment: One commenter stated that it is a common State statutory requirement or best practice for a provider to form a legal corporate entity

unique to the State. The commenter requested clarification for the legal basis for Federal enforceability of termination from or denied enrollment into a State's program based upon the termination or denial status in another State where the provider and its principals are the same individuals but the "provider" is a separate legally incorporated entity under State law.

Response: Section 1902(a)(39) of the Act requires State Medicaid agencies to terminate the participation of any individual or entity that has been terminated under Medicare or another State's Medicaid program. When a State is contemplating a termination as a result of a termination that was initiated by another State's Medicaid program, and there is a question regarding the identity of the provider who is the subject of the termination, it is generally up to the subsequent terminating State to determine whether a provider in their State is the same provider that was initially terminated by another State's Medicaid program. In order to determine whether a provider in one State is the same provider that was terminated in another State, a State could look at a variety of factors, including, but not limited to, NPI and correspondence address. The State could also communicate with the Medicaid agency that originally terminated the provider to help resolve the question of the provider's identity. If the State believes that background checks are required to verify the identity of a provider, then States should conduct such background checks. We believe the States should have flexibility to determine the best method for identity verification.

Comment: One commenter suggested that the regulatory definition of termination at § 455.101 should be revised to include the termination of persons or entities with an ownership or control interest or who is an agent or managing employee of a provider.

Response: The ACA does not contemplate termination based upon ownership or control. The statute requires termination of the same individual or entity that was terminated by Medicare or another State's Medicaid program.

Comment: A few commenters requested that CMS clarify in the final rule with comment period that termination from the Medicaid program must only occur when a provider has had billing privileges revoked or terminated by Medicare for cause.

Response: The requirement for States to terminate would only apply in cases where providers, suppliers or eligible professionals were terminated or had their billing privileges revoked for cause which may include, but is not limited to, fraud, integrity or quality issues. In addition, we have defined "termination" in the final rule with comment period as occurring when a State Medicaid program has taken action to terminate a provider and the provider has exhausted all applicable appeal rights that are available in the State or the Medicare program, or the timeline for appeal has expired, whichever is applicable.

Comment: One commenter requested information regarding how managed care organizations will be able to access provider termination information.

Response: We encourage States to share such information with their managed care entities.

Comment: One commenter requested that an appeals process be established for providers and suppliers that would permit a provider/supplier to continue to provide care under a program if they can demonstrate "good cause exemptions."

Response: While we appreciate the commenter's suggestion, section 6501 of the ACA requires States to terminate the participation of any provider that has been terminated under Medicare or another State's Medicaid program, and allows for exceptions only as permitted under sections 1128(c)(3)(B) and 1128(d)(3)(B) of the Act.

Comment: Commenters expressed concern that the proposed rule allows for the imposition of sanctions based upon findings made outside the agency. For example, if Medicare revokes a provider's billing privileges and a State initiates a termination action as a result of such revocation, then, in the commenter's view, the proposed rule gives the provider a right to use the State administrative appeal process to challenge anew the Medicare revocation.

Response: We disagree. The provider is not provided a new forum in which to litigate the Medicare termination action. The ACA does not give a State the authority to review a Medicare termination action. The statute requires a State to terminate a provider that was terminated by Medicare or another State's Medicaid program, with certain limited exceptions.

Comment: A few commenters indicated that the proposed regulation fails to state that termination from the Medicaid program must only occur in situations in which the provider or supplier had its billing privileges terminated or revoked for cause, that is, fraud, integrity or quality issues.

Response: We agree. In the regulatory definition for "termination," we will state that the requirement for States to terminate would only apply in cases where providers, suppliers or eligible professionals were terminated or had their billing privileges revoked for cause which may include, but is not limited to, fraud, integrity or quality issues.

Comment: Certain commenters requested a specific timeline for due process in connection with the appeal of termination actions and the parameters of the termination process in Medicaid.

Response: As we have indicated previously in these responses, we believe that States should have the flexibility to decide termination actions consistent with their individual State administrative appeals process. In addition, since State law and regulations may vary with regard to this issue, we defer to the States regarding their existing termination processes.

Comment: One commenter suggested that reciprocal termination must be limited to revocations of privileges due to fraud and where the physician has exhausted all possible appeal rights.

Response: We agree. As stated in the proposed rule, the requirement for States to terminate would only apply in cases where providers, suppliers or eligible professionals were terminated or had their billing privileges revoked for cause. In addition, we defined "termination" as occurring when a State Medicaid program has taken action to revoke a Medicaid provider's billing privileges and the provider has exhausted all applicable appeal rights that are available in that State, or the timeline for appeal has expired, or when the Medicare program has revoked the provider or supplier's billing privileges and the provider or supplier has exhausted all applicable appeal rights, or the timeline for appeal has expired.

Comment: One commenter requested a definition of "eligible professional."

Response: In the context of terminations, "eligible professional" is a term that is specific to the Medicare program. For purposes of the Medicare program, an eligible professional may include a physician assistant, nurse practitioner, or clinical nurse specialist, certified nurse-midwife, clinical social worker, clinical psychologist, registered dietitian or nutrition professional. *See* section 1842(b)(18) of the Act.

Comment: Certain commenters requested clarification regarding when a termination is triggered under the statute.

Response: A termination in a subsequent State is triggered when Medicare or a State Medicaid program has taken action to revoke a provider's billing privileges for cause *and* the provider has exhausted all applicable appeal rights that are available in

Medicare or the originally-terminating State or the timeline for appeal has expired.

Comment: A commenter stated that section 6 of Executive Order 13132 requires that: (1) Each agency have an accountable process to ensure meaningful and timely input by State officials in the development of regulatory policies that have Federalism implications, and (2) no agency shall promulgate any regulation that has Federalism implications that imposes substantial direct compliance cost on State governments. The commenter recommended that CMS explain the process that was used to ensure that meaningful and timely input was received from the States prior to the development of this proposed rule.

Response: We have worked closely with State Medicaid agencies on the proposed rule and in the development of the final rule with comment period.

Comment: One commenter requested clarification regarding the process of how Medicare reinstatements will be communicated to States and whether States will be required to automatically reinstate a provider in the Medicaid program once a provider "finishes the Medicare termination/revocation period."

Response: Presumably, States will be notified by providers who are seeking re-enrollment or reinstatement in the Medicaid program. It is the responsibility of the States to validate the status of a provider's termination with Medicare. When a provider may seek re-enrollment is up to the discretion of the States and should be consistent with State law. Similarly, the duration of termination should be consistent with existing State law.

4. Final Provisions for Termination of Provider Participation Under the Medicaid Program and CHIP if Terminated Under the Medicare Program or Another State Medicaid Program or CHIP

We have retained the provisions of the proposed rule, with the exception of the following:

- In § 455.101, we have added the following subsection (3) to the definition of termination: "The requirement for termination applies in cases where providers, suppliers, or eligible professionals were terminated or had their billing privileges revoked for cause which may include, but is not limited to: (i) Fraud; (ii) integrity; or (iii) quality."

G. Additional Medicare Provider Enrollment Provisions

1. Statutory Changes

Section 6501 of the ACA requires States to terminate a provider or supplier under the Medicaid program when the provider or supplier has been terminated by Medicare or by another State's Medicaid program. We believe that permitting CMS to revoke Medicare billing privileges when a State Medicaid agency terminates, revokes, or suspends a provider or supplier's Medicaid enrollment or billing privileges works in tandem with section 6501 of the ACA.

2. Proposed Provisions for Additional Medicare Provider Enrollment

In § 424.535(a)(11), we proposed allowing CMS, directly or through its contractor, to revoke Medicare billing privileges when a State Medicaid agency terminates, revokes, or suspends a provider or supplier's Medicaid enrollment or billing privileges. Moreover, we believe that providers and suppliers whose enrollment has been terminated by a State Medicaid program may pose an increased risk to the Medicare program.

3. Analysis of and Response to Public Comments

We received one comment on the proposed provision related to Medicare termination.

Comment: A commenter stated that proposed § 424.535(a)(11) contains an editorial error that makes the language of the proposed rule difficult to understand.

Response: Section 424.535(a) lists reasons for revocation of Medicare enrollment. § 424.535(a)(12) is one such reason—if a State has terminated a provider from Medicaid, Medicare can terminate the provider from Medicare. We will reword the language in § 424.535(a)(12) to clarify the circumstances being addressed.

4. Final Provisions for Additional Medicare Provider Enrollment

This final rule with comment period finalizes the provisions of the proposed rule in regards to our discretion to revoke a provider or supplier's Medicare billing privileges when terminated, revoked or suspended by a State Medicaid agency with no modifications.

H. Technical and General Comments

Comment: A commenter stated that the definition of "provider of services" in section 1861(u) of the Act and "supplier" in section 1861(d) of the Act differs from the meaning of "provider of services" and "supplier," respectively, in the proposed rule. The commenter also was unclear as to whether the proposed rule's references to "providers" refer to "provider of services." The commenter requested clarification on both issues.

Response: The proposed rule stated that in Medicare, the term provider of services under section 1861(u) of the Act means health care entities that furnish services primarily payable under Part A of Medicare, such as hospitals, home health agencies (including home health agencies providing services under Part B), hospices, and skilled nursing facilities. The term "suppliers" defined in section 1861(d) of the Act refers to health care entities that furnish services primarily payable under Part B of Medicare, such as independent diagnostic testing facilities (IDTFs), durable medical equipment prosthetics, orthotics, and supplies (DMEPOS) suppliers, and eligible professionals, which refers to health care suppliers who are individuals, that is, physicians and the other professionals listed in section 1848(k)(3)(B) of the Act. For Medicaid and CHIP, we use the terms "providers" or "Medicaid providers" or "CHIP providers" when referring to all Medicaid or CHIP health care providers, including individual practitioners, institutional providers, and providers of medical equipment or goods related to care. The term "supplier" has no meaning in the Medicaid program or CHIP.

Comment: A commenter suggested that to avoid misinterpretation, non-physician practitioners should be clearly defined in the final rule with comment period.

Response: The proposed and final rule with comment period refer to non-physician practitioners to mean any non-physician practitioner who is eligible to enroll in Medicare, Medicaid or CHIP under existing regulations and statutes. In addition, this term is already defined at section 1848(b)(18)(C) of the Act.

Comment: A commenter stated that with the issuance of CMS–1510–F on November 2, 2010, CMS should renumber the denial and revocation reasons found in this proposed rule. In CMS–1510–F, CMS finalized a new denial reason in § 424.530(a)(8) and a new revocation reason in § 424.535(a)(12).

Response: We have revised these provisions in the regulatory text.

Comment: A commenter stated that CMS violated section 6(a) of Executive Order 12866 by not giving the public a 60 day review period for this rule and that CMS only allowed a 55 day review period. The commenter also could not

find a CMS Press Release or information on the CMS Web site indicating that CMS notified the public that it placed this rule on display and began the public comment period in advance of the publication of the proposed rule in the **Federal Register**. The commenter recommended that CMS reissue a new proposed rule or extend the comment period for this proposed rule by additional 60 days.

Response: The Department of Health and Human Services released a press release on September 20, 2010 accessible on its Web site that announced the display of the proposed rule at the **Federal Register**. The press release is accessible at: *http://www.hhs.gov/news/press/2010pres/09/20100920e.html.* Additional media outlets reported the proposed rule display on September 17th, 2010. We do not believe it is appropriate to extend the comment period for an additional 60 days, and we have taken into account all comments received during the comment period.

Comment: Several commenters stated that the proposed timeframe for implementation and compliance is extremely aggressive. First, smaller, rural providers and suppliers may not be organizationally able to fully comply without significant cost and effort, thus impacting access to care. Second, the DME MACs and the NSC will have to be able to identify suppliers and implement payment edits, both by specialty code.

Response: As stated previously, the timeline is a required under the ACA. We have been working closely with our contractors and with providers and suppliers to ensure that compliance with this final rule with comment period will not affect patients' access to health care.

Comment: Several commenters stated that the implementation timetables for this proposed rule were too ambitious, and that sufficient lead time is necessary for CMS to have operational computer programs in place to administer these requirements correctly and consistently.

Response: This final rule with comment period is implementing provisions of the ACA which sets forth deadlines for implementation of the screening provisions.

Comment: A commenter stated that in its manual instructions, CMS describes the verification of legalized status for physicians and non-physician practitioners. However, the commenter stated that the proposed rule is silent regarding the verification or screening process that will be used to determine legal status of an owner, authorized official, delegated official, managing employee, physician or non-physician. The commenter recommended that CMS explain this process in the proposed rule. Another commenter urged CMS to revise its existing CMS–855 enrollment applications to include questions on residency, legal status, and/or citizenship, arguing that this would help reduce fraud.

Response: Information collected on the CMS–855 enrollment applications are used to verify residency, including the Social Security Number and the Date of Birth. This process is a part of the general screening process, and is applied to all screening levels, including limited.

Comment: A commenter stated that since illegal immigrants are not legally authorized to work in the United States or own or operate a business in the United States, CMS should: (1) Coordinate and verify both the identity and work status of any individual practitioner or owner with the United States Citizenship and Immigration Services, and (2) establish new Medicare, Medicaid and CHIP denial and revocation reasons when an individual is not authorized to work in the United States legally and that CMS refer any individuals to the appropriate authorities for expulsion from the United States.

Response: As stated previously, we have existing procedures in place that verify an applicant's eligibility to work in the United States.

Comment: One commenter recommended that CMS furnish the number of providers and suppliers by specialty type that have or do not have an enrollment record in PECOS. This will, the commenter believes, help clarify the impact of this rule on providers and suppliers.

Response: This final rule with comment period does not impact the enrollment requirements related to PECOS for providers and suppliers. In May of 2010, we published CMS—6010–IFC which required all physicians and eligible professionals who order and refer home health services or Part B items and services (excluding Part B drugs) to Medicare to be enrolled in PECOS. Additional communications have been published with regard to that interim final rule with comment period, and do not impact the provisions finalized here. This final rule with comment period established the screening requirements for providers under Medicare, Medicaid and CHIP, and application fees for newly enrolling or revalidating providers. All newly enrolling or revalidating providers must establish records in PECOS as this is the only available enrollment option at this time.

Comment: A commenter stated that Medicare, Medicaid and CHIP must work in tandem to assure compliance, so that bad actors cannot move from one program to another and shelter themselves through the lack of coordinated data, standards, information and enforcement.

Response: We concur with this comment. This final rule with comment period implements the ACA provision that requires State Medicaid Agencies, to terminate a provider when a provider has been terminated by Medicare added at § 455.416. This final rule with comment period also implements regulations at § 455.470 that authorizes State Medicaid agencies to impose a temporary moratoria when Medicare imposes such a moratoria, except when the State Medicaid agency determines an imposition would affect beneficiaries' access. These provisions are directly aimed at eliminating the type of program abuses addressed by the commenter.

Comment: A commenter stated that despite the additional burdens it will create, it supported the proposed rule because there is no alternative. The commenter stated that if fraud, abuse and waste are not eliminated and quality improvement is not made central to home health and hospice, it feared for the future of home-based care when it is needed most.

Response: We agree with the commenter. We believe that these provisions are intended to protect the integrity of these programs for future generations.

Comment: A commenter suggested that CMS should change its contractors' claims processing system to a system similar to that used by credit card companies. This will help ensure that fraud and abuse can be detected in real time, rather than later.

Response: We are continually exploring additional improvements to our data systems, but disagree with the commenter's suggestion that we must change all of our contractors systems to implement real time data analysis. We are committed to working with both private and public partners to evaluate technologies that can provide the scalability and safeguards to beneficiary access that are necessary to ensure accurate payments to legitimate providers for appropriate services supplied to enrolled beneficiaries.

Comment: A commenter stated that CMS should establish a new requirement that organized medical staffs and hospitals report the provision of (but not the results of) peer review as

a quality indicator, and that CMS should post the quality indicator for each hospital department on its Hospital Compare Web site, together with an explanation of the importance of peer review to assure patient safety, quality, and identification of medically unnecessary services.

Response: This comment is beyond the scope of this rule. This final rule with comment period does not address the reporting of quality indicators or the Hospital Compare Web site.

Comment: A commenter stated that MACs should no longer accept certain CPT codes for laboratory test payments.

Response: This comment is beyond the scope of this rule. This final rule with comment period does not address our coverage and payment decisions for CPT codes.

Comment: A commenter stated that CMS should consider bidding out laboratory coding to a contractor, similar to the manner in which the PDAC operates for DME coding.

Response: This comment is beyond the scope of this rule. This final rule with comment period does not address the bidding of laboratory coding to a contractor.

Comment: A commenter expressed support for many of the details and provisions contained within the proposed rule and requested that CMS continue to seek input from all stakeholders about matters related to hospitals and health systems.

Response: We concur with the commenter's request to continue to seek input from all stakeholders, and fully intend to do so in regard to the requirements of this final rule with comment, as well as annual payment regulations.

Comment: A commenter expressed concern that anti-fraud laws and regulations, adopted to root out unscrupulous activity resulting from criminal intent, are increasingly used to impose harsh penalties for inadvertent mistakes and contribute to the escalating costs of health care as providers attempt to comply with increasingly voluminous and sophisticated systems and requirements.

Response: We continually balance the necessity to eliminate fraud, waste, and abuse with reducing the burden on legitimate providers, suppliers, and beneficiaries. Section 6401 of the ACA requires that the Secretary determine the level of screening according to the risk of fraud, waste, and abuse. This final rule with comment period implements this provision by instituting levels of screening based on risk of fraud, waste, and abuse, and has the flexibility to adapt to future developments by adjusting the categories as appropriate. We will use this new authority to prevent just such situations as described by the commenter, and will reduce the burden on legitimate providers who may make mistakes, and target fraud prevention resources appropriately.

Comment: A commenter stated that serial number tracking should be considered for much of the equipment provided by DMEPOS suppliers, similar to the Vehicle Identifier Number (VIN) system used in the transportation manufacturing industry.

Response: While we appreciate this comment, it appears to be outside the scope of this rule. Also, this comment would require a thorough evaluation of the cost of such a requirement on DMEPOS suppliers, the access issues it could potentially cause to beneficiaries if we mandated that only serial numbered equipment must be provided to beneficiaries, the additional system requirements that we would need to enhance to track such equipment, and the estimated benefit from such a requirement.

Comment: A commenter stated that the fight against health care fraud would be bolstered if Medicare, Medicaid and private insurers would share information about providers' enrollment and billing patterns. The commenter therefore recommended that CMS: (1) Revise its regulations and the CMS–855 to collect information about all other health care payers, and (2) share the information it collects via the enrollment and payment process with private payers, Medicaid, and Medicare Advantage Organizations.

Response: We would have to carefully evaluate the commenter's proposal. We must go through notice of rulemaking and comment period before revising any regulation. Additionally, we would have to carefully consider the privacy issues that accompany increased data sharing, especially with private payers, and weigh the potential concerns of providers and suppliers with the expected benefit of such a measure. However, we have been working closely with private and public partners regarding strategies to effectively work together to have a broad view of the health care claim landscape, and will continue to evaluate opportunities to collaborate on the improved detection of health care fraud.

Comment: A commenter urged CMS to consider ways to enhance Medicare CoPs for home health and hospice providers to achieve more lasting changes. The commenter stated that CMS withdrew the proposed CoPs changes for home health in 1997 and has not taken further action. The commenter recommended that CMS consult with provider groups to revise and finalize the CoPs for home health as quickly as possible.

Response: This comment is outside of the scope of the final rule with comment period.

Comment: A commenter recommended that CMS: (1) Provide the direct savings that have resulted from provider screening activities between 2000 and 2010, (2) calculate the savings to the Medicare Trust Funds and the General Fund based on this proposed rule, and (3) explain whether the estimated savings will result in fewer actual dollars spent on health care or whether the changes proposed will only slow the expenditure growth.

Response: We believe that all of the agency's program integrity activities have resulted in savings to the Trust Fund and the General Fund. We are not required to report a return on investment regarding historical screening initiatives, or project savings regarding the statutory requirements. The fact that we have in the past denied any application means that we have prevented an unqualified provider or supplier from providing services and/or care to Medicare beneficiaries that could have resulted in physical harm or financial loss to such a beneficiary.

Comment: One commenter stated that this proposed rule will be ineffective in halting fraud because it is reactive, and it is impossible for any government entity to react in a timely manner.

Response: We disagree with the comment that the new authorities in this final rule with comment period are reactive. Particularly, the screening requirements for newly enrolling providers which will proactively prevent individuals from entering the Medicare, Medicaid and CHIP programs for the sole purpose of defrauding taxpayers. Temporary moratoria will also permit the agency to develop a strategy to mitigate the risk of fraud while stopping the pace of potentially fraudulent enrolling providers. We believe these new tools will enable us to become a more proactive gatekeeper of the Medicare Trust Fund.

Comment: A commenter recommended that all providers and suppliers be subject to the provisions associated with section 6401(a)(3) of the ACA.

Response: This comment is outside of the scope of this final rule with comment period.

Comment: A commenter contended that CMS's statement in the preamble that Medicare is the primary payer of health care for 45 million enrolled

beneficiaries is incorrect. The correct number should be more than 47 million. The commenter also recommended that CMS provide the number of Medicare beneficiaries that are enrolled in Medicare Advantage plans.

Response: We will address this correction in the preamble. The provisions of this final rule with comment period do not apply to Medicare Advantage plans, so the number of Medicare Advantage-enrolled beneficiaries would not be relevant to the preamble.

Comment: A commenter questioned whether CMS could implement the provisions of this proposed rule when information on its provider enrollment Web site is not regularly updated.

Response: We are implementing provisions of this proposed rule, and are working with the provider community in various outlets, including its provider Web site. The provider enrollment Web site will reflect the requirements of this final rule with comment period.

Comment: Several commenters stated that the Federal and State programs will be more efficient if they recognize another program's enrollment determinations, decisions to suspend payments, and imposition of moratoria. To handle the complexity and coordination of monitoring participation and appropriately suspending payments or terminating contracts with providers and suppliers, the commenter recommended CMS develop and maintain a central, consolidated database for housing participation status, suspension of payments and imposed moratoria for all three programs. The commenters stated that CMS should also strengthen and expand efforts to coordinate data sharing between government health programs across the various Federal agencies, as well sharing of information with MAOs, MCOs and CHIP sponsors.

Response: We agree with the previous comment that we should seek to become more efficient by sharing screening determinations, decisions to suspend payments and imposition of enrollment moratoria to the extent possible under applicable laws. We are continually evaluating and strengthening efforts to coordinate data sharing between health programs across various agencies.

Comment: A commenter stated that regulators and industry need to work together to minimize the impact of sham companies and other instances of fraud, and that this proposed regulation is a step in the right direction.

Response: We agree with this comment.

III. Collection of Information Requirements

Under the Paperwork Reduction Act of 1995, we are required to provide 60-day notice in the **Federal Register** and solicit public comment before a collection of information requirement is submitted to the Office of Management and Budget (OMB) for review and approval. In order to fairly evaluate whether an information collection should be approved by OMB, section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 requires that we solicit comment on the following issues:

- The need for the information collection and its usefulness in carrying out the proper functions of our agency.
- The accuracy of our estimate of the information collection burden.
- The quality, utility, and clarity of the information to be collected.
- Recommendations to minimize the information collection burden on the affected public, including automated collection techniques.

We solicited public comment on each of these issues for the following sections of this document that contain information collection requirements (ICRs):

For this final rule with comment period, we will be retaining the Collection of Information estimates in the proposed rule, in accordance with the discussion below.

A. ICRs Regarding Medicare Application Fee Hardship Exception (§ 424.514)

Section 424.514(e) states that a provider or supplier that believes it has a hardship that justifies a waiver exception of the application fee must include with its enrollment application a letter that describes the hardship and why the hardship justifies a waiver exception. The burden associated with this requirement is the time and effort necessary to submit a Medicare enrollment application, which is required currently of any individual or entity enrolling in Medicare. In addition to the enrollment application, a provider or supplier would have the new burden of drafting and submitting a letter to justify its hardship waiver request should it choose to submit one. The burden associated with submitting Medicare enrollment applications A, B, I, R and CMS–855S, are currently approved under Office of Management and Budget (OMB) control numbers 0938–0685 and 0938–1057, respectively). Although we have no way of knowing for certain how many entities will actually submit an application with a letter requesting a waiver, we know that there are likely to be more such requests in the early years of implementation than in later years. We estimated that in the first year, 12,000 providers or suppliers—or slightly over 50 percent of the total number of providers and suppliers that we believe will be subject to the application fee—will submit waiver request letters as part of their application packages. (As stated in the preamble, the application fee does not apply to individual eligible professionals nor to group practices of these individual professionals.) We also estimated that it will take each provider or supplier 1 hour to develop the letter. The total estimated annual burden associated with this requirement is therefore 12,000 hours at a cost of $600,000, or $50.00 per waiver request.

B. ICRs Regarding Medicare Fingerprinting Requirement (§ 424.518)

Consistent with § 424.518 we will require the submission of a set of fingerprints—either electronically collected by CMS' authorized channeler or using the FD–258 standard fingerprint card obtained from the local law enforcement agency that collected the fingerprints—from all individuals who maintain a 5 percent or greater direct or indirect ownership interest in a prospective HHA or DMEPOS supplier that is enrolling in Medicare. We estimate that CMS or its designated contractors will make 7,000 such requests per year. This is predicated on our projection that—based on 2009 statistics—roughly 7,000 DMEPOS suppliers and HHAs will annually enroll in Medicare. For purposes of this ICR statement only, and to ensure that we do not underestimate the possible burden, we estimate that all of these providers and suppliers will be required to submit fingerprints. We further estimate that an average of five individuals per provider or supplier will be required to comply with this request. (It must be noted that for purposes of this ICR and the RIA below, we sought comments on whether the estimate of five individuals per applicant is accurate. No comments were received.) Additionally, we estimate that it will take each of the 35,000 respondents (7,000 provider requests × 5 respondents per provider request) an average of 2 hours to obtain and submit fingerprints. Consequently, the total estimated annual burden associated with this requirement is 70,000 hours (35,000 responses × 2 hours per response) at a cost of $3.5 million (70,000 hours × $50 per hour).

Sections 424.518(c)(3)(ii) and (iii) call for the submission of a set of fingerprints for a national background

check from all individuals who maintain a 5 percent or greater direct or indirect ownership interest in a provider or supplier that has moved into the "high" risk category based on an adverse action or the lifting of a moratorium. The burden associated with this requirement is the time and effort necessary for the individual to submit the required information upon request. We estimate that CMS or its designated contractors will make 2,000 requests per year. This is based on the number of providers and suppliers that we estimate will attempt to enroll in Medicare: (1) After the lifting of a moratorium for their respective provider or supplier type, or (2) that have had one of the adverse actions in § 424.518(c)(3)(ii) imposed against it. This estimate of course, cannot be conclusively quantified because it is impossible for us to say with certainty which provider and supplier types will be subject to a moratorium. To ensure that we do not underestimate the potential burden, we also calculated projections should 5,000 or 10,000 requests be made.

We estimate that an average of five individuals per provider or supplier will be required to comply with this request. We further project that it will take each of the 10,000 respondents (2,000 provider or suppliers requests × 5 respondents per provider or supplier request) an average of 2 hours to obtain and submit the fingerprints. The estimated annual burden associated with this requirement, based on 2,000 requests is 20,000 hours (10,000 respondents × 1 response per respondent × 2 hours per response) at a cost of $1 million (20,000 hours × $50 per hour). If 5,000 requests are made, the burden is 50,000 hours at a cost of $2.5 million (5,000 requests × 5 responses per request × 2 hours per response × $50 per hour.) If 10,000 requests are made, the burden is 100,000 hours at a cost of $5 million (10,000 requests × 5 responses per request × 2 hours per response × $50 per hour).[6]

In addition, there are some limited circumstances when CMS could ask a physician to submit fingerprints. For example, a provider or supplier that is being enrolled in Medicare after the lifting of a temporary moratorium could automatically be classified as "high" risk and, as such, would be subject to criminal background checks and fingerprinting of owners of the company. If a physician were to have a 5 percent or greater direct or indirect ownership interest in the provider or supplier, CMS would have the authority to request fingerprints from him or her. Other circumstances might include when a physician has had an adverse action imposed against him or her and, in accordance with § 424.518(c)(3)(ii), has been placed in the "high" risk category. We estimate that CMS or its designated contractors will make 500 such requests for fingerprints per year. We further estimate that it will take each of the 500 respondents a total of 2 hours to obtain and submit the fingerprints. The total estimated annual burden associated with this requirement is 1,000 hours (500 respondents × 1 response per respondent × 2 hours per response) at a cost of $50,000 (1,000 hours × $50 per hour).

Therefore, assuming that 2,000 post-moratorium requests for fingerprints are made, the total estimated annual burden associated with the Medicare requirements in this ICR is 103,000 hours at a cost of $5,150,000. If 5,000 post-moratorium requests are made, the estimated annual burden is 133,000 hours at a cost of $6,650,000. If 10,000 post-moratorium requests are made, the estimated annual burden is 183,000 hours at a cost of $9,150,000.

Comment: In the collection of information requirements section of this proposed rule, CMS used 2009 statistics for estimating the number of individuals that will need to undergo fingerprinting. A commenter recommended that CMS update these estimates using 2010 data.

Response: We believe it is more appropriate to use the most recent full year's data.

Comment: A commenter contended that CMS's estimate that it will take 2 hours to obtain a set of fingerprints using the FD–258 standard fingerprint card seems low. The commenter recommended that CMS provide the analysis used, including literature review, to estimate the time it will take to obtain a set of fingerprints using the FD–258 fingerprint card. The commenter also asked that CMS explain whether there are any alternatives to the FD–258 standard fingerprint card and, if there are, the costs associated with these alternatives.

Response: We believe that the 2 hour figure, which was based on our analysis of a number of materials, is accurate. Since the FD–258 is the standard fingerprint card, we focused primarily on the use of this format in the proposed rule. However, as explained in the preamble to this final rule with comment period, electronic fingerprints will be an alternative—and one that we will encourage—to the FD–258.

C. ICRs Regarding Medicaid Fingerprinting Requirement (§ 455.434)

Section 455.434 states that when a State Medicaid agency determines that a provider is "high" risk, the State Medicaid agency will require that provider to submit fingerprints. We anticipate that States will be collecting fingerprints on a significantly smaller number of providers. However, as with our estimates of the potential burden for the Medicare requirements, we preferred to overestimate the potential burden rather than underestimate it. Therefore, we anticipate that States may require an additional 26,000 individuals to submit fingerprints prior to enrolling in a State's Medicaid program or CHIP. The total estimated annual burden associated with this requirement for Medicaid and CHIP is 52,000 hours (26,000 respondents × 1 response per respondent × 2 hours per response) at a cost of $2.6 million (52,000 hours × $50 per hour).

D. ICRs Regarding Suspension of Payments in Cases of Fraud or Willful Misrepresentation (§ 455.23)

As stated in § 455.23(a), a State Medicaid agency must suspend all Medicaid payments to a provider when there is pending an investigation of a credible allegation of fraud under the Medicaid program against an individual or entity unless it has good cause to not suspend payments or to suspend payment only in part. The State Medicaid agency may suspend payments without first notifying the provider of its intention to suspend such payments. A provider may request, and must be granted, administrative review where State law so requires.

The burden associated with this requirement is the time and effort necessary for a provider to request administrative review where State law so requires. While this requirement is subject to the PRA, we believe the associated burden is exempt in accordance with 5 CFR 1320.4.

E. ICRs Regarding Collection of SSNs and DOBs for Medicaid and CHIP Providers (§ 455.104)

As stated in § 455.104(b)(1), the State Medicaid agency must require that all persons with an ownership or control interest in a provider submit their SSN and DOB. The burden associated with the Medicaid requirements in § 455.104(b)(1) is the time and effort necessary for a provider to report the SSN and DOB for all persons with an ownership or control interest in a provider.

Although our data on Medicaid provider enrollment at the national level

[6] Note that these figures pertain only to individuals who are not physicians. Physicians are addressed in the following paragraph.

is very limited, we do collect annual data on State Medicaid program integrity activities. This annual data collection, known as the State Program Integrity Assessment (SPIA) program, approved under OCN 0938–1033, consists of self-reported data by States regarding a variety of program integrity related activities. The information is self-reported and has not been independently verified by CMS, and it undoubtedly represents some unknown degree of duplication among providers across States. Consequently, the estimated number of Medicaid providers nationally is likely overstated.

According to SPIA data for FFYs 2007 and 2008, there has been an average of 1,855,070 existing Medicaid providers nationally over the 2 year period of FFY 2007 and FFY 2008. We estimate that one-fifth or 371,014 (1,855,070 × 20 percent) of existing Medicaid providers would be required to re-enroll each year. Additionally, we estimate that there will be 56,250 newly enrolling Medicaid providers each year, for a total of 427,264 Medicaid providers that will be subject to the SSN and DOB reporting requirements each year. We further estimate that it will take each provider an average of 2 minutes to report the SSN and DOB for all persons with an ownership or control interest. Thus, the estimated annual burden associated with this requirement for Medicaid providers is 14,242 hours (427,264 × (2 minutes, divided by 60 minutes per hour)) at a cost of $712,100 (14,242 hours × $50 per hour).

F. ICRs Regarding Site Visits for Medicaid-Only or CHIP-Only Providers (§ 455.450)

As stated in § 455.450(b), a State Medicaid agency must conduct on-site visits for providers it determines to be "moderate" or "high" categorical risk. We anticipate that Medicare contractors will perform the screening activities for the overwhelming majority of providers that are dually enrolled in both Medicare and Medicaid and thus, we estimate that State Medicaid agencies will conduct approximately 5,000 site visits for Medicaid-only providers nationally per year. We further estimate that it will take one individual 8 hours to perform each on-site visit (including travel time). Thus, the total estimated annual burden associated with this requirement for Medicaid is 40,000 hours (5,000 site visits × 8 hours) at a cost of $2,000,000 (40,000 hours × $50 per hour).

G. ICRs Regarding the Rescreening of Medicaid Providers Every 5 Years (§ 455.414)

As stated in § 455.414, a State Medicaid agency must screen all providers at least every 5 years. This requirement is consistent with the Medicare requirement that providers, suppliers, and eligible professionals must re-enroll at least every 5 years (more often for certain types of suppliers). The burden associated with this requirement would be the time and effort necessary for Medicaid-only providers to re-enroll in Medicaid, and the time and effort necessary for a State to conduct the provider screening,

Although our data on Medicaid provider enrollment at the national level is very limited, we do collect annual data on State Medicaid program integrity activities. As previously explained, this annual data collection, known as the State Program Integrity Assessment (SPIA) program, consists of self-reported data by States regarding a variety of program integrity related activities. The information is self-reported and has not been independently verified by CMS, and it undoubtedly represents some unknown degree of duplication among providers across States. Consequently, the estimated number of Medicaid providers nationally is likely overstated.

According to SPIA data for FFYs 2007 and 2008, there has been an average of 1,855,070 existing Medicaid providers nationally over the 2 year period of FFY 2007 and FFY 2008. We estimate that one fifth, or 371,014 (1,855,070 × 20 percent), of existing Medicaid providers would be required to re-enroll each year. Although provider enrollment requirements vary by State, we further estimate that it will take each provider an average of 2 hours to complete the Medicaid re-enrollment requirements. Thus, the estimated annual burden associated with this requirement for Medicaid providers is 742,028 hours (371,014 responses × 2 hours per response) at a cost of $37,101,400 (742,028 hours × $50 per hour).

In addition, we estimate that 80 percent of Medicaid providers also participate in Medicare, and thus would have provider screening activities performed by the Medicare contractors. Thus, we estimate that States would be required to conduct provider screening activities for 74,203 (371,014 × 20 percent) re-enrolling Medicaid-only providers each year. We further estimate that it will take States, on average, 4 hours to perform the required provider screening activities—noting that currently enrolled providers would generally be categorized as lower risk than newly-enrolling providers. The estimated burden associated with this requirement for State Medicaid agencies is 296,812 hours (74,203 responses × 4 hours per response) at a cost of $14,840,600 (296,812 hours × $50 per hour). We believe that the burden on States will be in large part offset by the application fees collected and by the Federal share for the amounts not covered by the application fee.

The total estimate annual burden associated with the Medicaid prescreening requirement is 1,038,840 hours at a cost of $51,942,000 ($37,101,400 + $14,840,600).

TABLE 10—ESTIMATED ANNUAL REPORTING/RECORDKEEPING BURDEN

Regulation section(s)	OMB Control No.	Respondents	Responses	Burden per response (hours)	Total annual burden (hours)	Hourly labor cost of reporting ($)	Total labor cost of reporting ($)	Total capital/maintenance costs ($)	Total cost ($)
§ 424.514(e)**	0938–0685; 0938–1057	12,000	12,000	1	12,000	50	600,000	0	600,000
§ 424.518(c)(2)(b) and (d)	0938–New	35,000	35,000	2	70,000	50	3,500,000	0	3,500,000
§ 424.518(c)(3)(iv) and (d)	0938–New	10,500	10,500	2	21,000	50	1,050,000	0	1,050,000
§ 455.434	0938–New	26,000	26,000	2	52,000	50	2,600,000	0	2,600,000
§ 455.104	0938–New	427,264	427,264	.033	14,242	50	712,100	0	712,100
§ 455.450	0938–New	5000	5000	8	40,000	50	2,000,000	0	2,000,000
§ 455.414 (Providers)	0938–New	371,014	371,014	2	742,028	50	37,101,400	0	37,101,400
§ 455.414 (State Medicaid Agencies)	0938–New	74,203	74,203	4	296,812	50	14,840,600	.....	14,840,600

TABLE 10—ESTIMATED ANNUAL REPORTING/RECORDKEEPING BURDEN—Continued

Regulation section(s)	OMB Control No.	Respondents	Responses	Burden per response (hours)	Total annual burden (hours)	Hourly labor cost of reporting ($)	Total labor cost of reporting ($)	Total capital/maintenance costs ($)	Total cost ($)
Total		960,981	960,981		1,248,082				62,404,100

** Denotes that we will be submitting revisions of the currently approved information collection requests for OMB review and approval.

Comment: A commenter requested clarification on whether the dollar figure of $62 million in Table 6 of the proposed rule (entitled "Estimated Annual Reporting/Recordkeeping Burden") is the cost shared by the Federal Medicare programs as well as all of the State Medicaid agencies collectively.

Response: It includes Medicare costs, and those of the State Medicaid agencies.

IV. Response to Comments

Because of the large number of public comments we normally receive on **Federal Register** documents, we are not able to acknowledge or respond to them individually. We will consider all comments we receive by the date and time specified in the "**DATES**" section of this preamble, and, when we proceed with a subsequent document, we will respond to the comments in the preamble to that document.

V. Regulatory Impact Analysis

A. Statement of Need

This final rule with comment period is needed to implement the following provisions of the ACA: (1) Section 6401(a) and section 6401(b) of the ACA added section 1866(j)(2) to the Act and requires the establishment of screening procedures for providers and suppliers in the Medicare, Medicaid and CHIP programs; (2) section 6401(a) of the ACA added section 1866(j)(2)(C) to the Act and requires the establishment of application fees for institutional providers and suppliers; (3) section 6401(a) of the ACA added a new section 1866(j)(7) to the act establishing the use of temporary moratoria regarding the enrollment of providers and suppliers in Medicare, and section 6401(b)(1) of the ACA added a new section 1902(kk)(4) of the Act for a parallel requirement in the Medicaid and CHIP programs; (4) section 6501 of the ACA added section 1902(a)(39) to the Act establishing guidance for States regarding the termination of providers from Medicaid and CHIP if terminated by Medicare or another Medicaid State plan or CHIP; and permitting guidance regarding the termination of providers and suppliers from Medicare if terminated by a Medicaid State agency; and (5) Section 6402(h) of the ACA added 1862(o) to the Act establishing the requirements for the suspension of payments pending credible allegations of fraud in the Medicare and Medicaid programs. As previously explained, we believe these provisions are necessary to assist us in preventing fraud, waste and abuse in the Medicare, Medicaid and CHIP programs.

B. Overall Impact

We have examined the impact of this rule as required by Executive Order 12866 on Regulatory Planning and Review (September 1993), the Regulatory Flexibility Act (RFA) (September 19, 1980, Pub. L. 96–354), section 1102(b) of the Social Security Act, section 202 of the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4), Executive Order 13132 on Federalism (August 4, 1999), and the Congressional Review Act (U.S.C. 804(s)).

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 with comment period does reach the economic threshold and thus is considered an economically significant rule.

The RFA requires agencies to analyze options for regulatory relief for small businesses. Under the RFA, we must either prepare an Initial Regulatory Flexibility Analysis or certify that the final rule with comment period will not have a significant impact on a substantial number of small entities. For purposes of the RFA, small entities include small businesses, nonprofit organizations, and government agencies. Most hospitals and most other providers and suppliers are small entities, either by nonprofit status or by having revenues of less than $7.0 to $34.5 million (depending on provider type) in any one year. Individuals and States are not included in the definition of a small entity. We do not believe that our application fees will have a significant impact on any small entities. Likewise, we do not believe that other screening provisions, such as the provision of fingerprints or accommodating unannounced visits, will have a significant impact on any small entities. We believe this final rule with comment period could have significant impact on a relatively small proportion of small businesses in terms of restrictions on federal health monies paid to small businesses participating in the Medicare or Medicaid programs or CHIP. Clearly, imposition of an enrollment moratorium would have an impact on a small business that is attempting to do business with any of the Federal health programs. Similarly, suspension of payments to any small entity could create a significant impact on that entity. However, we have no basis for estimating how many entities might be affected by these provisions. Finally, we believe that this final rule with comment period will reduce fraud and abuse among potential providers.

We believe there will be a significant impact on their ability to defraud the taxpayer in several ways. First, closer screening of certain high-risk providers and suppliers will better enable CMS to detect those individuals and entities that pose a risk to the Medicare program. We expect that the prevention of unqualified providers and suppliers from enrolling in Medicare will protect the Medicare Trust Fund and save the taxpayers millions of dollars. Second, the temporary moratoria provisions will enable CMS to restrict the entry of certain providers and suppliers into Medicare in order to prevent or combat fraud, waste, and abuse, thus, again, saving millions of Federal dollars. While we cannot quantify with exactitude the amount of money that the Medicare program will save as a result of these measures, we do believe that the figure will exceed the costs outlined in this RIA. We solicited comment on the overall proposed screening processes of the proposed rule, including how the risk of fraud is determined, the administrative

interventions proposed to address the risk, and the criteria for exceptions to the enrollment application fee and any temporary enrollment moratoria. We requested that small businesses comment on these provisions and offer suggestions about how to mitigate what they might see as adverse administrative or financial impacts. This RIA, taken together with the remainder of the preamble, constitutes an Initial Regulatory Flexibility Analysis under the RFA.

In addition, section 1102(b) of the Act requires us to prepare a regulatory impact analysis if a rule may have a significant impact on the operations of a substantial number of small rural hospitals. This analysis must conform to the provisions of section 604 of the RFA. For purposes of section 1102(b) of the Act, we define a small rural hospital as a hospital that is located outside of a Metropolitan Statistical Area and has fewer than 100 beds. We did not prepare an analysis for section 1102(b) of the Act because we have determined that this final rule with comment period will not have a significant impact on the operations of a substantial number of small rural hospitals.

Section 202 of the Unfunded Mandates Reform Act of 1995 also requires that agencies assess anticipated costs and benefits before issuing any rule that may result in expenditure in any 1 year by State, local, or tribal governments, in the aggregate, or by the private sector, of $135 million. This rule does mandate expenditures by State and local governments, in order to enforce the Medicaid-related provisions, but we believe that those expenditures will be relatively minor. The mandated costs on providers—primarily for application fees—may approach or exceed the threshold for the private sector. Accordingly, this RIA constitutes the required assessment of costs and benefits under UMRA.

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. Since this final rule with comment period would not impose any substantial direct requirement costs on State or local governments, preempt State law, or otherwise have Federalism implication, the requirements of E.O. 13132 are not applicable.

We received several comments on the RIA. They are as follows:

Comment: A commenter noted that, under the proposed rule, Medicare contractors will not begin processing an enrollment application until the application fee is received and credited to the United States Treasury. The commenter recommended that CMS estimate the increase in enrollment application processing times due to the fee requirement and the impact this additional time will have on private sector.

Response: It is not possible to qualify the additional time, if any, that this requirement would have on processing times. Moreover, we do not believe that a minor delay in processing would result in any quantifiable and definable monetary cost to a particular provider.

Comment: Several commenters contended that CMS did not comply with section 6(a)(3)(C)(i) of Executive Order 12866. Specifically, CMS: (1) Did not include an assessment or quantification of benefits associated from this regulatory action; (2) the underlying analysis of the costs and benefits of potentially effective and reasonably feasible alternatives to the planned regulation; (3) explain why the planned regulatory action is preferable to the identified potential alternatives; (4) include any feasible alternatives to the planned screening process; (5) include alternatives to the payment suspension portions; (6) include the cost impact on health care providers due to increased processing times; (7) solicit comments on or consider the costs or benefits of reasonably feasible alternatives, such as assessing the application fee by NPI or TIN or assessing the risk based on as past experience with the Medicare program or other health plans; or (8) consider the Medicare error rate in determining the category of risk. The commenter stated that CMS should therefore not finalize the provisions of this proposed rule until a new proposed rule is published.

Response: The proposed rule and the final rule with comment period both contain a Regulatory Impact Analysis as required by Executive Order 12866. As explained in section IV.E. and throughout this final rule with comment period, we believe that this regulation will have a significant benefit by reducing the ability of potential providers to defraud taxpayers. The proposed rule solicited comments on the proposed screening categories, on the use of fingerprinting and other alternatives to identity verification, on the kind of documentation that must be submitted to assert a hardship exception to the application fee, an alternative definition of the term "resolution of an investigation," on criteria that would justify the reclassification of a provider from one risk category to another, on the applicability of geography in the determination of a risk category, and on additional triggers that would move a provider into a different risk category.

We did not believe the use of NPIs or TINs in the assessment of the application fee was appropriate because the requirement to submit an enrollment application is separate from the requirement to have an NPI or a TIN. We believe that basing the fee on the submission of an application is most consistent with the statute. With respect to the Medicare error rate, an erroneously paid claim does not necessarily mean that the claim was fraudulently submitted. For this reason, we believe it would be improper to use it in our placement of providers into risk categories when there were other factors—including comprehensive studies of fraudulent behavior, such as OIG and GAO reports—that were more conclusive. We have solicited comments on proposals and potential alternatives, and have considered such comments in the development of this final rule with comment period.

Comment: A commenter stated that the proposed rule contained a number of internal inconsistencies between the preamble and regulation impact statement, such as: (1) use of 2.34 percent as the CPI in preamble and 3.0 percent as the CPI in the regulation impact section; (2) the lack of an "Alternatives Considered" section in the regulation impact section, and (3) a failure to account for the cost or impact of the additional off-cycle revalidations in the regulation impact section. The commenter recommended that CMS publish a new proposed rule.

Response: The use of 2.34 percent in the preamble was simply for illustrative purposes. Having said that we have revised the 3 percent figure to more accurately reflect actual and projected CPI–U statistics we have received. Specifically, the rates we used for 2011, 2012, 2013, 2014 and 2015 are, respectively, 1.0 percent, 2.0 percent, 2.0 percent, 2.0 percent and 2.0 percent. The figure for 2011 is based on data obtained from the Bureau of Labor Statistics, while the data for years 2012 through 2015 represent the estimated CPI–U figures offered in the Budget of the U.S. Government, Fiscal Year 2011. The CPI–U figures reflect the percentage change in the consumer price index for all urban consumers (all items; United States city average), for the 12-month period ending with June of the previous year. Moreover, we have added an "Alternative Considered" section to the RIA.

As stated previously, we solicited comments on multiple issues in the

proposed rule. Additionally, we are implementing provisions of the ACA that had already outlined certain requirements for the regulations. The ACA, for example, required that we determine the level of screening to be conducted with respect to the category of provider or supplier, to require an application fee of $500 adjusted after 2010 for the consumer price index, and to suspend payments pending an investigation of credible allegations of fraud.

The RIA took into account the cost of revalidations beginning on March 25, 2011, prior to the date at which CMS could begin off-cycle validations under § 424.515(e), but the same date at which the new screening requirements will go into effect. Any provider validated after March 25, 2011 but before March 23, 2012 will not be subject to off-cycle revalidation and any provider that is revalidated will begin a new cycle of revalidation requirements. Therefore, any off-cycle revalidations that occur after March 23, 2012 will restart the revalidation cycle, and only DMEPOS suppliers who are on 3 year validations will be revalidated, in cycle, prior to the end of CY 2015. We believe the RIA is valid.

Comment: A commenter noted that, under the proposed rule, Medicare contractors will not begin processing an enrollment application until the application fee is received and credited to the United States Treasury. The commenter recommended that CMS estimate the increase in enrollment application processing times due to the fee requirement and the impact this additional time will have on private sector.

Response: It is not possible to qualify the additional time, if any, that this requirement would have on processing times. Moreover, we do not believe that a minor delay in processing would result in any quantifiable and definable monetary cost to a particular provider.

Comment: One commenter stated that the preamble of this proposed regulation uses 2.34 percent as the Consumer Price Index (CPI) for the application fee, while the regulatory impact section uses 3 percent as the CPI for the application fee. The commenter recommended that CMS: (1) Use the official percentage by the Bureau of Labor Statistics in calculating the change in application fee year by year, (2) explain if a negative CPI will result in a decrease in the application fee, and (3) use the actual CPI for 2010 in developing the final rule with comment period and establishing the application fee that must be paid by providers and suppliers in 2011.

Response: We agree and, as previously explained, have incorporated more accurate CPI–U rates into this final rule with comment period. A negative CPI would result in a fee decrease; however, the RIA projects a continued increase in the CPI.

Comment: A commenter noted that CMS states in the RIA that 400,000 providers and suppliers would need to revalidate their enrollment over a 5 year period. However, CMS excluded groups and clinics from the impact of the application fee. The commenter did not believe there are 400,000 providers and suppliers to revalidate, since a large number of providers and suppliers are designated as medical groups/clinics. The commenter recommended that CMS furnish a breakdown of the providers and suppliers that would be required to revalidate their enrollment in Medicare and adjust, if necessary, the amount collected via the application fee. The commenter also suggested that CMS provide the number of providers and suppliers by year that were subject to revalidation since 2006.

Response: We do not believe that a specific breakdown by provider type and year is necessary, and maintain our view that approximately 400,000 providers and suppliers will revalidate their enrollment over a 5 year period—even accounting for medical groups/clinics. This figure, admittedly, may be a little high, but we would prefer to overestimate the potential burden than underestimate it.

In light of these comments, we have revised our calculations based on new and more accurate CPI–U rates and have added an "Alternative Considered" section.

C. Anticipated Effects

1. Medicare

a. Enhanced Screening Procedures—Medicare

Based on statistics obtained from PECOS and our Medicare contractors, there are approximately 400,000 providers and suppliers currently enrolled in the Medicare program. (This does not include eligible professionals.) This figure includes ambulance service suppliers; ambulatory surgical centers; community mental health centers; comprehensive outpatient rehabilitation facilities; suppliers of DMEPOS; end-stage renal disease facilities; federally qualified health centers; histocompatibility laboratories; home health agencies; hospices; hospitals, including physician-owned specialty hospitals; critical access hospitals; independent clinical laboratories; independent diagnostic testing facilities; Indian health service facilities; mammography centers; mass immunizers (roster billers); medical groups/clinics, including single and multi-specialty clinics; organ procurement organizations; outpatient physical therapy/occupational therapy/speech pathology services; portable x-ray suppliers; skilled nursing facilities; radiation therapy centers; religious non-medical health care institutions; and rural health clinics. We note the following in section III. of this final rule with comment period:

- Based on 2009 experience we estimated that there will be 7,000 DMEPOS suppliers and HHAs that will submit an application to become a new Medicare enrolled provider in 2011. We would require approximately 35,000 individuals (7,000 providers/suppliers x 5 individuals per applicant) to undergo fingerprinting to participate in the Medicare program as an owner of an HHA or supplier of DMEPOS. We have found that the cost of having a set (two prints) of fingerprints done through law enforcement is approximately $50.00 per individual. (This includes the time spent in obtaining the fingerprints.) The cost of this fingerprinting requirement would therefore be $1.75 million per year (35,000 individuals x $50).
- We estimated that 10,000 individuals (2,000 providers or suppliers × 5 individuals per applicant) would undergo fingerprinting following the lifting of a moratorium on a particular provider or supplier type, at a cost of $500,000 per year (10,000 × $50). Should requests be made of 5,000 providers or suppliers, the annual figure would be $1,250,000 (5,000 × 5 individuals per applicant × $50). Should requests be made of 10,000 providers or suppliers, the annual figure would be $2.5 million (10,000 × 5 × $50).
- We estimate that 500 physicians would undergo fingerprinting per year, at a cost of $25,000.

This results in a total cost of the fingerprinting requirement of $2,275,000 per year ($1,750,000 + $500,000 + $25,000), or $11,375,000 over 5 years. If 5,000 post-moratorium requests are made, the annual cost is $3,025,000, with a 5 year cost of $15,125,000. Should 10,000 post-moratorium requests be made, the annual cost is $4,275,000, with a 5 year cost of $21,375,000.

As we believe that 2,000 post-moratorium requests is the most likely scenario, we will hereafter use the $2,275,000 amount as the annual cost of this requirement. This results in an estimated 5 year cost of $11,375,000.

b. Application Fee—Medicare

The Secretary shall impose an application fee on each institutional provider. The amount of the fee is $500 per provider or supplier for 2010. For 2011 and each subsequent year, the fee amount will be determined by the statutorily required formula using the consumer price index for all urban consumers (CPI–U). The enrollment application fee does not apply to individual eligible professionals (for example, physicians). The fee is to be paid by institutional providers only. The new screening provisions are applicable to new and revalidating providers and suppliers effective March 25, 2011, and to currently enrolled providers and suppliers as of March 23, 2012. We will to begin collecting the enrollment application fee for new providers and suppliers and for currently enrolled providers revalidating enrollment effective March 25, 2011.

c. General Enrollment Framework

(1) New Enrollment

Medicare contractors report that over the last several years, approximately 32,000 is the annual number of newly enrolling providers and suppliers that would—without accounting for the possible granting of waivers—be subject to the enrollment application fee—(approximately 20,000 for Medicare Part B, approximately 7,000 DMEPOS suppliers and HHAs (as explained in the Collection of Information section), and approximately 5,000 non-HHA Medicare Part A providers).[7]

We assumed that no more than 2.5 percent of these 32,000 providers and suppliers—or 800—will receive a hardship exception; as indicated earlier, exceptions will only be approved infrequently.

In CY 2011, we reduced the estimate number of institutional providers subject to the application fee by 25 percent because the application fee will not begin until March 25, 2011. Accordingly, the number of institutional providers that we anticipate paying the application fee will be 23,400 (or 31,200 × .75) in CY 2011. Therefore, the impacts of the enrollment application fee are as follows. If we use 23,400 as the number of newly enrolling providers and suppliers in 2011 and multiply this number by an application fee of $505 (or $500 × 1.0 percent), we get $ 11,817,000 collected for the first year (that is, CY 2011). If we assume that the number of newly enrolling providers and suppliers will remain constant at 31,200 for years 2012 through 2015, the cost to the number of newly enrolling providers and suppliers would be $78,054,600. Although we have no way to predict that the number of new enrollments will change in future years, it is possible that the number of enrolling providers and suppliers vary from what has been the norm. If our estimate of the number of newly enrolling providers is inaccurate and we enroll a different number of providers and suppliers after the effective date of the new screening and other provisions contained in the ACA, we estimate based on the $500 enrollment application fee—a rough difference of $1 million for each increment of 2,000 new enrollments, whether fewer or greater.

TABLE 11—CUMULATIVE APPLICATION FEES FOR NEWLY ENROLLING MEDICARE PROVIDERS AND SUPPLIERS FOR THE FIRST 5 YEARS OF THE PROVISION

Calendar year	Newly enrolling institutional providers and suppliers	Newly enrolling institutional providers and suppliers paying the application fee (based on a 2.5% hardship exception rate)	CPI–U increase (%)	Consumer price index adjusted fee in dollars *	Total fees for each year in dollars	Cumulative fees in dollars
2011	24,000	23,400	1.0	505	11,817,000	11,817,000
2012	32,000	31,200	2.0	515	16,068,000	27,885,000
2013	32,000	31,200	2.0	525	16,380,000	44,265,000
2014	32,000	31,200	2.0	536	16,723,200	60,988,200
2015	32,000	31,200	2.0	547	17,066,400	78,054,600
Total					78,054,600	78,054,600

* As already mentioned, section 6401(a)(3) of the ACA called for a $500 application fee for institutional providers in 2010. Since the effective date of this final rule with comment period is March 25, 2011, we have added a 1.0 percent increase to the $500 fee for 2011. Moreover, each fee amount in this category was rounded up to the nearest dollar.

(2) Revalidation

There are approximately 100,000 currently enrolled suppliers of DMEPOS who are required to revalidate their enrollment every 3 years and 300,000 additional providers and suppliers that do not provide DMEPOS that are required to revalidate their enrollment every 5 years. On a yearly basis, we estimate that approximately 33,000 DMEPOS suppliers (one-third of the total) and 60,000 other, non-DMEPOS providers/suppliers (one-fifth of the total) would revalidate their enrollment in Medicare, for an annual total of 93,000. Since, as explained earlier, we estimate that no more than 2.5 percent of these providers and suppliers will receive a waiver from the application fee, we project that 90,675 such providers and suppliers will be subject to the fee.

This final rule with comment period contemplates collecting the application fee for currently enrolled providers that revalidate their enrollment on or after March 25, 2011—almost 3 months into CY 2011. Therefore, we have adjusted the number of existing Medicare institutional providers subject to an application fee by 25 percent, from 90,675 to 68,006 (or 90,675 × .75) in CY 2011. With respect to the period between CY 2012 and 2015, it is possible that, as previously alluded to in the preamble, we may perform an elevated number of revalidations early in this 4-year timeframe—specifically, in CY 2012. This would be done

[7] For purposes of the calculations in this RIA, newly-enrolling Medicare providers and suppliers include those that were once enrolled, departed, and are now seeking to enroll again.

pursuant to our authority under § 424.515(e) to require off-cycle revalidations. We cannot say for certain how many will be performed in CY 2012. For purposes of this RIA only, however, we will estimate that 111,000 will be conducted in CY 2012, with 87,000 performed in each of the remaining 3 years. Further accounting for projected annual CPI–U rate increases, we estimate that the cost associated with these fees for revalidating providers and suppliers would be approximately $226,477,505 over the first 5 years that the ACA provisions are in effect, as shown in Table 12.

TABLE 12—CUMULATIVE APPLICATION FEES FOR REVALIDATING MEDICARE PROVIDERS AND SUPPLIERS FOR THE FIRST 5 YEARS OF THE PROVISION

Calendar year	Revalidating institutional providers and suppliers	Revalidating institutional providers & suppliers paying application fee (based on 2.5% hardship exception rate)	CPI–U increase	Consumer price index adjusted fee in dollars	Total fees for each year (in dollars)	Cumulative fees (in dollars)
2011	69,750	68,006	1.0%	505	34,343,030	34,343,030
2012	111,000	108,225	2.0%	515	55,735,875	90,078,905
2013	87,000	84,825	2.0%	525	44,533,125	134,612,030
2014	87,000	84,825	2.0%	536	45,466,200	180,078,230
2015	87,000	84,825	2.0%	547	46,399,275	226,477,505
Total					226,477,505	226,477,505

Therefore, we estimate that the total impact of the provisions for the application fee to be approximately $304,532,105 over the next 5 years. This number was approximated by adding the cumulative application fees for newly enrolling providers and suppliers ($78,054,600 as shown in Table 11) to the cumulative application fees for revalidating providers and suppliers ($226,477,505).

2. Medicaid

a. Enhanced Screening Procedures

Although our data on Medicaid provider enrollment at the national level is very limited, we do collect annual data on State Medicaid program integrity activities. This annual data collection, known as the State Program Integrity Assessment (SPIA) program, consists of self-reported data by States regarding a variety of program integrity related activities. The information is self-reported and has not been independently verified by CMS, and it undoubtedly represents some unknown degree of duplication among providers across States. Consequently, the estimated number of Medicaid providers nationally is likely overstated. According to SPIA data for FFYs 2007 and 2008, there has been an average of 1,855,070 existing Medicaid providers nationally over the 2-year period of FFY 2007 and FFY 2008. This universe of Medicaid providers includes all provider types, both institutional providers and individual practitioners. In the Medicare program, eligible practitioners make up approximately 70 percent of the total universe of providers, suppliers, and eligible practitioners. Because we do not have detailed information regarding the breakdown of Medicaid providers by type nationally, we will apply the same ratio to determine the percentage of institutional Medicaid providers. Therefore, we estimate that there are approximately 556,521 Medicaid-only providers nationally that are not individual practitioners.

We also estimate almost all CHIP providers are also Medicaid providers. So, for purposes of this section, we are considering CHIP providers to also be Medicaid providers and will subsequently refer to them only as Medicaid providers.

As previously stated in the Medicare section of the analysis, we estimated that we would require the following:

- Approximately 35,000 individuals will undergo fingerprinting to enroll in the Medicare program as owners, of a home health agency or supplier of DMEPOS. Based on data collected as part of the State survey and certification activities for home health agencies, less than 1 percent of home health agencies are Medicaid-only. And, although there is no data available on the number of Medicaid-only suppliers of DMEPOS, we estimated that the number is minimal as well, as a number of States require suppliers of DMEPOS to be enrolled in Medicare prior to enrolling in Medicaid. Therefore, we estimated that States may require approximately 1,000 additional individuals with ownership interests in suppliers of DMEPOS or home health agencies, to undergo fingerprinting for enrollment in the Medicaid program. The cost of this fingerprinting requirement would be approximately $50,000 (1,000 × $50 = $50,000), though we solicited comments on the accuracy of this figure.
- We anticipated that Medicare contractors will perform the screening activities for the overwhelming majority of providers following the lifting of a Secretary-imposed temporary moratorium and for the limited circumstances in which physicians may be fingerprinted. However, given that States may also classify certain Medicaid-only providers as "high" categorical risks, we are estimating that States may require approximately 25,000 additional individuals to undergo fingerprinting prior to enrolling in a State's Medicaid program, at a cost of $1,250,000 (25,000 × $50 = $1,250,000).

Consequently, we estimated that fingerprinting individuals for purposes of Medicaid enrollment will cost $1,300,000. When averaged across 50 States, the District of Columbia and Puerto Rico, the annual cost of fingerprinting per State will be $26,000.

b. Application Fee—Medicaid

For those providers not screened by Medicare, the State may impose a fee on each institutional provider being screened. The amount of the fee is $500 per provider for 2010. For 2011 and each subsequent year, the amount will be determined by the statutorily-required formula using the consumer price index for all urban consumers (CPI–U).

c. General Enrollment Framework

For purposes of this section, we assume that 80 percent of institutional Medicaid providers will be dually participating in both Medicare and Medicaid, and thus will be subject to the application fee as part of the Medicare screening and enrollment. Therefore we estimated that 20 percent, or 111,304 (556,521 × 20 percent), of the institutional Medicaid-only providers will not be screened by Medicare and thus will be subject to the application fee under Medicaid. We project that a significant number of existing and future Medicaid providers will request a hardship exception, or that a State will request a waiver of the application fee for certain Medicaid provider types of the application fee on the basis of ensuring access to care. For purposes of this section, although we have no way to estimate the exact number of providers that will ultimately request and be approved for a hardship exception, or the number of States that will request a waiver of the fee for certain Medicaid provider types, we predict that 25 percent of all Medicaid providers subject to the fee will receive the hardship exception or be granted a waiver of the fee on the basis of ensuring beneficiary access to care. We recognize that this 25 percent figure is significantly higher than the 2.5 percent waiver rate we are using for Medicare application fees. Yet we believe the difference is justified because of the greater access to care issues that may arise in Medicaid. Consequently, we estimated that 83,478 existing Medicaid providers will be required to pay the application fee (111,304 existing Medicaid providers that are not dually enrolled less 25 percent or 27,826 existing providers).

(1) New Enrollments

We apply the 80 percent rate for newly-enrolling Medicaid institutional providers that will be dually participating in both Medicare and Medicaid and thus not subject to the fee under Medicaid, and 25 percent hardship exception rate to the annual number of newly-enrolling Medicaid institutional providers not dually enrolled. The 45,000 newly-enrolling Medicare institutional providers annually represent 80 percent of the total newly-enrolling Medicaid institutional providers annually. Therefore, we estimate that there will be 11,250 newly-enrolling Medicaid institutional providers annually that are subject to the application fee under Medicaid (45,000 providers divided by 80 percent, − 45,000 = 11,250). We project another 25 percent will be exempted for hardship or be granted a waiver of the fee on the basis of ensuring beneficiary access to care, resulting in 8,438 newly-enrolling Medicaid institutional providers being subject to the application fee each year nationally.

Consistent with the Medicare analysis, in CY 2011, we reduced the estimated number of institutional providers subject to the application fee by 25 percent because the application fee will not begin until March 25, 2011. Accordingly, the number of institutional providers that we anticipate paying the application fee will be 6,329 in CY 2011. Consequently, we projected the dollars due from application fees for newly-enrolling Medicaid institutional providers who are not dually enrolled to be $21,110,019 for the first 5 years in total. When averaged across 50 States, the District of Columbia and Puerto Rico, the total application fees for the 5 years in total per State will be approximately $405,962.

TABLE 13—CUMULATIVE APPLICATION FEES FOR NEWLY ENROLLED MEDICAID PROVIDERS FOR THE FIRST 5 YEARS OF THE PROVISION

Calendar year	New Medicaid providers not exempted from the application fee	CPI–U increase	Consumer price index adjusted fee (in dollars)	Total fees for each year (in dollars)	Cumulative fees (in dollars)
2011	6,329	1.0%	505	3,196,145	3,196,145
2012	8,438	2.01.1%	515	4,345,570	7,541,715
2013	8,438	2.0%	525	4,429,950	11,971,665
2014	8,438	2.0%	536	4,522,768	16,494,433
2015	8,438	2.0%	547	4,615,586	21,110,019
Total				21,110,019	21,110,019

(2) Re-enrollment

This rule contemplates that States would require Medicaid providers to re-enroll every 5 years. On a yearly basis, we estimate that approximately 16,696 Medicaid institutional providers (one fifth of the total) would re-enroll with the State Medicaid agency. We contemplate collecting the application fee for currently enrolled providers beginning on March 24, 2011. States would not collect an application fee with any re-enrollments until that time—almost 3 months into CY 2011. Therefore, we have adjusted the number of existing Medicaid institutional providers subject to an application fee by 25 percent, from 16,696 to 12,522 in CY 2011. Consequently, we project the dollars due from application fees for currently-enrolled Medicaid institutional providers who are not dually enrolled is $41,769,218 for the first 5 years in total. When averaged across 50 States, the District of Columbia and Puerto Rico, the total application fees for the 5 years in total per State will be approximately $803,254.

TABLE 14—CUMULATIVE APPLICATION FEES FOR RE-ENROLLING MEDICAID PROVIDERS FOR THE FIRST 5 YEARS OF THE PROVISION

Calendar year	Existing Medicaid providers not exempted from the application fee	CPI–U increase	Consumer price index adjusted fee in dollars	Total fees for each year in dollars	Cumulative fees in dollars
2011	12,522	1.0%	505	6,323,610	6,323,610

TABLE 14—CUMULATIVE APPLICATION FEES FOR RE-ENROLLING MEDICAID PROVIDERS FOR THE FIRST 5 YEARS OF THE PROVISION—Continued

Calendar year	Existing Medicaid providers not exempted from the application fee	CPI–U increase	Consumer price index adjusted fee in dollars	Total fees for each year in dollars	Cumulative fees in dollars
2012	16,696	2.0%	515	8,598,440	14,922,050
2013	16,696	2.0%	525	8,765,400	23,687,450
2014	16,696	2.0%	536	8,949,056	32,636,506
2015	16,696	2.0%	547	9,132,712	41,769,218
Total				41,769,218	41,769,218

3. Medicare and Medicaid

a. Moratoria on Enrollment of New Medicare Providers and Suppliers and Medicaid Providers

Although we have no way of predicting the exact cost savings associated with enrollment moratoria, we expect there will be program savings achieved by implementation of this section. As stated previously, these provisions will enable us to restrict the entry of certain providers and suppliers into Medicare in order to prevent or combat fraud, waste, and abuse. However, there are no cost burdens to the public or to the provider community. Therefore, we have not estimated the cost impacts of this provision.

b. Suspension of Payments in Medicare and Medicaid

As with payment moratoria, although we have no way of predicting the exact cost savings to Medicare and Medicaid associated with implementation of the provisions contained in this final rule with comment period, we certainly expect that there will be program savings that result from implementation of this provision. CMS and its law enforcement partners already have a process for payment suspension when possible fraud is involved. The changes finalized in this rule will strengthen the existing process and its applicability to Medicaid, but it will not create any different impact or burden on the provider community in circumstances of payment suspension. There are no new cost burdens to the public or the provider community associated with this provision.

D. Accounting Statement and Table

As required by OMB Circular A–4 (available at *http://www.whitehouse.gov/sites/default/files/omb/assets/omb/circulars/a004/a-4.pdf*), we have prepared an accounting statement. This statement only addresses: (1) The costs of the fingerprinting requirement, and (2) the monetary transfer associated with the application fee. It does not address the potential financial benefits of these two requirements from the standpoint of their possible effectiveness in deterring certain unscrupulous providers and suppliers from enrolling in or maintaining their enrollment in Medicare and Medicaid. This is because it is impossible for us to quantify these benefits in monetary terms. Moreover, we cannot predict how many potentially fraudulent providers and suppliers will be kept out of the Medicare and Medicaid programs due to these requirements.

1. Medicare

As stated previously, we estimate a total cost of the fingerprinting requirement of $2,275,000 per year ($1,750,000 + $500,000 + $25,000), or $11,375,000 over 5 years, if 2,000 post-moratorium requests are made. If 5,000 post-moratorium requests are made, the annual cost is $3,025,000, with a 5 year cost of $15,125,000. Should 10,000 post-moratorium requests be made, the annual cost is $4,275,000, with a 5 year cost of $21,375,000. We also stated in the RIA that the expected total application fees:

- For newly enrolling providers and suppliers would be $11,817,000 in 2011, $16,068,000 in 2012, $16,380,000 in 2013, $16,723,200 in 2014, and $17,066,400 in 2015. This results in a 5 year total of $78,054,600.
- For revalidating providers and suppliers would be $34,343,030 in 2011, $55,735,875 in 2012, $44,533,125 in 2013, $45,466,200 in 2014, and $46,399,275 in 2015. This results in a 5-year total of $226,477,505.

The accounting statement reflects the: (1) Annual cost of the fingerprinting requirement, and (2) the application of the 3 percent and 7 percent discount rate to the combined amounts of the application fees for CY 2012—that is, $16,068,000 (newly enrolling) plus $55,735,875 (revalidations), for a total of $71,803,875; this constitutes a transfer of funds to the Federal government. We chose the CY 2012 figures so as to reflect the maximum amount of transferred funds in a given year during the initial 5-year period.

2. Medicaid

As stated in the RIA, we estimate that the annual cost of the fingerprint requirement for Medicaid will be $1,300,000, or $6,500,000 over a 5 year period. We also stated in the RIA that the expected total application fees:

- For newly enrolling providers and suppliers would be $3,196,145 in 2011, $4,345,570 in 2012, $4,429,950 in 2013, $4,522,768 in 2014, and $4,615,586 in 2015. This results in a 5-year total of $21,110,019.
- For revalidating providers and suppliers would be $6,323,610 in 2011; $8,598,440 in 2012; $8,765,400 in 2013; $8,949,056 in 2014; and $9,132,712 in 2015. This results in a 5-year total of $41,769,218.

The accounting statement reflects: (1) The annual cost of the fingerprinting requirement: And (2) the application of the 3 percent and 7 percent discount rate to the combined amounts of the application fees for CY 2015—specifically, $4,615,586 (new applicants) plus $9,132,712 (revalidations), for a total of $13,748,298. This constitutes a transfer of funds to the Federal government. We chose the figures from CY 2015 for Medicaid so as to reflect the maximum amount of transferred funds in a given year during the initial 5-year period.

TABLE 15—ACCOUNTING STATEMENT: CLASSIFICATION OF ESTIMATED EXPENDITURES AND COSTS FROM CY 2011 TO CY 2015 (IN MILLIONS)

Medicare Fingerprint Requirement	COSTS	
Annualized Monetized Costs (2,000 post-moratorium requests)	3 percent Discount Rate $2.275	7 percent Discount Rate $2.275
Annualized Monetized Costs (5,000 post-moratorium requests)	$3.025	$3.025
Annualized Monetized Costs (10,000 post-moratorium requests)	$4.275	$4.275
Who is Affected?	Providers and Suppliers	
Medicare Application Fee	TRANSFERS	
Annualized Monetized Transfers (through 2015)	3 percent Discount Rate $48.2	7 percent Discount Rate $47.3
From Whom to Whom?	Providers and Suppliers to Federal Government	
Medicaid Fingerprint Requirement	COSTS	
Annualized Monetized Costs	3 percent Discount Rate $1.3	7 percent Discount Rate $1.3
Who is Affected?	Providers and Suppliers	
Medicaid Application Fee	TRANSFERS	
Annualized Monetized Costs	3 percent Discount Rate $10.1	7 percent Discount Rate $10.0
From Whom to Whom?	Providers and Suppliers to Federal Government	
	BENEFITS	
Qualitative: The above-referenced requirements will: (1) Allow CMS to more closely screen providers and suppliers that pose risks to the Medicare and Medicaid programs; (2) help offset the costs of administering the Medicare and Medicaid programs; (3) limit, via the imposition of moratoria, the entry of certain categories of providers and suppliers into Medicare if this is deemed necessary to protect the Medicare Trust Fund; and (4) suspend payments to certain providers and suppliers that pose a risk to the Trust Fund. We believe these and other financial benefits outlined in this rule will exceed the costs outlined above.		

E. Alternatives Considered

1. General Burden Minimization Efforts

The RFA requires agencies to analyze options for the regulatory relief of small entities. In compliance with section 604 of the RFA, we have incorporated several options designed to minimize the burden of the requirements in this final rule with comment period.

First, we have waived the application fee for individual physicians, non-physician practitioners, and physician and non-physician practitioner groups, which are generally small businesses. We believe this is consistent with congressional intention as expressed in section 6401(a) of ACA. We also believe this will ease the financial burden on this large category of small businesses.

Second, the high-risk category is limited to relatively few types of providers and suppliers. We could have elected to include many more providers and supplier types within this category and, subsequently, subjected them to the enhanced screening requirements of fingerprint-based criminal background checks. However, in part so as not to overly burden these entities, many of which are small businesses, we chose to restrict the high-risk category to a limited number of provider types.

2. Fingerprinting

We received several comments proposing alternatives to fingerprinting as a screening mechanism. The two principal suggested alternatives were the submission of a: (1) U.S. or foreign passport; and (2) copies of the individual's Federal tax returns. However, we explained in the preamble, we are adopting fingerprint-based criminal background checks.

There are several reasons for our decision to proceed with fingerprinting as opposed to passports and tax returns. First, we are, to a large extent, combining the fingerprinting and criminal background check processes for providers and suppliers. These will be done though the FBI IAFIS, which we believe is the most reliable and appropriate avenue available. The submission of fingerprints is the only way to obtain a criminal history record check from the FBI IAFIS. Information from a U.S. or foreign passport or a Federal tax return, on the other hand, could only be used to process a name-based criminal history record check—and the FBI does not process name-based requests for non-criminal justice purposes.

Second, we believe that fingerprinting—more than any other mechanism—will allow us to conclusively identify the individuals that will be participating in the Medicare program. Indeed, a tax return, while containing certain identifying information, does not—in our view—produce the level of assurance in this area that fingerprinting does.

Finally, the use of passports or tax returns would require CMS to forgo the unified approach of the FBI IAFIS and instead have two separate processes—one for verifying identify and another for analyzing the person's criminal history. This would result in: (1) A verification process that is not as reliable as fingerprinting, and (2) a

distinct and potentially costly process for criminal background checks through private entities that, we believe, will probably not involve access to the scope of data that the FBI has.

We believe that the overall costs involved in maintaining such a two-part approach would, in the end, exceed that of the FBI IAFIS approach, especially if—as we expect—the overwhelming majority of individuals subject to the fingerprinting requirement submit them electronically. Indeed, with respect to the cost differential between the paper and electronic fingerprinting processes, we stated earlier in the RIA that we estimate an average annual cost of the fingerprinting requirement of $2,275,000 (if 2,000 post-moratorium requests are made), based on: (1) The fingerprinting of 45,500 individuals; and (2) a $50 cost per person for obtaining a set of fingerprints via the FD–258. We believe that the per person cost for submitting fingerprints electronically will be approximately $35. If we assume that 40,000 of the 45,500 individuals submit fingerprints electronically and the remaining 5,500 use the FD–258, this results in an annual cost of $1,675,000, or $600,000 less than $2,275,000. This leads to a savings over 5 years of $3,000,000 ($600,000 × 5).

It is not possible for us to quantify the costs involved in having the FBI IAFIS perform the criminal background checks. However, we can estimate that it would cost approximately $40 per person to perform a criminal background check via private entities. This would result in an annual cost of $1,820,000, or $9,100,000 over 5 years. With the efficiency furnished through the use of the FBI–IAFIS, we do not believe the cost of these checks would ultimately exceed $9,100,000.

We concede that the submission of a passport or tax return would not involve the processing costs that would come with fingerprinting. But the ability to verify one's identity via fingerprinting is, we believe, sufficiently greater than with the latter two documents, such that the overall program integrity savings would substantially exceed any additional cost incurred in using fingerprints in lieu of passports and tax returns.

3. Other Suggested Alternatives

We received several other suggested alternatives to our proposed provisions. One was to assess the application fee based on the NPI or TIN. As stated earlier in this RIA, we did not believe this approach was appropriate because the requirement to submit an enrollment application is separate from the requirement to have an NPI or a TIN. We believe that basing the fee on the submission of an application is most consistent with the statute. Another involved taking into account factors such as: (1) Error rates; (2) past history with Medicare, Medicaid and other health plans; and (3) ownership, when assessing a provider or supplier's risk. In section II of this final rule with comment period, we stated that the ACA requires levels of screening according to the risk of fraud, waste, and abuse posed by categories of providers and suppliers as a whole. The approach taken in this final rule with comment period whereby we assign specific categories of providers and suppliers to screening levels determined by risk of fraud, waste, and abuse is consistent with the requirements of the statute. Therefore, in general, we chose to use a categorical approach to our classifications, rather than assign individual providers within a particular provider type to certain risk levels.

F. Conclusion

This final rule with comment period contains provisions that are of critical importance in the transition of CMS' antifraud activities from "pay and chase" to fraud prevention. "Pay and chase" refers to the traditional approach under which we met our obligations to provide beneficiaries access to qualified providers and suppliers and to pay claims quickly by making it relatively easy for providers to sign up to bill Medicare, Medicaid or CHIP, paying their claims rapidly, and then detecting overpayments or fraudulent bills and pursuing recoveries of overpayments after the fact. That system functions reasonably well when the problems arise with legitimate providers and suppliers that will be solvent and in business when CMS seeks to recover overpayments or law enforcement pursues civil or criminal penalties. It is not adequate when the fraud is committed by sham operations that provide no services or supplies and exist simply to steal from Medicare or Medicaid and thrive on stealing or subverting the identities of beneficiaries and providers.

This final rule with comment period strikes a balance that will permit us to continue to assure that eligible beneficiaries receive appropriate services from qualified providers whose claims are paid on a timely basis while implementing enhanced measures to prevent outright fraud. The new and strengthened provisions in the ACA that are the subject of this final rule with comment period will help assure that only legitimate providers and suppliers are enrolled in Medicare, Medicaid, and CHIP, and that only legitimate claims will be paid. These provisions are applied according to the level of risk of fraud, waste, and abuse posed by different provider and supplier types. We will use screening tools for a particular provider or supplier type based on 3 distinct categories of risk: (1) Limited; (2) moderate; and (3) high. Limited risk providers will have enrollment requirements, license and database verifications; moderate risk will have those verifications plus unscheduled site visits; high risk will have verifications, unscheduled site visits, criminal background check and fingerprinting. CMS and the States will impose moratoria on the enrollment of new providers in situations when doing so is necessary to protect against a high risk of fraud. Working in conjunction with the OIG, CMS and States will suspend payments pending an investigation of a credible allegation of fraud and legitimate providers will be assisted in avoiding problems by implementing effective compliance programs.

This final rule with comment period is an essential tool in protecting public resources and assuring that they are devoted to providing health care rather than enriching fraudulent actors.

In accordance with the provisions of Executive Order 12866, this regulation was reviewed by the Office of Management and Budget.

List of Subjects

42 CFR Part 405

Administrative practice and procedure, Health facilities, Health professions, Kidney diseases, Medical devices, Medicare, Reporting and recordkeeping requirements, Rural areas, X-rays.

42 CFR Part 424

Emergency medical services, Health facilities, Health professions, Medicare, and Reporting and recordkeeping requirements.

42 CFR Part 438

Grant programs—health, Medicaid, Reporting and recordkeeping requirements.

42 CFR Part 447

Accounting, Administrative practice and procedure, Drugs, Grant programs—health, Health facilities, Health professions, Medicaid, Reporting and recordkeeping requirements, and Rural areas.

42 CFR Part 455

Fraud, Grant programs—health, Health facilities, Health professions, Investigations, Medicaid, and Reporting and recordkeeping requirements.

42 CFR Part 457

Administrative practice and procedure, Grant programs—health, Health insurance, and Reporting and recordkeeping requirements.

42 CFR Part 498

Administrative practice and procedure, Health facilities, Health professions, Medicare, Reporting and recordkeeping requirements.

42 CFR Part 1007

Administrative practice and procedure, Fraud, Grant programs—health, Medicaid, and Reporting and recordkeeping requirements.

For the reasons set forth in the preamble, the Centers for Medicare & Medicaid Services amends 42 CFR chapter IV and the Office of the Inspector General amends 42 CFR chapter V, as set forth below:

CHAPTER IV—CENTERS FOR MEDICARE & MEDICAID SERVICES, DEPARTMENT OF HEALTH AND HUMAN SERVICES

PART 405—FEDERAL HEALTH INSURANCE FOR THE AGED AND DISABLED

■ 1. The authority citation for part 405 continues to read as follows:

Authority: Secs. 205(a), 1102, 1861, 1862(a), 1869, 1871, 1874, 1881, and 1886(k) of the Social Security Act (42 U.S.C. 405(a), 1302, 1395x, 1395y(a), 1395ff, 1395hh, 1395kk, 1395rr and 1395ww(k)), and sec. 353 of the Public Health Service Act (42 U.S.C. 263a).

Subpart C—Suspension of Payment, Recovery of Overpayments, and Repayment of Scholarships and Loans

■ 2. The authority citation for subpart C is revised to read as follows:

Authority: Secs. 1102, 1815, 1833, 1842, 1862, 1866, 1870, 1871, 1879 and 1892 of the Social Security Act (42 U.S.C. 1302, 1395g, 1395l, 1395u, 1395y, 1395cc, 1395gg, 1395hh, 1395pp and 1395ccc) and 31 U.S.C. 3711.

■ 3. In subpart C, remove the phrase "intermediary or carrier" wherever it appears and add the phrase "Medicare contractor" in its place.

■ 4. Section 405.370 is amended as follows:

■ A. In paragraph (a), adding the definitions of "Credible allegation of fraud," "Medicare contractor," and "Resolution of an investigation" in alphabetical order.

■ B. In paragraph (a), revising the definitions of "Offset," "Recoupment," and "Suspension of payment".

The additions and revisions read as follows:

§ 405.370 Definitions.

(a) * * *

Credible allegation of fraud. A credible allegation of fraud is an allegation from any source, including but not limited to the following:

(1) Fraud hotline complaints.

(2) Claims data mining.

(3) Patterns identified through provider audits, civil false claims cases, and law enforcement investigations. Allegations are considered to be credible when they have indicia of reliability.

Medicare contractor. Unless the context otherwise requires, includes, but is not limited to the any of following:

(1) A fiscal intermediary.

(2) A carrier.

(3) Program safeguard contractor.

(4) Zone program integrity contractor.

(5) Part A/Part B Medicare administrative contractor.

Offset. The recovery by Medicare of a non-Medicare debt by reducing present or future Medicare payments and applying the amount withheld to the indebtedness. (Examples are Public Health Service debts or Medicaid debts recovered by CMS).

Recoupment. The recovery by Medicare of any outstanding Medicare debt by reducing present or future Medicare payments and applying the amount withheld to the indebtedness.

Resolution of an investigation. An investigation of credible allegations of fraud will be considered resolved when legal action is terminated by settlement, judgment, or dismissal, or when the case is closed or dropped because of insufficient evidence to support the allegations of fraud.

Suspension of payment. The withholding of payment by a Medicare contractor from a provider or supplier of an approved Medicare payment amount before a determination of the amount of the overpayment exists, or until the resolution of an investigation of a credible allegation of fraud.

* * * * *

■ 5. Section 405.371 is revised to read as follows:

§ 405.371 Suspension, offset, and recoupment of Medicare payments to providers and suppliers of services.

(a) *General rules.* Medicare payments to providers and suppliers, as authorized under this subchapter (excluding payments to beneficiaries), may be—

(1) Suspended, in whole or in part, by CMS or a Medicare contractor if CMS or the Medicare contractor possesses reliable information that an overpayment exists or that the payments to be made may not be correct, although additional information may be needed for a determination;

(2) In cases of suspected fraud, suspended, in whole or in part, by CMS or a Medicare contractor if CMS or the Medicare contractor has consulted with the OIG, and, as appropriate, the Department of Justice, and determined that a credible allegation of fraud exists against a provider or supplier, unless there is good cause not to suspend payments; or

(3) Offset or recouped, in whole or in part, by a Medicare contractor if the Medicare contractor or CMS has determined that the provider or supplier to whom payments are to be made has been overpaid.

(b) *Good cause exceptions applicable to payment suspensions.*

(1) CMS may find that good cause exists not to suspend payments or not to continue to suspend payments to an individual or entity against which there are credible allegations of fraud if—

(i) OIG or other law enforcement agency has specifically requested that a payment suspension not be imposed because such a payment suspension may compromise or jeopardize an investigation;

(ii) It is determined that beneficiary access to items or services would be so jeopardized by a payment suspension in whole or part as to cause a danger to life or health;

(iii) It is determined that other available remedies implemented by CMS or a Medicare contractor more effectively or quickly protect Medicare funds than would implementing a payment suspension; or

(iv) CMS determines that a payment suspension or a continuation of a payment suspension is not in the best interests of the Medicare program.

(2) Every 180 days after the initiation of a suspension of payments based on credible allegations of fraud, CMS will—

(i) Evaluate whether there is good cause to not continue such suspension under this section; and

(ii) Request a certification from the OIG or other law enforcement agency that the matter continues to be under investigation warranting continuation of the suspension.

(3) Good cause not to continue to suspend payments to an individual or

entity against which there are credible allegations of fraud must be deemed to exist if a payment suspension has been in effect for 18 months and there has not been a resolution of the investigation, except CMS may extend a payment suspension beyond that point if —

(i) The case has been referred to, and is being considered by, the OIG for administrative action (for example, civil money penalties); or such administrative action is pending or

(ii) The Department of Justice submits a written request to CMS that the suspension of payments be continued based on the ongoing investigation and anticipated filing of criminal or civil action or both or based on a pending criminal or civil action or both. At a minimum, the request must include the following:

(A) Identification of the entity under suspension.

(B) The amount of time needed for continued suspension in order to conclude the criminal or civil proceeding or both.

(C) A statement of why or how criminal or civil action or both may be affected if the requested extension is not granted.

(c) *Steps necessary for suspension of payment, offset, and recoupment.*

(1) Except as provided in paragraph (d) of this section, CMS or the Medicare contractor suspends payments only after it has complied with the procedural requirements set forth at § 405.372.

(2) The Medicare contractor offsets or recoups payments only after it has complied with the procedural requirements set forth at § 405.373.

(d) *Suspension of payment in the case of unfiled cost reports.* (1) If a provider has failed to timely file an acceptable cost report, payment to the provider is immediately suspended in whole or in part until a cost report is filed and determined by the Medicare contractor to be acceptable.

(2) In the case of an unfiled cost report, the provisions of § 405.372 do not apply. (See § 405.372(a)(2) concerning failure to furnish other information.)

■ 6. Section 405.372 is amended as follows:

■ A. Remove the phrase "intermediary, carrier" wherever it appears and adding the phrase "Medicare contractor" in its place.

■ B. Revising paragraphs (a)(4), (c), and (d)(3).

■ C. In paragraph (e), removing the cross-reference "§ 405.371(b)" and adding the cross-reference "§ 405.371(a)" in its place.

§ 405.372 Proceeding for suspension of payment.

(a) * * *

(4) *Fraud.* If the intended suspension of payment involves credible allegations of fraud under § 405.371(a)(2), CMS—

(i) In consultation with OIG and, as appropriate, the Department of Justice, determines whether to impose the suspension and if prior notice is appropriate;

(ii) Directs the Medicare contractor as to the timing and content of the notification to the provider or supplier; and

(iii) Is the real party in interest and is responsible for the decision.

* * * * *

(c) *Subsequent action.* (1) If a suspension of payment is put into effect under § 405.371(a)(1), CMS or the Medicare contractor takes timely action after the suspension to obtain the additional information it may need to make a determination as to whether an overpayment exists or the payments may be made.

(i) CMS or the Medicare contractor makes all reasonable efforts to expedite the determination.

(ii) As soon as the determination is made, CMS or the Medicare contractor informs the provider or supplier and, if appropriate, the suspension is rescinded or any existing recoupment or offset is adjusted to take into account the determination.

(2)(i) If a suspension of payment is based upon credible allegations of fraud in accordance with § 405.371(a)(2), subsequent action must be taken by CMS or the Medicare contractor to make a determination as to whether an overpayment exists.

(ii) The rescission of the suspension and the issuance of a final overpayment determination to the provider or supplier may be delayed until resolution of the investigation.

(d) * * *

(3) *Exceptions to the time limits.* (i) The time limits specified in paragraphs (d)(1) and (d)(2) of this section do not apply if the suspension of payments is based upon credible allegations of fraud under § 405.371(a)(2).

(ii) Although the time limits specified in paragraphs (d)(1) and (d)(2) of this section do not apply to suspensions based on credible allegations of fraud, all suspensions of payment in accordance with § 405.371(a)(2) will be temporary and will not continue after the resolution of an investigation, unless a suspension is warranted because of reliable evidence of an overpayment or that the payments to be made may not be correct, as specified in § 405.371(a)(1).

* * * * *

PART 424—CONDITIONS FOR MEDICARE PAYMENT

■ 7. The authority citation for part 424 continues to read as follows:

Authority: Secs. 1102 and 1871 of the Social Security Act (42 U.S.C. 1302 and 1395hh).

■ 8. Section 424.57 is amended by revising paragraph (e) to read as follows:

§ 424.57 Special payment rules for items furnished by DMEPOS suppliers and issuance of DMEPOS supplier billing privileges.

* * * * *

(e) *Revalidation of billing privileges.* A supplier must revalidate its application for billing privileges every 3 years after the billing privileges are first granted. (Each supplier must complete a new application for billing privileges 3 years after its last revalidation.)

* * * * *

■ 9. Section 424.502 is amended by adding the definition of "Institutional provider" in alphabetical order to read as follows:

§ 424.502 Definitions.

* * * * *

Institutional provider means any provider or supplier that submits a paper Medicare enrollment application using the CMS–855A, CMS–855B (not including physician and nonphysician practitioner organizations), CMS–855S or associated Internet-based PECOS enrollment application.

* * * * *

■ 10. Section 424.514 is added to read as follows:

§ 424.514 Application fee.

(a) *Application fee requirements for prospective institutional providers.* Beginning on or after March 25, 2011, prospective institutional providers that are submitting an initial application or currently enrolled institutional providers that are submitting an application to establish a new practice location must submit either or both of the following:

(1) The applicable application fee.

(2) A request for a hardship exception to the application fee at the time of filing a Medicare enrollment application.

(b) *Application fee requirements for revalidating institutional providers.* Beginning March 25, 2011, institutional providers that are subject to CMS revalidation efforts must submit either or both of the following:

(1) The applicable application fee.

(2) A request for a hardship exception to the application fee at the time of filing a Medicare enrollment application.

(c) *Hardship exception for disaster areas.* CMS will assess on a case-by-case basis whether institutional providers enrolling in a geographic area that is a Presidentially-declared disaster under the Robert T. Stafford Disaster Relief and Emergency Assistance Act, 42 U.S.C. 5121–5206 (Stafford Act) should receive an exception to the application fee.

(d) *Application fee.* The application fee and associated requirements are as follows:

(1) For 2010, $500.00.

(2) For 2011 and subsequent years—

(i) Is adjusted by the percentage change in the consumer price index for all urban consumers (all items; United States city average) for the 12-month period ending with June of the previous year;

(ii) Is effective from January 1 to December 31 of a calendar year;

(iii) Is based on the submission of an initial application, application to establish a new practice location or the submission of an application in response to a CMS revalidation request;

(iv) Must be in the amount calculated by CMS in effect for the year during which the application for enrollment is being submitted;

(v) Is nonrefundable, except if submitted with one of the following:

(A) A request for hardship exception that is subsequently approved;

(B) An application that is rejected prior to initiation of screening processes;

(C) An application that is subsequently denied as a result of the imposition of a temporary moratorium;

(e) *Denial or revocation based on application fee.* A Medicare contractor may deny or revoke Medicare billing privileges of a provider or supplier based on noncompliance if, in the absence of a written request for a hardship exception from the application fee that accompanies a Medicare enrollment application, the bank account on which the check that is submitted with the enrollment application is drawn does not contain sufficient funds to pay the application fee.

(f) *Information needed for submission of a hardship exception request.* A provider or supplier requesting an exception from the application fee must include with its enrollment application a letter that describes the hardship and why the hardship justifies an exception.

(g) *Failure to submit application fee or hardship exception request.* A Medicare contractor may—

(1) Reject an enrollment application from a newly-enrolling institutional provider that, with the exceptions described in § 424.514(b), is not accompanied by the application fee or by a letter requesting a hardship exception from the application fee.

(2) Revoke the billing privileges of a currently enrolled institutional provider that, with the exceptions described in § 424.514(b), is not accompanied by the application fee or by a letter requesting a hardship exception from the application fee.

(3)(i) Notwithstanding the foregoing, the contractor must first inform the provider that the application fee was not submitted in accordance with this section.

(ii) Within 30 days after the date of the notification, the contractor may reject the application of the newly-enrolling institutional provider or revoke the billing privileges of the currently enrolled institutional provider that has not submitted the fee.

(h) *Consideration of hardship exception request.* CMS has 60 days in which to approve or disapprove a hardship exception request. If a provider submits a request for hardship exception to the fee and the provider or supplier has not already submitted the fee consistent with provisions in § 424.514(a) and (b), and the request for hardship exception is not approved, CMS notifies the provider or supplier that the hardship exception request was not approved and allows the provider or supplier 30 days from the date of notification to submit the application fee.

(1) A Medicare contractor does not—

(i) Begin processing an enrollment application that is accompanied by a hardship exception request until CMS has made a decision to approve or disapprove the hardship exception request; and

(ii) Deny an enrollment application that is accompanied by a hardship exception request unless the hardship exception request is denied by CMS and the provider or supplier fails to submit the required application fee within 30 days of being notified that the request for a hardship exception was denied.

(2) A hardship exception determination made by CMS is appealable using § 405.874 of this chapter.

■ 11. Section 424.515 is amended by adding a new paragraph (e) to read as follows:

§ 424.515 Requirements for reporting changes and updates to, and the periodic revalidation of Medicare enrollment information.

* * * * *

(e) *Additional off-cycle revalidation.* On or after March 23, 2012, Medicare providers and suppliers, including DMEPOS suppliers, may be required to revalidate their enrollment outside the routine 5-year revalidation cycle (3-year DMEPOS supplier revalidation cycle).

(1) CMS will contact providers or suppliers to revalidate their enrollment for off-cycle revalidation.

(2) As with all revalidations, revalidations described in this paragraph are conducted in accordance with the screening procedures specified at § 424.518.

■ 12. Section 424.518 is added to read as follows:

§ 424.518 Screening levels for Medicare providers and suppliers.

A Medicare contractor is required to screen all initial applications, including applications for a new practice location, and any applications received in response to a revalidation request based on a CMS assessment of risk and assignment to a level of "limited," "moderate," or "high."

(a) *Limited categorical risk.* (1) *Limited categorical risk: Provider and supplier categories.* CMS has designated the following providers and suppliers as "limited" categorical risk:

(i) Physician or nonphysician practitioners (including nurse practitioners, CRNAs, occupational therapists, speech/language pathologists, and audiologists) and medical groups or clinics.

(ii) Ambulatory surgical centers.

(iii) Competitive Acquisition Program/Part B Vendors.

(iv) End-stage renal disease facilities.

(v) Federally qualified health centers.

(vi) Histocompatibility laboratories.

(vii) Hospitals, including critical access hospitals, Department of Veterans Affairs hospitals, and other federally owned hospital facilities.

(viii) Health programs operated by an Indian Health Program (as defined in section 4(12) of the Indian Health Care Improvement Act) or an urban Indian organization (as defined in section 4(29) of the Indian Health Care Improvement Act) that receives funding from the Indian Health Service pursuant to Title V of the Indian Health Care Improvement Act.

(ix) Mammography screening centers.

(x) Mass immunization roster billers

(xi) Organ procurement organizations.

(xii) Pharmacies newly enrolling or revalidating via the CMS–855B application.

(xiii) Radiation therapy centers.

(xiv) Religious non-medical health care institutions.

(xv) Rural health clinics.

(xvi) Skilled nursing facilities.

(2) *Limited screening level: Screening requirements.* When CMS designates a provider or supplier as a "limited" categorical level of risk, the Medicare contractor does all of the following:

(i) Verifies that a provider or supplier meets all applicable Federal regulations and State requirements for the provider or supplier type prior to making an enrollment determination.

(ii) Conducts license verifications, including licensure verifications across State lines for physicians or nonphysician practitioners and providers and suppliers that obtain or maintain Medicare billing privileges as a result of State licensure, including State licensure in States other than where the provider or supplier is enrolling.

(iii) Conducts database checks on a pre- and post-enrollment basis to ensure that providers and suppliers continue to meet the enrollment criteria for their provider/supplier type.

(b) *Moderate categorical risk.* (1) *Moderate categorical risk: Provider and supplier categories.* CMS has designated the following providers and suppliers as "moderate" categorical risk:

(i) Ambulance service suppliers.

(ii) Community mental health centers.

(iii) Comprehensive outpatient rehabilitation facilities.

(iv) Hospice organizations.

(v) Independent clinical laboratories.

(vi) Independent diagnostic testing facilities.

(vii) Physical therapists enrolling as individuals or as group practices.

(viii) Portable x-ray suppliers.

(ix) Revalidating home health agencies.

(x) Revalidating DMEPOS suppliers.

(2) *Moderate screening level: Screening requirements.* When CMS designates a provider or supplier as a "moderate" categorical level of risk, the Medicare contractor does all of the following:

(i) Performs the "limited" screening requirements described in paragraph (a)(2) of this section.

(ii) Conducts an on-site visit.

(c) *High categorical risk.* (1) *High categorical risk: Provider and supplier categories.* CMS has designated the following home health agencies and suppliers of DMEPOS as "high" categorical risk:

(i) Prospective (newly enrolling) home health agencies.

(ii) Prospective (newly enrolling) DMEPOS suppliers.

(2) *High screening level: Screening requirements.* When CMS designates a provider or supplier as a "high" categorical level of risk, the Medicare contractor does all of the following:

(i) Performs the "limited" and "moderate" screening requirements described in paragraphs (a)(2) and (b)(2) of this section.

(ii)(A) Requires the submission of a set of fingerprints for a national background check from all individuals who maintain a 5 percent or greater direct or indirect ownership interest in the provider or supplier; and

(B) Conducts a fingerprint-based criminal history record check of the Federal Bureau of Investigation's Integrated Automated Fingerprint Identification System on all individuals who maintain a 5 percent or greater direct or indirect ownership interest in the provider or supplier.

(3) *Adjustment in the categorical risk.* CMS adjusts the screening level from "limited" or "moderate" to "high" if any of the following occur:

(i) CMS imposes a payment suspension on a provider or supplier at any time in the last 10 years.

(ii) The provider or supplier—

(A) Has been excluded from Medicare by the OIG; or

(B) Had billing privileges revoked by a Medicare contractor within the previous 10 years and is attempting to establish additional Medicare billing privileges by—

(*1*) Enrolling as a new provider or supplier; or

(*2*) Billing privileges for a new practice location;

(C) Has been terminated or is otherwise precluded from billing Medicaid;

(D) Has been excluded from any Federal health care program; or

(E) Has been subject to any final adverse action, as defined at § 424.502, within the previous 10 years.

(iii) CMS lifts a temporary moratorium for a particular provider or supplier type and a provider or supplier that was prevented from enrolling based on the moratorium, applies for enrollment as a Medicare provider or supplier at any time within 6 months from the date the moratorium was lifted.

(d) *Fingerprinting requirements.* An individual subject to the fingerprint-based criminal history record check requirement specified in paragraph (c)(2)(ii)(B) of this section—

(1) Must submit a set of fingerprints for a national background check.

(i) Upon submission of a Medicare enrollment application; or

(ii) Within 30 days of a Medicare contractor request.

(2) In the event the individual(s) required to submit fingerprints under paragraph (c)(2) of this section fail to submit such fingerprints in accordance with paragraph (d)(1) of this section, the provider or supplier will have its billing privileges—

(i) Denied under § 424.530(a)(1); or

(ii) Revoked under § 424.535(a)(1).

■ 13. Section 424.525 is amended by:

■ A. Revising paragraph (a) introductory text.

■ B. Adding a new paragraph (a)(3).

The revision and addition read as follows:

§ 424.525 Rejection of a provider or supplier's enrollment application for Medicare enrollment.

(a) *Reasons for rejection.* CMS may reject a provider's or supplier's enrollment application for any of the following reasons:

* * * * *

(3) The prospective institutional provider or supplier does not submit the application fee in the designated amount or a hardship waiver request with the Medicare enrollment application at the time of filing.

* * * * *

■ 14. Section 424.530 is amended by adding new paragraphs (a)(9) and (a)(10) to read as follows:

§ 424.530 Denial of enrollment in the Medicare program.

(a) * * *

(9) *Application fee/hardship exception.* An institutional provider's or supplier's hardship exception request is not granted, and the provider or supplier does not submit the application fee within 30 days of notification that the hardship exception request was not approved.

(10) *Temporary moratorium.* A provider or supplier submits an enrollment application for a practice location in a geographic area where CMS has imposed a temporary moratorium.

* * * * *

■ 15. Section 424.535 is amended as follows:

■ A. Revising paragraph (a)(6).

■ B. Adding a new paragraph (a)(12).

■ C. Revising paragraph (c).

§ 424.535 Revocation of enrollment billing and billing privileges in the Medicare program.

(a) * * *

(6) *Grounds related to provider and supplier screening requirements.* (i)(A) An institutional provider does not submit an application fee or hardship exception request that meets the requirements set forth in § 424.514 with

the Medicare revalidation application; or

(B) The hardship exception is not granted and the institutional provider does not submit the applicable application form or application fee within 30 days of being notified that the hardship exception request was denied.

(ii)(A) Either of the following occurs:

(*1*) CMS is not able to deposit the full application amount into a government-owned account.

(*2*) The funds are not able to be credited to the U.S. Treasury.

(B) The provider or supplier lacks sufficient funds in the account at the banking institution whose name is imprinted on the check or other banking instrument to pay the application fee; or

(C) There is any other reason why CMS or its Medicare contractor is unable to deposit the application fee into a government-owned account.

* * * * *

(12) *Medicaid termination.* (i) Medicaid billing privileges are terminated or revoked by a State Medicaid Agency.

(ii) Medicare may not terminate unless and until a provider or supplier has exhausted all applicable appeal rights.

* * * * *

(c) *Reapplying after revocation.* (1) After a provider, supplier, delegated official, or authorizing official has had its billing privileges revoked, it is barred from participating in the Medicare program from the effective date of the revocation until the end of the re-enrollment bar.

(2) The re-enrollment bar is a minimum of 1 year, but not greater than 3 years depending on the severity of the basis for revocation.

(3) CMS may waive the re-enrollment bar if it has revoked a provider or supplier under § 424.535(a)(6)(i) based upon the failure of the provider or supplier to submit an application fee or a hardship exception request with an enrollment application upon revalidation.

* * * * *

■ 16. A new § 424.570 is added to read as follows:

§ 424.570 Moratoria on newly enrolling Medicare providers and suppliers.

(a) *Temporary moratoria.* (1) *General rules.* (i) CMS may impose a moratorium on the enrollment of new Medicare providers and suppliers of a particular type or the establishment of new practice locations of a particular type in a particular geographic area.

(ii) CMS will announce the temporary enrollment moratorium in a **Federal Register** document that includes the rationale for imposition of the temporary enrollment moratorium.

(iii) The temporary moratorium does not apply to changes in practice location, changes in provider or supplier information such as phone number, address or changes in ownership (except changes in ownership of home health agencies that would require an initial enrollment under § 424.550).

(iv) The temporary enrollment moratorium does not apply to any enrollment application that has been approved by the enrollment contractor but not yet entered into PECOS at the time the moratorium is imposed.

(2) *Imposition of a temporary moratoria.* CMS may impose the temporary moratorium if—

(i) CMS determines that there is a significant potential for fraud, waste or abuse with respect to a particular provider or supplier type or particular geographic area or both. CMS's determination is based on its review of existing data, and without limitation, identifies a trend that appears to be associated with a high risk of fraud, waste or abuse, such as a—

(A) Highly disproportionate number of providers or suppliers in a category relative to the number of beneficiaries; or

(B) Rapid increase in enrollment applications within a category;

(ii) A State Medicaid program has imposed a moratorium on a group of Medicaid providers or suppliers that are also eligible to enroll in the Medicare program;

(iii) A State has imposed a moratorium on enrollment in a particular geographic area or on a particular provider or supplier type or both; or

(iv) CMS, in consultation the HHS OIG or the Department of Justice or both and with the approval of the CMS Administrator identifies either or both of the following as having a significant potential for fraud, waste or abuse in the Medicare program:

(A) A particular provider or supplier type.

(B) Any particular geographic area.

(b) *Duration of moratoria.* A moratorium under this section may be imposed for a period of 6 months and, if deemed necessary by CMS, may be extended in 6-month increments. CMS will publish a document in the **Federal Register** when it extends a moratorium.

(c) *Denial of enrollment: Moratoria.* A Medicare contractor denies the enrollment application of a provider or supplier if the provider or supplier is subject to a moratorium as specified in paragraph (a) of this section.

(d) *Lifting moratoria.* CMS will publish a document in the **Federal Register** when a moratorium is lifted. CMS may lift a temporary moratorium at any time after imposition of the moratorium if one of the following occur:

(1) The President declares an area a disaster under the Robert T. Stafford Disaster Relief and Emergency Assistance Act, 42 U.S.C. 5121–5206 (Stafford Act).

(2) Circumstances warranting the imposition of a moratorium have abated or CMS has implemented program safeguards to address the program vulnerability.

(3) The Secretary has declared a public health emergency under section 319 of the Public Health Service Act in the area subject to a temporary moratorium.

(4) In the judgment of the Secretary, the moratorium is no longer needed.

PART 447—PAYMENT FOR SERVICES

■ 19. The authority citation for part 447 continues to read as follows:

Authority: Sec. 1102 of the Social Security Act (42 U.S.C. 1302).

■ 20. A new § 447.90 is added to subpart A to read as follows:

§ 447.90 FFP: Conditions related to pending investigations of credible allegations of fraud against the Medicaid program.

(a) *Basis and purpose.* This section implements section 1903(i)(2)(C) of the Act which prohibits payment of FFP with respect to items or services furnished by an individual or entity with respect to which there is pending an investigation of a credible allegation of fraud except under specified circumstances.

(b) *Denial of FFP.* No FFP is available with respect to any amount expended for an item or service furnished by any individual or entity to whom a State has failed to suspend payments in whole or part as required by § 455.23 of this chapter unless—

(1) The item or service is furnished as an emergency item or service, but not including items or services furnished in an emergency room of a hospital; or

(2) The State determines and documents that good cause as specified at § 455.23(e) or (f) of this chapter exists not to suspend such payments, to suspend payments only in part, or to discontinue a previously imposed payment suspension.

PART 455—PROGRAM INTEGRITY: MEDICAID

■ 21. The authority citation for part 455 continues to read as follows:

Authority: Sec. 1102 of the Social Security Act (42 U.S.C. 1302).

■ 22. Section 455.2 is amended by adding the definition of "Credible allegation of fraud" to read as follows:

§ 455.2 Definitions.

* * * * *

Credible allegation of fraud. A credible allegation of fraud may be an allegation, which has been verified by the State, from any source, including but not limited to the following:

(1) Fraud hotline complaints.

(2) Claims data mining.

(3) Patterns identified through provider audits, civil false claims cases, and law enforcement investigations. Allegations are considered to be credible when they have indicia of reliability and the State Medicaid agency has reviewed all allegations, facts, and evidence carefully and acts judiciously on a case-by-case basis.

* * * * *

■ 23. Section 455.23 is revised to read as follows:

§ 455.23 Suspension of payments in cases of fraud.

(a) *Basis for suspension.* (1) The State Medicaid agency must suspend all Medicaid payments to a provider after the agency determines there is a credible allegation of fraud for which an investigation is pending under the Medicaid program against an individual or entity unless the agency has good cause to not suspend payments or to suspend payment only in part.

(2) The State Medicaid agency may suspend payments without first notifying the provider of its intention to suspend such payments.

(3) A provider may request, and must be granted, administrative review where State law so requires.

(b) *Notice of suspension.* (1) The State agency must send notice of its suspension of program payments within the following timeframes:

(i) Five days of taking such action unless requested in writing by a law enforcement agency to temporarily withhold such notice.

(ii) Thirty days if requested by law enforcement in writing to delay sending such notice, which request for delay may be renewed in writing up to twice and in no event may exceed 90 days.

(2) The notice must include or address all of the following:

(i) State that payments are being suspended in accordance with this provision.

(ii) Set forth the general allegations as to the nature of the suspension action, but need not disclose any specific information concerning an ongoing investigation.

(iii) State that the suspension is for a temporary period, as stated in paragraph (c) of this section, and cite the circumstances under which the suspension will be terminated.

(iv) Specify, when applicable, to which type or types of Medicaid claims or business units of a provider suspension is effective.

(v) Inform the provider of the right to submit written evidence for consideration by State Medicaid Agency.

(vi) Set forth the applicable State administrative appeals process and corresponding citations to State law.

(c) *Duration of suspension.* (1) All suspension of payment actions under this section will be temporary and will not continue after either of the following:

(i) The agency or the prosecuting authorities determine that there is insufficient evidence of fraud by the provider.

(ii) Legal proceedings related to the provider's alleged fraud are completed.

(2) A State must document in writing the termination of a suspension including, where applicable and appropriate, any appeal rights available to a provider.

(d) *Referrals to the Medicaid fraud control unit.* (1) Whenever a State Medicaid agency investigation leads to the initiation of a payment suspension in whole or part, the State Medicaid Agency must make a fraud referral to either of the following:

(i) To a Medicaid fraud control unit established and certified under part 1007 of this title; or

(ii) In States with no certified Medicaid fraud control unit, to an appropriate law enforcement agency.

(2) The fraud referral made under paragraph (d)(1) of this section must meet all of the following requirements:

(i) Be made in writing and provided to the Medicaid fraud control unit not later than the next business day after the suspension is enacted.

(ii) Conform to fraud referral performance standards issued by the Secretary.

(3)(i) If the Medicaid fraud control unit or other law enforcement agency accepts the fraud referral for investigation, the payment suspension may be continued until such time as the investigation and any associated enforcement proceedings are completed.

(ii) On a quarterly basis, the State must request a certification from the Medicaid fraud control unit or other law enforcement agency that any matter accepted on the basis of a referral continues to be under investigation thus warranting continuation of the suspension.

(4) If the Medicaid fraud control unit or other law enforcement agency declines to accept the fraud referral for investigation the payment suspension must be discontinued unless the State Medicaid agency has alternative Federal or State authority by which it may impose a suspension or makes a fraud referral to another law enforcement agency. In that situation, the provisions of paragraph (d)(3) of this section apply equally to that referral as well.

(5) A State's decision to exercise the good cause exceptions in paragraphs (e) or (f) of this section not to suspend payments or to suspend payments only in part does not relieve the State of the obligation to refer any credible allegation of fraud as provided in paragraph (d)(1) of this section.

(e) *Good cause not to suspend payments.* A State may find that good cause exists not to suspend payments, or not to continue a payment suspension previously imposed, to an individual or entity against which there is an investigation of a credible allegation of fraud if any of the following are applicable:

(1) Law enforcement officials have specifically requested that a payment suspension not be imposed because such a payment suspension may compromise or jeopardize an investigation.

(2) Other available remedies implemented by the State more effectively or quickly protect Medicaid funds.

(3) The State determines, based upon the submission of written evidence by the individual or entity that is the subject of the payment suspension, that the suspension should be removed.

(4) Recipient access to items or services would be jeopardized by a payment suspension because of either of the following:

(i) An individual or entity is the sole community physician or the sole source of essential specialized services in a community.

(ii) The individual or entity serves a large number of recipients within a HRSA-designated medically underserved area.

(5) Law enforcement declines to certify that a matter continues to be under investigation per the requirements of paragraph (d)(3) of this section.

(6) The State determines that payment suspension is not in the best interests of the Medicaid program.

(f) *Good cause to suspend payment only in part.* A State may find that good cause exists to suspend payments in part, or to convert a payment suspension previously imposed in whole to one only in part, to an individual or entity against which there is an investigation of a credible allegation of fraud if any of the following are applicable:

(1) Recipient access to items or services would be jeopardized by a payment suspension in whole or part because of either of the following:

(i) An individual or entity is the sole community physician or the sole source of essential specialized services in a community.

(ii) The individual or entity serves a large number of recipients within a HRSA-designated medically underserved area.

(2) The State determines, based upon the submission of written evidence by the individual or entity that is the subject of a whole payment suspension, that such suspension should be imposed only in part.

(3)(i) The credible allegation focuses solely and definitively on only a specific type of claim or arises from only a specific business unit of a provider; and

(ii) The State determines and documents in writing that a payment suspension in part would effectively ensure that potentially fraudulent claims were not continuing to be paid.

(4) Law enforcement declines to certify that a matter continues to be under investigation per the requirements of paragraph (d)(3) of this section.

(5) The State determines that payment suspension only in part is in the best interests of the Medicaid program.

(g) *Documentation and record retention.* State Medicaid agencies must meet the following requirements:

(1) Maintain for a minimum of 5 years from the date of issuance all materials documenting the life cycle of a payment suspension that was imposed in whole or part, including the following:

(i) All notices of suspension of payment in whole or part.

(ii) All fraud referrals to the Medicaid fraud control unit or other law enforcement agency.

(iii) All quarterly certifications of continuing investigation status by law enforcement.

(iv) All notices documenting the termination of a suspension.

(2)(i) Maintain for a minimum of 5 years from the date of issuance all materials documenting each instance where a payment suspension was not imposed, imposed only in part, or discontinued for good cause.

(ii) This type of documentation must include, at a minimum, detailed information on the basis for the existence of the good cause not to suspend payments, to suspend payments only in part, or to discontinue a payment suspension and, where applicable, must specify how long the State anticipates such good cause will exist.

(3) Annually report to the Secretary summary information on each of following:

(i) Suspension of payment, including the nature of the suspected fraud, the basis for suspension, and the outcome of the suspension.

(ii) Situation in which the State determined good cause existed to not suspend payments, to suspend payments only in part, or to discontinue a payment suspension as described in this section, including describing the nature of the suspected fraud and the nature of the good cause.

■ 24. Section 455.101 is amended by adding the definitions of "Health insuring organization (HIO)," "Managed care entity (MCE)," "Prepaid ambulatory health plan (PAHP)," "Prepaid inpatient health plan (PIHP)," "Primary care case manager (PCCM)," and "Termination" in alphabetical order to read as follows:

§ 455.101 Definitions.

* * * * *

Health insuring organization (HIO) has the meaning specified in § 438.2.

* * * * *

Managed care entity (MCE) means managed care organizations (MCOs), PIHPs, PAHPs, PCCMs, and HIOs.

* * * * *

Prepaid ambulatory health plan (PAHP) has the meaning specified in § 438.2.

Prepaid inpatient health plan (PIHP) has the meaning specified in § 438.2.

Primary care case manager (PCCM) has the meaning specified in § 438.2.

* * * * *

Termination means—

(1) For a—

(i) Medicaid or CHIP provider, a State Medicaid program or CHIP has taken an action to revoke the provider's billing privileges, and the provider has exhausted all applicable appeal rights or the timeline for appeal has expired; and

(ii) Medicare provider, supplier or eligible professional, the Medicare program has revoked the provider or supplier's billing privileges, and the provider has exhausted all applicable appeal rights or the timeline for appeal has expired.

(2)(i) In all three programs, there is no expectation on the part of the provider or supplier or the State or Medicare program that the revocation is temporary.

(ii) The provider, supplier, or eligible professional will be required to reenroll with the applicable program if they wish billing privileges to be reinstated.

(3) The requirement for termination applies in cases where providers, suppliers, or eligible professionals were terminated or had their billing privileges revoked for cause which may include, but is not limited to—

(i) Fraud;

(ii) Integrity; or

(iii) Quality.

* * * * *

■ 25. Section 455.104 is revised to read as follows:

§ 455.104 Disclosure by Medicaid providers and fiscal agents: Information on ownership and control.

(a) *Who must provide disclosures.* The Medicaid agency must obtain disclosures from disclosing entities, fiscal agents, and managed care entities.

(b) *What disclosures must be provided.* The Medicaid agency must require that disclosing entities, fiscal agents, and managed care entities provide the following disclosures:

(1)(i) The name and address of any person (individual or corporation) with an ownership or control interest in the disclosing entity, fiscal agent, or managed care entity. The address for corporate entities must include as applicable primary business address, every business location, and P.O. Box address.

(ii) Date of birth and Social Security Number (in the case of an individual).

(iii) Other tax identification number (in the case of a corporation) with an ownership or control interest in the disclosing entity (or fiscal agent or managed care entity) or in any subcontractor in which the disclosing entity (or fiscal agent or managed care entity) has a 5 percent or more interest.

(2) Whether the person (individual or corporation) with an ownership or control interest in the disclosing entity (or fiscal agent or managed care entity) is related to another person with ownership or control interest in the disclosing entity as a spouse, parent, child, or sibling; or whether the person (individual or corporation) with an ownership or control interest in any subcontractor in which the disclosing entity (or fiscal agent or managed care entity) has a 5 percent or more interest is related to another person with

ownership or control interest in the disclosing entity as a spouse, parent, child, or sibling.

(3) The name of any other disclosing entity (or fiscal agent or managed care entity) in which an owner of the disclosing entity (or fiscal agent or managed care entity) has an ownership or control interest.

(4) The name, address, date of birth, and Social Security Number of any managing employee of the disclosing entity (or fiscal agent or managed care entity).

(c) *When the disclosures must be provided.*

(1) *Disclosures from providers or disclosing entities.* Disclosure from any provider or disclosing entity is due at any of the following times:

(i) Upon the provider or disclosing entity submitting the provider application.

(ii) Upon the provider or disclosing entity executing the provider agreement.

(iii) Upon request of the Medicaid agency during the re-validation of enrollment process under § 455.414.

(iv) Within 35 days after any change in ownership of the disclosing entity.

(2) *Disclosures from fiscal agents.* Disclosures from fiscal agents are due at any of the following times:

(i) Upon the fiscal agent submitting the proposal in accordance with the State's procurement process.

(ii) Upon the fiscal agent executing the contract with the State.

(iii) Upon renewal or extension of the contract.

(iv) Within 35 days after any change in ownership of the fiscal agent.

(3) *Disclosures from managed care entities.* Disclosures from managed care entities (MCOs, PIHPs, PAHPs, and HIOs), except PCCMs are due at any of the following times:

(i) Upon the managed care entity submitting the proposal in accordance with the State's procurement process.

(ii) Upon the managed care entity executing the contract with the State.

(iii) Upon renewal or extension of the contract.

(iv) Within 35 days after any change in ownership of the managed care entity.

(4) *Disclosures from PCCMs.* PCCMs will comply with disclosure requirements under paragraph (c)(1) of this section.

(d) *To whom must the disclosures be provided.* All disclosures must be provided to the Medicaid agency.

(e) *Consequences for failure to provide required disclosures.* Federal financial participation (FFP) is not available in payments made to a disclosing entity that fails to disclose ownership or control information as required by this section.

■ 26. A new subpart E is added to part 455 to read as follows:

Subpart E—Provider Screening and Enrollment

Sec.
455.400 Purpose.
455.405 State plan requirements.
455.410 Enrollment and screening of providers.
455.412 Verification of provider licenses.
455.414 Revalidation of enrollment.
455.416 Termination or denial of enrollment.
455.420 Reactivation of provider enrollment.
455.422 Appeal rights.
455.432 Site visits.
455.434 Criminal background checks.
455.436 Federal database checks.
455.440 National Provider Identifier.
455.450 Screening levels for Medicaid providers.
455.452 Other State screening methods.
455.460 Application fee.
455.470 Temporary moratoria.

Subpart E—Provider Screening and Enrollment

§ 455.400 Purpose.

This subpart implements sections 1866(j), 1902(a)(39), 1902(a)(77), and 1902(a)(78) of the Act. It sets forth State plan requirements regarding the following:

(a) Provider screening and enrollment requirements.

(b) Fees associated with provider screening.

(c) Temporary moratoria on enrollment of providers.

§ 455.405 State plan requirements.

A State plan must provide that the requirements of § 455.410 through § 455.450 and § 455.470 are met.

§ 455.410 Enrollment and screening of providers.

(a) The State Medicaid agency must require all enrolled providers to be screened under to this subpart.

(b) The State Medicaid agency must require all ordering or referring physicians or other professionals providing services under the State plan or under a waiver of the plan to be enrolled as participating providers.

(c) The State Medicaid agency may rely on the results of the provider screening performed by any of the following:

(1) Medicare contractors.

(2) Medicaid agencies or Children's Health Insurance Programs of other States.

§ 455.412 Verification of provider licenses.

The State Medicaid agency must—

(a) Have a method for verifying that any provider purporting to be licensed in accordance with the laws of any State is licensed by such State.

(b) Confirm that the provider's license has not expired and that there are no current limitations on the provider's license.

§ 455.414 Revalidation of enrollment.

The State Medicaid agency must revalidate the enrollment of all providers regardless of provider type at least every 5 years.

§ 455.416 Termination or denial of enrollment.

The State Medicaid agency—

(a) Must terminate the enrollment of any provider where any person with a 5 percent or greater direct or indirect ownership interest in the provider did not submit timely and accurate information and cooperate with any screening methods required under this subpart.

(b) Must deny enrollment or terminate the enrollment of any provider where any person with a 5 percent or greater direct or indirect ownership interest in the provider has been convicted of a criminal offense related to that person's involvement with the Medicare, Medicaid, or title XXI program in the last 10 years, unless the State Medicaid agency determines that denial or termination of enrollment is not in the best interests of the Medicaid program and the State Medicaid agency documents that determination in writing.

(c) Must deny enrollment or terminate the enrollment of any provider that is terminated on or after January 1, 2011, under title XVIII of the Act or under the Medicaid program or CHIP of any other State.

(d) Must terminate the provider's enrollment or deny enrollment of the provider if the provider or a person with an ownership or control interest or who is an agent or managing employee of the provider fails to submit timely or accurate information, unless the State Medicaid agency determines that termination or denial of enrollment is not in the best interests of the Medicaid program and the State Medicaid agency documents that determination in writing.

(e) Must terminate or deny enrollment if the provider, or any person with a 5 percent or greater direct or indirect ownership interest in the provider, fails to submit sets of fingerprints in a form and manner to be determined by the Medicaid agency within 30 days of a CMS or a State Medicaid agency request, unless the State Medicaid

agency determines that termination or denial of enrollment is not in the best interests of the Medicaid program and the State Medicaid agency documents that determination in writing.

(f) Must terminate or deny enrollment if the provider fails to permit access to provider locations for any site visits under § 455.432, unless the State Medicaid agency determines that termination or denial of enrollment is not in the best interests of the Medicaid program and the State Medicaid agency documents that determination in writing.

(g) May terminate or deny the provider's enrollment if CMS or the State Medicaid agency—

(1) Determines that the provider has falsified any information provided on the application; or

(2) Cannot verify the identity of any provider applicant.

§ 455.420 Reactivation of provider enrollment.

After deactivation of a provider enrollment number for any reason, before the provider's enrollment may be reactivated, the State Medicaid agency must re-screen the provider and require payment of associated provider application fees under § 455.460.

§ 455.422 Appeal rights.

The State Medicaid agency must give providers terminated or denied under § 455.416 any appeal rights available under procedures established by State law or regulations.

§ 455.432 Site visits.

The State Medicaid agency—

(a) Must conduct pre-enrollment and post-enrollment site visits of providers who are designated as "moderate" or "high" categorical risks to the Medicaid program. The purpose of the site visit will be to verify that the information submitted to the State Medicaid agency is accurate and to determine compliance with Federal and State enrollment requirements.

(b) Must require any enrolled provider to permit CMS, its agents, its designated contractors, or the State Medicaid agency to conduct unannounced on-site inspections of any and all provider locations.

§ 455.434 Criminal background checks.

The State Medicaid agency—

(a) As a condition of enrollment, must require providers to consent to criminal background checks including fingerprinting when required to do so under State law or by the level of screening based on risk of fraud, waste or abuse as determined for that category of provider.

(b) Must establish categorical risk levels for providers and provider categories who pose an increased financial risk of fraud, waste or abuse to the Medicaid program.

(1) Upon the State Medicaid agency determining that a provider, or a person with a 5 percent or more direct or indirect ownership interest in the provider, meets the State Medicaid agency's criteria hereunder for criminal background checks as a "high" risk to the Medicaid program, the State Medicaid agency will require that each such provider or person submit fingerprints.

(2) The State Medicaid agency must require a provider, or any person with a 5 percent or more direct or indirect ownership interest in the provider, to submit a set of fingerprints, in a form and manner to be determined by the State Medicaid agency, within 30 days upon request from CMS or the State Medicaid agency.

§ 455.436 Federal database checks.

The State Medicaid agency must do all of the following:

(a) Confirm the identity and determine the exclusion status of providers and any person with an ownership or control interest or who is an agent or managing employee of the provider through routine checks of Federal databases.

(b) Check the Social Security Administration's Death Master File, the National Plan and Provider Enumeration System (NPPES), the List of Excluded Individuals/Entities (LEIE), the Excluded Parties List System (EPLS), and any such other databases as the Secretary may prescribe.

(c)(1) Consult appropriate databases to confirm identity upon enrollment and reenrollment; and

(2) Check the LEIE and EPLS no less frequently than monthly.

§ 455.440 National Provider Identifier.

The State Medicaid agency must require all claims for payment for items and services that were ordered or referred to contain the National Provider Identifier (NPI) of the physician or other professional who ordered or referred such items or services.

§ 455.450 Screening levels for Medicaid providers.

A State Medicaid agency must screen all initial applications, including applications for a new practice location, and any applications received in response to a re-enrollment or revalidation of enrollment request based on a categorical risk level of "limited," "moderate," or "high." If a provider could fit within more than one risk level described in this section, the highest level of screening is applicable.

(a) *Screening for providers designated as limited categorical risk.* When the State Medicaid agency designates a provider as a limited categorical risk, the State Medicaid agency must do all of the following:

(1) Verify that a provider meets any applicable Federal regulations, or State requirements for the provider type prior to making an enrollment determination.

(2) Conduct license verifications, including State licensure verifications in States other than where the provider is enrolling, in accordance with § 455.412.

(3) Conduct database checks on a pre- and post-enrollment basis to ensure that providers continue to meet the enrollment criteria for their provider type, in accordance with § 455.436.

(b) *Screening for providers designated as moderate categorical risk.* When the State Medicaid agency designates a provider as a "moderate" categorical risk, a State Medicaid agency must do both of the following:

(1) Perform the "limited" screening requirements described in paragraph (a) of this section.

(2) Conduct on-site visits in accordance with § 455.432.

(c) *Screening for providers designated as high categorical risk.* When the State Medicaid agency designates a provider as a "high" categorical risk, a State Medicaid agency must do both of the following:

(1) Perform the "limited" and "moderate" screening requirements described in paragraphs (a) and (b) of this section.

(2)(i) Conduct a criminal background check; and

(ii) Require the submission of a set of fingerprints in accordance with § 455.434.

(d) *Denial or termination of enrollment.* A provider, or any person with 5 percent or greater direct or indirect ownership in the provider, who is required by the State Medicaid agency or CMS to submit a set of fingerprints and fails to do so may have its—

(1) Application denied under § 455.434; or

(2) Enrollment terminated under § 455.416.

(e) *Adjustment of risk level.* The State agency must adjust the categorical risk level from "limited" or "moderate" to "high" when any of the following occurs:

(1) The State Medicaid agency imposes a payment suspension on a provider based on credible allegation of fraud, waste or abuse, the provider has

an existing Medicaid overpayment, or the provider has been excluded by the OIG or another State's Medicaid program within the previous 10 years.

(2) The State Medicaid agency or CMS in the previous 6 months lifted a temporary moratorium for the particular provider type and a provider that was prevented from enrolling based on the moratorium applies for enrollment as a provider at any time within 6 months from the date the moratorium was lifted.

§ 455.452 Other State screening methods.

Nothing in this subpart must restrict the State Medicaid agency from establishing provider screening methods in addition to or more stringent than those required by this subpart.

§ 455.460 Application fee.

(a) Beginning on or after March 25, 2011, States must collect the applicable application fee prior to executing a provider agreement from a prospective or re-enrolling provider other than either of the following:

(1) Individual physicians or nonphysician practitioners.

(2)(i) Providers who are enrolled in either of the following:

(A) Title XVIII of the Act.

(B) Another State's title XIX or XXI plan.

(ii) Providers that have paid the applicable application fee to—

(A) A Medicare contractor; or

(B) Another State.

(b) If the fees collected by a State agency in accordance with paragraph (a) of this section exceed the cost of the screening program, the State agency must return that portion of the fees to the Federal government.

§ 455.470 Temporary moratoria.

(a)(1) The Secretary consults with any affected State Medicaid agency regarding imposition of temporary moratoria on enrollment of new providers or provider types prior to imposition of the moratoria, in accordance with § 424.570 of this chapter.

(2) The State Medicaid agency will impose temporary moratoria on enrollment of new providers or provider types identified by the Secretary as posing an increased risk to the Medicaid program.

(3)(i) The State Medicaid agency is not required to impose such a moratorium if the State Medicaid agency determines that imposition of a temporary moratorium would adversely affect beneficiaries' access to medical assistance.

(ii) If a State Medicaid agency makes such a determination, the State Medicaid agency must notify the Secretary in writing.

(b)(1) A State Medicaid agency may impose temporary moratoria on enrollment of new providers, or impose numerical caps or other limits that the State Medicaid agency identifies as having a significant potential for fraud, waste, or abuse and that the Secretary has identified as being at high risk for fraud, waste, or abuse.

(2) Before implementing the moratoria, caps, or other limits, the State Medicaid agency must determine that its action would not adversely impact beneficiaries' access to medical assistance.

(3) The State Medicaid agency must notify the Secretary in writing in the event the State Medicaid agency seeks to impose such moratoria, including all details of the moratoria; and obtain the Secretary's concurrence with imposition of the moratoria.

(c)(1) The State Medicaid agency must impose the moratorium for an initial period of 6 months.

(2) If the State Medicaid agency determines that it is necessary, the State Medicaid agency may extend the moratorium in 6-month increments.

(3) Each time, the State Medicaid agency must document in writing the necessity for extending the moratorium.

PART 457—ALLOTMENTS AND GRANTS TO STATES

■ 27. The authority citation for part 457 continues to read as follows:

Authority: Section 1102 of the Social Security Act (42 U.S.C. 1302).

■ 28. Section 457.900 is amended by adding a new paragraph (a)(2)(x) to read as follows:

§ 457.900 Basis, scope and applicability.

(a) * * *

(2) * * *

(x) Sections 1902(a)(77) and 1902(kk) of the Act relating to provider and supplier screening, oversight, and reporting requirements.

* * * * *

■ 29. A new § 457.990 is added to subpart I to read as follows:

§ 457.990 Provider and supplier screening, oversight, and reporting requirements.

The following provisions and their corresponding regulations apply to a State under title XXI of the Act, in the same manner as these provisions and regulations apply to a State under title XIX of the Act:

(a) Part 455, Subpart E, of this chapter.

(b) Sections 1902(a)(77) and 1902(kk) of the Act pertaining to provider and supplier screening, oversight, and reporting requirements.

PART 498—APPEALS PROCEDURES FOR DETERMINATIONS THAT AFFECT PARTICIPATION IN THE MEDICARE PROGRAM AND FOR DETERMINATIONS THAT AFFECT THE PARTICIPATION OF ICFs/MR AND CERTAIN NFs IN THE MEDICAID PROGRAM

■ 30. The authority citation for part 498 continues to read as follows:

Authority: Secs. 1102 and 1871 of the Social Security Act (42 U.S.C. 1302 and 1395hh).

■ 31. Section 498.5 is amended by adding a new paragraph (l)(4) to read as follows:

§ 498.5 Appeal rights.

* * * * *

(l) * * *

(4) *Scope of review.* For appeals of denials based on § 424.530(a)(9) of this chapter related to temporary moratoria, the scope of review will be limited to whether the temporary moratorium applies to the provider or supplier appealing the denial. The agency's basis for imposing a temporary moratorium is not subject to review.

CHAPTER V-OFFICE OF INSPECTOR GENERAL-HEALTH CARE, DEPARTMENT OF HEALTH AND HUMAN SERVICES

PART 1007—STATE MEDICAID FRAUD CONTROL UNITS

■ 32. The authority citation for part 1007 continues to read as follows:

Authority: 42 U.S.C. 1320 and 1395hh.

■ 33. Section 1007.9 is amended by adding paragraphs (e) through (g) to read as follows:

§ 1007.9 Relationship to, and agreement with, the Medicaid agency.

* * * * *

(e)(1) The unit may refer any provider with respect to which there is pending an investigation of a credible allegation of fraud under the Medicaid program to the State Medicaid agency for payment suspension in whole or part under § 455.23 of this title.

(2) Referrals may be brief, but must be in writing and include sufficient information to allow the State Medicaid agency to identify the provider and to explain the credible allegations forming the grounds for the payment suspension.

(f) Any request by the unit to the State Medicaid agency to delay notification to the provider of a payment suspension under § 455.23 of this title must be in writing.

(g) When the unit accepts or declines a case referred by the State Medicaid agency, the unit notifies the State Medicaid agency in writing of the acceptance or declination of the case.

Catalog of Federal Domestic Assistance Program No. 93.778, Medical Assistance Program) (Catalog of Federal Domestic Assistance Program No. 93.773, Medicare—Hospital Insurance; and Program No. 93.774, Medicare—Supplementary Medical Insurance Program)

Dated: January 14, 2011.

Donald Berwick,

Administrator, Centers for Medicare & Medicaid Services.

Approved: January 21, 2011.

Kathleen Sebelius,

Secretary, Department of Health and Human Services.

[FR Doc. 2011–1686 Filed 1–24–11; 12:15 pm]

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Part III

Commodity Futures Trading Commission

Privacy Act of 1974; Publication of the Systems of Records Managed by the Commodity Futures Trading Commission; Notice

COMMODITY FUTURES TRADING COMMISSION

Privacy Act of 1974; Notice; Publication of the Systems of Records Managed by the Commodity Futures Trading Commission

AGENCY: Commodity Futures Trading Commission.

ACTION: Notice; publication of existence and character of revised systems of records and proposed routine uses.

SUMMARY: The Commodity Futures Trading Commission (Commission) is revising the notices it is required to publish under the Privacy Act of 1974 to describe the systems of records that contain information about individuals. This revision incorporates address and title changes and updated system descriptions. It also incorporates new systems of records that were compiled since the last publication of the Commission's systems of records notices in 2001. This revision proposes to add routine uses that are applicable to all of the Commission's systems of records and to re-identify the systems of records already in existence in a more consistent format.

DATES: Comments should be postmarked by March 14, 2011. This notice will become effective without further notice, on the date which is 60 days from the date given above unless otherwise revised pursuant to comments received.

ADDRESSES: Written comments may be mailed or delivered to: Office of the Secretariat, Commodity Futures Trading Commission, Three Lafayette Centre, 1155 21st Street, NW., Washington, DC 20581. Comments may also be sent by *e-mail* to *http://comments.cftc.gov.*

FOR FURTHER INFORMATION CONTACT: Kathy Harman-Stokes, Chief Privacy Officer, Office of the Executive Director, Commodity Futures Trading Commission, Three Lafayette Centre, 1155 21st Street, NW., Washington, DC 20581. Telephone: (202) 418–6629 or *e-mail: kharman-stokes@cftc.gov*.

SUPPLEMENTARY INFORMATION: This notice alerts the public to the information the Commission collects and maintains on individuals. In compiling and publishing the complete text for all of the Commission systems of records, new routine uses (blanket routine uses) have been added that apply to all of the notices. Since routine uses are permissive in nature, the blanket routine uses and the routine uses listed for each of the systems of records may be used to make a disclosure, but are not required to be used when a requester seeks a record. The responsibility to decide whether a routine use is applicable rests with the Commission. The Commission is also proposing to add a new system of records entitled, Emergency Locator System as CFTC–9. This system of records will contain information about Commission employees and those identified by the employee to contact in the event of a medical or other emergency concerning the employee.

The system report, as required by 5 U.S.C. 552a(r) has been submitted to the Committee on Homeland Security and Governmental Affairs of the United States Senate, the Committee on Oversight and Government Reform of the House of Representatives, and the Office of Management and Budget.

The Privacy Act

The Privacy Act is a Federal law that protects information about individuals that is collected and maintained in a "system of records" by an agency of the United States government. In addition to providing the public with information about these systems, the Privacy Act and the Commission's rules limit the agency's ability to use or disclose personal information except for specific purposes.

Systems of Records

A "system of records" is a collection of information about individuals in paper, electronic, or other format, from which information is retrieved by the name of the individual or by some other identifying particular assigned to the individual, such as a social security number or address. The Privacy Act does not cover information about businesses or about individuals who are not U.S. citizens or lawfully admitted aliens. *See* 5 U.S.C. 522a(5).

Each system of records notice contains the following information:

- The name of the system;
- The location of the system;
- The categories of individuals whose records are maintained in the system;
- The types of records maintained in the system;
- The authority for maintaining the system;
- The routine uses of records maintained in the system, including the categories of users and the purposes of such uses;
- The policies and practices for storing, retrieving, accessing, retaining, and disposing of records in the system;
- The title and business address of the system manager, the agency official who is responsible for the system of records;
- How to find out whether the system of records contains a record pertaining to the individual, how the individual may gain access to any record pertaining to the individual contained in the system of records, and how the individual can contest the content of the records; and
- The categories of sources of records in the system.

Exempt Systems of Records

The Commission has exempted four systems of records from certain requirements of the Privacy Act, as authorized under 5 U.S.C. 552a(k), because they contain investigatory material:

- CFTC–1 Enforcement matter register and matter indices (exempted, to the extent it contains records that refer or relate to records covered under CFTC–10, Investigatory Records (exempted)).
- CFTC–10 Investigatory materials compiled for law enforcement purposes.
- CFTC–31 Information pertaining to individuals discussed at closed Commission meetings.
- CFTC–32 Investigatory materials compiled by the Office of the Inspector General.

Locations of Systems of Records

Each system of records notice tells the public where records are kept. Records may be kept at one or more Commission offices. The Commission offices are in the following locations:

- *Washington, DC:* Three Lafayette Centre, 1155 21st Street, NW., Washington, DC 20581, Telephone: (202) 418–5000.
- *Chicago:* 525 West Monroe Street, Suite 1100, Chicago, Illinois 60661, Telephone: (312) 596–0700.
- *Kansas City:* Two Emanuel Cleaver II Blvd., Suite 300, Kansas City, Missouri 64112, Telephone: (816) 960–7700.
- *New York:* 140 Broadway, 19th Floor, New York, New York 10005, Telephone: (646) 746–9700.

In the system of records notice, the Commission headquarters office in Washington, DC, is referred to as the "principal office." The regional offices are referred to collectively as the "regional offices." "All Commission offices" means the headquarters office and the regional offices.

General Statement of CFTC Routine Uses

The following "blanket routine uses" of records, numbered "1" through "19" below, apply to every system of records maintained within the Commission. These blanket routine uses of the records are published below only once in the interest of simplicity, economy,

and to avoid redundancy. Additional routine uses that apply to a particular Commission system notice are listed in the applicable system notice. The release of records under all routine uses is permissive rather than mandatory. Each of the blanket routine uses is for a purpose which is compatible with the purpose for which the information was originally collected.

The following routine uses apply to all CFTC systems of records:

1. Information may be used by the Commission in any administrative proceeding before the Commission, in any injunctive action authorized under the Commodity Exchange Act or in any other action or proceeding in which the Commission or its staff participates as a party or the Commission participates as amicus curiae.

2. Information may be disclosed to the Department of Justice, the Securities and Exchange Commission, the United States Postal Service, the Internal Revenue Service, the Department of Agriculture, the Office of Personnel Management, and to other Federal, State, local, territorial or Tribal law enforcement or regulatory agencies for use in meeting their statutory and regulatory requirements.

3. Information may be given to any "registered entity," as defined in section 1a of the Commodity Exchange Act, 7 U.S.C. 1, *et seq.* ("the Act"), if the Commission has reason to believe that such information will assist the registered entity in carrying out its responsibilities under the Act. Information may also be given to any registered futures association registered under section 17 of the Act (*e.g.,* the National Futures Association) to assist it in carrying out its self-regulatory responsibilities under the Act, and to any national securities exchange or national securities association registered with the Securities and Exchange Commission to assist those organizations in carrying out their self-regulatory responsibilities under the Securities Exchange Act of 1934, 15 U.S.C. 78a, *et seq.*

4. At the discretion of the Commission staff, information may be given or shown to anyone during the course of a Commission investigation if the staff has reason to believe that the person to whom it is disclosed may have further information about the matters discussed therein, and those matters appear relevant to the subject of the investigation.

5. Information may be included in a public report issued by the Commission following an investigation, to the extent that this is authorized under section 8 of the Commodity Exchange Act, 7 U.S.C. 12. Section 8 authorizes publication of such reports but contains restrictions on the publication of certain types of sensitive business information developed during an investigation. In certain contexts, some of this information might be considered personal in nature.

6. Information may be disclosed to a Federal agency in response to its request in connection with the hiring or retention of an employee, the issuance of a security clearance, the reporting of an investigation of an employee, the letting of a contract or the issuance of a license, or a grant or other benefit by the requesting agency, to the extent that the information may be relevant to the requesting agency's decision on the matter.

7. Information may be disclosed to a prospective employer in response to its request in connection with the hiring or retention of an employee, to the extent that the information is believed to be relevant to the prospective employer's decision in the matter.

8. Information may be disclosed to any person, pursuant to Section 12(a) of the Commodity Exchange Act, 7 U.S.C. 16(a), when disclosure will further the policies of that Act or of other provisions of law. Section 12(a) authorizes the Commission to cooperate with various other government authorities or with "any person."

9. Where information, either alone or in conjunction with other information indicates a violation or potential violation of law—criminal, civil, or regulatory in nature—the relevant information may be disclosed to the appropriate Federal, State, local, territorial, Tribal, or foreign law enforcement authority or other appropriate entity charged with the responsibility for investigating or prosecuting such violation or charged with enforcing or implementing such law.

10. Information may be disclosed to the General Services Administration for the purpose of records management inspections conducted under the authority of 44 U.S.C. 2904 and 2906.

11. Information may be disclosed to the National Archives and Records Administration for the purpose of records management inspections being conducted under the authority of 44 U.S.C. 2904 and 2906.

12. Information may be disclosed to foreign law enforcement, investigatory, or administrative authorities in order to comply with requirements set forth in international arrangements, such as memoranda of understanding.

13. Information may be disclosed to contractors, grantees, volunteers, experts, students, and others performing or working on a contract, service, grant, cooperative agreement, or job for the Federal government when necessary to accomplish an agency function.

14. Information may be disclosed to the Merit Systems Protection Board, including the Office of Special Counsel for the purpose of litigation, including administrative proceedings, appeals, special studies of the civil service and other merit systems.

15. Information may be disclosed to the Department of Justice or in a proceeding before a court, adjudicative body, or other administrative body which the agency is authorized to appear, when:

a. The agency, or any component thereof; or

b. Any employee of the agency in his or her official capacity; or

c. Any employee of the agency in his or her official capacity where the Department of Justice or the agency has agreed to represent the employee; or

d. The United States, when the agency determines that litigation is likely to affect the agency or any of its components;

Is a party to litigation or has an interest in such litigation, and the use of such records by the Department of Justice or the agency is deemed by the agency to be relevant and necessary to the litigation provided, however, that in each case it has been determined that the disclosure is compatible with the purpose for which the records were collected.

16. Information may be disclosed to a Member of Congress or staff acting upon the Member's behalf when the Member or staff requests the information on behalf of, or at the request of, the individual who is the subject of the record.

17. Information related to any traders or the amount or quantity of any commodity purchased or sold by such traders may be disclosed to any committee of either House of Congress upon its request, acting within the scope of its jurisdiction, pursuant to the Commodity Exchange Act, 7 U.S.C. 1 *et seq.,* including Section 8(e) of such Act at 7 U.S.C. 12, and the rules and regulations promulgated thereunder.

18. Information may be disclosed to another Federal agency, to a court, or a party in litigation before a court or in an administrative proceeding being conducted by a Federal agency, when the Government is a party to the judicial or administrative proceeding.

19. Information may be disclosed to appropriate agencies, entities, and individuals when:

a. The Commission suspects or has confirmed that the security or confidentiality of information in the system of records has been compromised;

b. The Commission has determined that as a result of the suspected or confirmed compromise there is a risk of harm to economic or property interests, identity theft or fraud, or harm to the security or integrity of this system or other systems or programs (whether maintained by the Commission or another agency or entity) that rely upon the compromised information; and

c. The disclosure made to such agencies, entities, and individuals is reasonably necessary to assist in connection with the Commission's efforts to respond to the suspected or confirmed compromise and prevent, minimize, or remedy such harm.

CFTC Systems of Records Notices

Below is a list of the Commission's systems of records, followed by the complete text of all of the systems of records notices.

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CFTC–1 Enforcement Matter Register and Matter Indices (exempted)
CFTC–2 Commission Correspondence Files
CFTC–3 Proceedings Docket Files Forwarded for Adjudication
CFTC–4 Employee Leave, Time, and Attendance
CFTC–5 Employee Personnel/Payroll Records
CFTC–6 Employee Travel and Transportation Records
CFTC–7 Formal Employment Discrimination Complaint and Reasonable Accommodation Files
CFTC–8 Employment Applications
CFTC–9 Emergency Locator System
CFTC–10 Investigatory Records (exempted)
CFTC–12 Fitness Investigations
CFTC–13 Interpretative, Exemptive, and No-Action Files
CFTC–14 Commodity Futures Trading Commission Alumni Records
CFTC–15 Large Trader Report Files
CFTC–16 Enforcement Case Files
CFTC–17 Litigation Files—OGC
CFTC–18 Logbook on Speculative Limit Violations
CFTC–20 Registration
CFTC–28 Self-Regulatory Organization Disciplinary Action Files
CFTC–29 Reparations Complaints
CFTC–30 Open Commission Meetings
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CFTC–32 Office of the Inspector General Investigative Files (exempted)
CFTC–33 Electronic Access Card
CFTC–34 Telephone System (BlackBerry or Calling Card)
CFTC–35 Interoffice and Internet *E-mail*
CFTC–36 Internet Security Gateway Systems (Firewall, Web Content Filter, and *E-mail* Filter)
CFTC–37 Lexis/Westlaw Billing Information System
CFTC–38 Automated Library Circulation System
CFTC–39 Freedom of Information Act Requests
CFTC–40 Privacy Act Requests
CFTC–41 Requests for Confidential Treatment
CFTC–42 Debt Collection Files
CFTC–43 Visitor Information System
CFTC–44 Personnel Security Files

CFTC–1

SYSTEM NAME:

Enforcement Matter Register and Matter Indices (exempted, to the extent it contains records that refer or relate to records covered under CFTC–10, Investigatory Records (exempted)).

SYSTEM LOCATION:

This system is located in the Division of Enforcement in the Commission's principal office at Commodity Futures Trading Commission, Three Lafayette Centre, 1155 21st Street, NW., Washington DC, 20581, and regional offices in Chicago at 525 West Monroe Street, Suite 1100 Chicago, IL 60661, in Kansas City at Two Emanuel Cleaver II Blvd., Suite 300, Kansas City, MO 64112, and New York at 140 Broadway, 19th Floor, New York, NY 10005.

CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

a. Individuals found or alleged to have, or suspected of having, violated the Commodity Exchange Act or the rules, regulations or orders of the Commission adopted thereunder.

b. Individuals whom the Commission staff has reason to believe have violated, are violating or are about to violate a law or regulation or order of another Federal, State or foreign authority.

c. Individuals lodging complaints with the Commission concerning third parties.

d. Individuals whom the Commission staff has identified as relevant to an enforcement matter, such as complainants, witnesses and counsel.

e. Individuals whom a foreign law enforcement authority has found or alleges to have, or suspects of having, violated foreign laws, rules, regulations or orders of such foreign law enforcement authority.

CATEGORIES OF RECORDS IN THE SYSTEM:

An index system to CFTC–10 Investigatory Records (exempted) and CFTC–16 Enforcement Case Files, including:

a. The matter register records are organized by docket number and/or matter name. The register also indicates the date opened, the disposition and status, the date closed, and the staff member assigned.

b. The matter register also includes reports recommending openings and closings of investigations.

AUTHORITY FOR THE MAINTENANCE OF THE SYSTEM:

The Commodity Exchange Act, 7 U.S.C. 1 *et seq.,* including Section 8 of such Act at 7 U.S.C. 12, and the rules and regulations promulgated thereunder.

ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND THE PURPOSES OF SUCH USES:

Information in this system may be disclosed in accordance with the blanket routine uses numbered 1 through 19 that appear at the beginning of the Commission's compilation of its systems of records notices.

POLICIES AND PRACTICES FOR STORING, RETRIEVING, ACCESSING, RETAINING, AND DISPOSING OF RECORDS IN THE SYSTEM:

STORAGE:

Paper records are stored in file folders, binders, computer files (eLaw) and computer disks. Electronic records, including computer files, are stored on the Commission's network and other electronic media as needed, such as encrypted hard drives.

RETRIEVABILITY:

By matter name or docket number.

SAFEGUARDS:

Records are protected from unauthorized access and improper use through administrative, technical and physical security measures. Technical security measures within CFTC include restrictions on computer access to authorized individuals, required use of strong passwords frequently changed, use of encryption for certain data types and transfers, and regular review of security procedures and best practices to enhance security. Physical measures include restrictions on building access to authorized individuals and maintenance of records in lockable offices and filing cabinets.

RETENTION AND DISPOSAL:

Records related to CFTC–10, Investigatory Records (exempted), and CFTC–16, Enforcement Case Files, are maintained indefinitely.

SYSTEM MANAGER(S) AND ADDRESS:

Director, Division of Enforcement, in the Commission's principal office at Commodity Futures Trading Commission, Three Lafayette Centre, 1155 21st Street, NW., Washington, DC 20581 and Regional Counsels in the

regional offices: in Chicago at 525 West Monroe Street, Suite 1100 Chicago, IL 60661; in Kansas City at Two Emanuel Cleaver II Blvd., Suite 300, Kansas City, MO 64112; and in New York at 140 Broadway, 19th Floor, New York, NY 10005.

NOTIFICATION PROCEDURE:

Individuals seeking to determine whether this system of records contains non-exempt information about themselves or seeking access to non-exempt records about themselves in this system of records, or contesting the content of non-exempt records about themselves contained in this system of records should address written inquiry to the Office of General Counsel, Paralegal Specialist, Three Lafayette Centre, 1155 21st Street, NW., Washington, DC 20581. Telephone (202) 418–5011.

RECORD SOURCE CATEGORIES:

Individuals submitting complaints to the Commission, and miscellaneous sources including customers, law enforcement and regulatory agencies, commodity exchanges, National Futures Association, trade sources, and Commission-staff-generated items.

SYSTEMS EXEMPTED FROM CERTAIN PROVISIONS OF THE ACT:

The records in this system that refer or relate to records contained in CFTC–10, Investigatory Records (exempted), have been exempted by the Commission from certain provisions of the Privacy Act of 1974 pursuant to the terms of the Privacy Act, 5 U.S.C. 552a(k)(2), and the Commission's rules promulgated thereunder, 17 CFR 146.12. These records are exempt from the notification procedures, records access procedures, and record contest procedures set forth in the system notices of other systems of records, and from the requirement that the sources of records in the system be described.

CFTC–2

SYSTEM NAME:

Commission Correspondence Files.

SYSTEM LOCATION:

This system is located in the Commission's principal office at Commodity Futures Trading Commission, Three Lafayette Centre, 1155 21st Street, NW., Washington, DC 20581.

CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

Individuals corresponding with the Commission, directly or through their representatives. Individuals discussed in correspondence to or from the Commission.

CATEGORIES OF RECORDS IN THE SYSTEM:

Incoming and outgoing correspondence and indices of correspondence, and certain internal reports and memoranda related to the correspondence. This system also includes e-mail, Internet and Web-based correspondence submitted by the public. This system includes only those records that are part of a general correspondence file maintained by the office involved. It includes correspondence indexed by assigned number and, in certain offices, by individual name of the correspondent.

AUTHORITY FOR MAINTENANCE OF THE SYSTEM:

44 U.S.C. 3101.

ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND THE PURPOSES OF SUCH USES:

Information in this system may be disclosed in accordance with the blanket routine uses numbered 1 through 19 that appear at the beginning of the Commission's compilation of its systems of records notices.

POLICIES AND PRACTICES FOR STORING, RETRIEVING, ACCESSING, RETAINING, AND DISPOSING OF RECORDS IN THE SYSTEM:

STORAGE:

Paper records are stored in file folders, binders or on index cards. Electronic records, including computer files, are stored on the Commission's network and other electronic media as needed, including desktop applications and the Correspondence System.

RETRIEVABILITY:

By name of correspondent, subject matter, date or assigned number. The name may be either the name of the person who sent or received the letter, or the person on whose behalf the letter was sent or received. It may also be another person who was the principal subject of the letter, where circumstances appear to justify this treatment. *See* previous discussion concerning the category of records maintained in this system.

SAFEGUARDS:

Records are protected from unauthorized access and improper use through administrative, technical and physical security measures. Technical security measures within CFTC include restrictions on computer access to authorized individuals, required use of strong passwords frequently changed, use of encryption for certain data types and transfers, and regular review of security procedures and best practices to enhance security. Physical measures include restrictions on building access to authorized individuals and maintenance of records in lockable offices and filing cabinets.

RETENTION AND DISPOSAL:

The retention and disposal period depends on the nature of the correspondence. For example, correspondence with the Commission that pertains to the programs and policies of the Commission becomes part of the agency's central files and is kept permanently. Other correspondence may be kept for between one and 10 years, depending on the subject matter.

SYSTEM MANAGER(S) AND ADDRESS:

Office of the Secretariat; Director, Office of International Affairs, Office of External Affairs; Executive Director; General Counsel; Director, Division of Enforcement; Director, Division of Market Oversight; Director, Division of Clearing and Intermediary Oversight, and Office of the Chief Economist. All are located at the Commodity Futures Trading Commission, Three Lafayette Centre, 1155 21st Street, NW., Washington, DC 20581.

NOTIFICATION PROCEDURE:

Individuals seeking to determine whether this system of records contains information about themselves or seeking access to records about themselves in this system of records, or contesting the content of records about themselves contained in this system of records should address written inquiry to the Office of General Counsel, Paralegal Specialist, Commodity Futures Trading Commission, Three Lafayette Centre, 1155 21st Street, NW., Washington, DC 20581. Telephone (202) 418–5011.

RECORD SOURCE CATEGORIES:

Individuals corresponding with the Commission and correspondence and memoranda prepared by the Commission.

CFTC–3

SYSTEM NAME:

Docket Files for Reparations and Administrative Adjudication.

SYSTEM LOCATION:

This system is located in the Office of Proceedings, Commodity Futures Trading Commission, Three Lafayette Centre, 1155 21st Street, NW., Washington, DC 20581.

CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

All individuals involved in any CFTC administrative enforcement or reparations proceeding.

CATEGORIES OF RECORDS IN THE SYSTEM:

All pleadings, motions, applications, stipulations, affidavits, transcripts and documents introduced as evidence, briefs, orders, findings, opinions, and other matters that are part of the record of an administrative or reparations proceeding. They also include related correspondence and indices.

AUTHORITY FOR MAINTENANCE OF THE SYSTEM:

The Commission is authorized or required to conduct proceedings under several provisions of the Commodity Exchange Act, 7 U.S.C. 1 *et seq.* These files are necessary for the conduct of orderly proceedings. *See also* 44 U.S.C. 3101.

ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND THE PURPOSES OF SUCH USES:

These records are public records unless the Commission or assigned presiding officer determines for good cause to treat them as nonpublic records consistent with the provisions of the Freedom of Information Act. Nonpublic portions may be used for any purpose specifically authorized by the Commission or by the presiding officer who ordered such nonpublic treatment of the records.

Information in this system may be disclosed in accordance with the blanket routine uses numbered 1 through 19 that appear at the beginning of the Commission's compilation of its systems of records notices.

POLICIES AND PRACTICES FOR STORING, RETRIEVING, ACCESSING, RETAINING, AND DISPOSING OF RECORDS IN THE SYSTEM:

STORAGE:

Paper records are stored in file folders, on index cards, paper docket cards, and microfilm. Electronic records, including computer files, are stored on the Commission's network and other electronic media as needed.

RETRIEVABILITY:

By the docket number and cross-indexed by complainant and respondent names.

SAFEGUARDS:

Records are protected from unauthorized access and improper use through administrative, technical and physical security measures. Technical security measures within CFTC include restrictions on computer access to authorized individuals, required use of strong passwords frequently changed, use of encryption for certain data types and transfers, and regular review of security procedures and best practices to enhance security. Physical measures include restrictions on building access to authorized individuals and maintenance of records in lockable offices and filing cabinets. Records that the Commission or presiding officer has directed be held nonpublic, such as material submitted in a proceeding "in camera" or "under seal," are maintained in file folders, binders or in the Commission's computer network (*e.g.,* eLaw), separate from public records.

RETENTION AND DISPOSAL:

Docket files for reparations cases are maintained for 10 years after final disposition of the case. Docket files in administrative/enforcement cases are maintained for 15 years after final disposition of the case. Docket files for reparations sanctions files are maintained until the sanction is satisfied. Docket files of unique or precedent setting cases are permanent records that are transferred to the National Archives when 20 years old.

SYSTEM MANAGER(S) AND ADDRESS:

Proceedings Clerk, Office of Proceedings, Commodity Futures Trading Commission, Three Lafayette Centre, 1155 21st Street, NW., Washington, DC 20581.

NOTIFICATION PROCEDURE:

Individuals seeking to determine whether this system of records contains information about themselves or seeking access to records about themselves in this system of records, or contesting the content of records about themselves contained in this system of records should address written inquiry to the Office of General Counsel, Paralegal Specialist, Commodity Futures Trading Commission, Three Lafayette Centre, 1155 21st Street, NW., Washington, DC 20581. Telephone (202) 418–5011.

RECORD SOURCE CATEGORIES:

Commission staff members; opposing parties and their attorneys; proceeding witnesses; and miscellaneous sources.

CFTC–4

SYSTEM NAME:

Employee Leave, Time, and Attendance.

SYSTEM LOCATION:

The information in the system is located in the same Commission office as the employee described by the records. Information is also kept centrally on the computer system located in the Department of Agriculture's National Finance Center, New Orleans, Louisiana.

CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

All Commission employees.

CATEGORIES OF RECORDS IN THE SYSTEM:

Various records reflecting Commission employees' time and attendance and leave status, as well as the allocation of employee time to designated budget account codes.

AUTHORITY FOR MAINTENANCE OF THE SYSTEM:

5 U.S.C. 6101–6133; 5 U.S.C. 6301–6326; 44 U.S.C. 3101.

ROUTINE USES OF THE RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND THE PURPOSES OF SUCH USES:

a. The information may be provided to the Department of Justice or other Federal agencies in connection with any investigation, or administrative or legal proceeding involving any violation or potential violation of any Federal law, rule, or regulation.

Information in this system may also be disclosed in accordance with the blanket routine uses numbered 1 through 19 that appear at the beginning of the Commission's compilation of its systems of records notices.

POLICIES AND PRACTICES FOR STORING, RETRIEVING, ACCESSING, RETAINING, AND DISPOSING OF RECORDS IN THE SYSTEM:

STORAGE:

Paper records are stored in file folders, including paper copies of time and attendance worksheets, leave request slips and signed computer printouts. Electronic records are stored on the Commission's network and in other electronic media as needed, and certain computer files (STARweb) are located at the National Finance Center (NFC).

RETRIEVABILITY:

By the name of the employee or by the employee number, cross-indexed by name.

SAFEGUARDS:

Records are protected from unauthorized access and improper use through administrative, technical and physical security measures. Technical security measures within CFTC include restrictions on computer access to authorized individuals, required use of strong passwords frequently changed, use of encryption for certain data types and transfers, and regular review of security procedures and best practices to enhance security. Physical measures include restrictions on building access

to authorized individuals and maintenance of records in lockable offices and filing cabinets. Only specifically authorized individuals may access the NFC computer system, and UserID and password are required.

RETENTION AND DISPOSAL:

Hard copy records, including leave slips, signed computer printouts from the STARweb system, overtime approval slips and budget account code worksheets are retained for six years, and then destroyed.

SYSTEM MANAGER AND ADDRESS:

Director, Office of Human Resources, Commodity Futures Trading Commission, Three Lafayette Centre, 1155 21st Street, NW., Washington, DC 20581.

NOTIFICATION PROCEDURE:

Individuals seeking to determine whether this system of records contains information about themselves or seeking access to records about themselves in this system of records, or contesting the content of records about themselves contained in this system of records should address written inquiry to the Office of General Counsel, Paralegal Specialist, Commodity Futures Trading Commission, Three Lafayette Centre, 1155 21st Street, NW., Washington, DC 20581. Telephone (202) 418–5011.

RECORD SOURCE CATEGORIES:

The individual about whom the record is maintained.

CFTC–5

SYSTEM NAME:

Employee Personnel/Payroll Records.

SYSTEM LOCATION:

This system is located in the Office of Human Resources, and the Office of General Counsel, Commodity Futures Trading Commission, Three Lafayette Centre, 1155 21st Street, NW., Washington, DC 20581 and on a computer system located in the Department of Agriculture's National Finance Center, New Orleans, LA.

CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

All Commission employees.

CATEGORIES OF RECORDS IN THE SYSTEM:

Payroll related information for current Commission employees, including payroll and leave data for each employee relating to rate and amount of pay, leave and hours worked, and leave balances, tax and retirement deductions, life insurance and health insurance deductions, savings allotments, savings bonds and charity deductions, student loan repayment program information, other benefits information, mailing addresses and home addresses, direct deposit information, and copies of the Commission time and attendance reports as well as authorities relating to deductions, including salary offset under part 141 of the Commission's rules. The records maintained in the principal office for all employees may also include: (a.) Various summary materials received in computer printout form; (b.) Awards information; (c.) Recruitment, relocation or retention bonuses; and (d.) Training information.

The official personnel records maintained by the Commission are described in the system notices published by the Office of Personnel Management (OPM/GOVT–1 and OPM/GOVT–2), and are not included within this system. OPM/GOVT–1 is the General Personnel Records System for OPM. This system includes employee personal identifying information, such as name, date of birth, home address, mailing address, social security number, and home telephone. OPM/GOVT–2 is the OPM Employee Performance File System Records System, which covers employee performance ratings of record and conduct-related documents maintained by first line supervisors and managers. *See https://www.opm.gov/fedregis/2006/71-061906-35363-a.htm.*

AUTHORITY FOR MAINTENANCE OF THE SYSTEM:

44 U.S.C. 3101, Ethics in Government Act of 1978 (5 U.S.C. 7301APP); Executive Order Nos. 12674 (as modified by 12731), 12565, and 11222: 5 CFR parts 2634, 2635. (Personnel Financial Disclosure Requirements).

ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND THE PURPOSES OF SUCH USES:

a. The information may be provided to the Department of Justice, the Office of Personnel Management or other Federal agencies, or used by the Commission in connection with any investigation or administrative or legal proceeding involving any violation of Federal law or regulation thereunder.

b. Certain information will be provided, as required by law, to the Office of Child Support Enforcement, Administration for Children and Families, Department of Health and Human Services Federal Parent Locator System (FPLS) and Federal Tax Offset System to enable State jurisdictions to locate individuals and identify their income sources to establish paternity, establish and modify orders of support, and for enforcement action.

c. Certain information will be provided, as required by law, to the Office of Child Support Enforcement for release to the Social Security Administration for verifying social security numbers in connection with the operation of the FPLS by the Office of Child Support Enforcement.

d. Certain information will be provided, as required by law, to the Office of Child Support Enforcement for release to the Department of Treasury for purposes of administering the Earned Income Tax Credit Program (Section 32, Internal Revenue Code of 1986) and verifying a claim with respect to employment in a tax return.

e. The information may be provided to insurance companies providing, or proposing to bid on a solicitation to provide, health benefits to Commission employees. This data may include, but is not limited to: name, social security number, date of birth, age, gender, marital status, service computation date, date of initial appointment with the Commission, geographic location, standard metropolitan service area, home phone number, home address, of the Commission employee. For each enrolled dependent of the Commission employee, this information may include, but is not limited to: dependent's name, relationship of the dependent to the Commission employee, date of birth, age, gender, social security number, home address, marital status, student status, and handicap status where applicable. This information may be used to verify eligibility, pay claims, or provide accurate bids.

f. For employees who request repayment of student loans through the CFTC Student Loan Repayment Program, certain information will be provided to the organizations that hold the requesting employees' loan notes for the purpose of verifying outstanding loan amounts and administering such program.

Information in this system may also be disclosed in accordance with the blanket routine uses numbered 1 through 19 that appear at the beginning of the Commission's compilation of its systems of records notices.

POLICIES AND PRACTICES FOR STORING, RETRIEVING, ACCESSING, RETAINING, AND DISPOSING OF RECORDS IN THE SYSTEM:

STORAGE:

Paper records are stored in file folders, and electronic records, including computer files, are stored on the Commission's network, the National Finance Center Personnel/Payroll System/CFTC–Network, and other electronic media as needed.

RETRIEVABILITY:

By the name or social security number of the employee.

SAFEGUARDS:

Records are protected from unauthorized access and improper use through administrative, technical and physical security measures. Technical security measures within CFTC include restrictions on computer access to authorized individuals, required use of strong passwords frequently changed, use of encryption for certain data types and transfers, and regular review of security procedures and best practices to enhance security. Physical measures include restrictions on building access to authorized individuals and maintenance of records in lockable offices and filing cabinets.

RETENTION AND DISPOSAL:

These records are maintained according to retention schedules prescribed by the General Records Schedule for each type of personnel/payroll record.

SYSTEM MANAGER(S) AND ADDRESS:

Director, Office of Human Resources, Commodity Futures Trading Commission, Three Lafayette Centre, 1155 21st Street, NW., Washington, DC 20581.

NOTIFICATION PROCEDURE:

Individuals seeking to determine whether this system of records contains information about themselves or seeking access to records about themselves in this system of records, or contesting the content of records about themselves contained in this system of records should address written inquiry to the Office of General Counsel, Paralegal Specialist, Commodity Futures Trading Commission, Three Lafayette Centre, 1155 21st Street, NW., Washington, DC 20581. Telephone (202) 418–5011.

RECORD SOURCE CATEGORIES:

Individual about whom the record is maintained; personnel office records; and miscellaneous sources.

CFTC–6

SYSTEM NAME:

Employee Travel and Transportation Records.

SYSTEM LOCATION:

Employee travel records are part of the GovTrip System operated by the Northrop Grumman Mission Systems located at 12900 Federal Park System Drive, Fairfax, VA 22033. Access to these records is through Office of Financial Management, Commodity Futures Trading Commission, Three Lafayette Centre, 1155 21st Street, NW., Washington, DC 20581. The transit subsidy system is located in the Office of Management Operations, Commodity Futures Trading Commission, Three Lafayette Centre, 1155 21st Street, NW., Washington, DC 20581.

CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

Any Commission member, employee, witness, expert, advisory committee member or non-Commission employee traveling on official business for the Commission and any Commission employee who applies for and receives a transit subsidy.

CATEGORIES OF RECORDS IN THE SYSTEM:

Travel records contain the name, social security number, address, destination, itinerary, mode and purpose of travel, dates, expenses, miscellaneous claims, amounts advanced, amounts claimed, and amounts reimbursed. Includes travel authorizations, travel vouchers, requests, receipts, invoices from credit card vendors' receipts, and other records. Transit subsidy records contain the employee's name, home address, office, office phone, the last four digits of the social security number, the mode of transportation, the monthly amount of transportation expenses, and the monthly amount received.

AUTHORITY FOR MAINTENANCE OF THE SYSTEM:

5 U.S.C. 5701–5752; 31 U.S.C. 1, *et seq.;* 44 U.S.C. 3101.

ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND THE PURPOSE OF SUCH USES:

Information in this system may be disclosed in accordance with the blanket routine uses numbered 1 through 19 that appear at the beginning of the Commission's compilation of its systems of records notices.

POLICIES AND PRACTICES FOR STORING, RETRIEVING, ACCESSING, RETAINING, AND DISPOSING OF RECORDS IN THE SYSTEM:

STORAGE:

Paper records are stored in file folders; electronic records, including computer files, are stored on the Commission's network, including GovTrip, and in other electronic media as needed.

RETRIEVABILITY:

By the name of the Commission member, employee witness, expert, advisory committee member or Commission employee traveling on official business for the Commission or the name of the employee applying for or receiving a transit subsidy and by the last four digits of the social security number.

SAFEGUARDS:

Records are protected from unauthorized access and improper use through administrative, technical and physical security measures. Technical security measures within CFTC include restrictions on computer access to authorized individuals, required use of strong passwords frequently changed, use of encryption for certain data types and transfers, and regular review of security procedures and best practices to enhance security. Physical measures include restrictions on building access to authorized individuals and maintenance of records in lockable offices and filing cabinets.

RETENTION AND DISPOSAL:

Travel records are retained for six years and three months after the period covered by the account. Records of travel that is non-Federally funded are retained for six years, three months. Transit subsidy applications maintained by Commission are retained for three years after the employee is no longer in the program or the application is superseded.

SYSTEM MANAGER(S) AND ADDRESS:

Deputy Director for Accounting and Financial Systems and Network Manager (travel and transportation records) and Director, Office of Management Operations (transit subsidy records), both at Commodity Futures Trading Commission, Three Lafayette Centre, 1155 21st Street, NW., Washington, DC 20581.

NOTIFICATION PROCEDURE:

Individuals seeking to determine whether this system of records contains information about themselves or seeking access to records about themselves in this system of records, or contesting the content of records about themselves contained in this system of records should address written inquiry to the Office of General Counsel, Paralegal Specialist, Commodity Futures Trading Commission, Three Lafayette Centre, 1155 21st Street, NW., Washington, DC 20581. Telephone (202) 418–5011.

RECORD SOURCE CATEGORIES:

The individual on whom the record is maintained.

CFTC–7

SYSTEM NAME:

Formal Employment Discrimination Complaint and Reasonable Accommodation Files.

SYSTEM LOCATION:

The system is located in the Office of Equal Employment Opportunity Office (EEO), Commodity Futures Trading Commission, Three Lafayette Centre, 1155 21st St., NW., Washington, DC 20581.

CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

Individuals or groups (employees or applicants), who believe they have been discriminated against, and/or subjected to harassment (sexual or non-sexual) on the basis of their race color, religion, sex (gender), national origin, age, disability (mental or physical), retaliation or sexual orientation. Employees seeking work-related accommodations for disabilities (mental/physical), and disabled applicants seeking accommodations to participate in the employment process.

CATEGORIES OF RECORDS IN THE SYSTEM:

Reports to Commission officials from supervisors, managers, or members of the Commission, the Equal Employment Opportunity Commission, and Congress relating to discrimination claims or concerning observed instances of sexual harassment; records relating to the complaint or incident, relating to any investigation, and to any disposition of the matter. Records of accommodation requests and the disposition of those requests. The potential contents of the system are not limited to complaints or other material under the Commission's Sexual Harassment Policy. Complaints concerning other forms of employment discrimination would be made part of this system.

AUTHORITY FOR MAINTENANCE OF THE SYSTEM:

29 CFR 1614.102(a); 5 U.S.C. Sec. 2302(b); 29 CFR 1614.203.

ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM INCLUDING CATEGORIES OF USERS AND THE PURPOSES OF SUCH USES:

a. Information may be disclosed where the Commission or a present member of the Commission is a party to a lawsuit or the records are needed for investigatory purposes.

Information in this system may also be disclosed in accordance with the blanket routine uses numbered 1 through 19 that appear at the beginning of the Commission's compilation of its systems of records notices.

POLICIES AND PRACTICES FOR STORING, RETRIEVING, ACCESSING, RETAINING AND DISPOSING OF RECORDS IN THE SYSTEM:

STORAGE:

Paper records are stored in file folders; electronic records, including computer files, are stored on the Commission's network and in other electronic media as needed.

RETRIEVABILITY:

Records are retrievable by the name of the complainant and/or the complainant case number for discrimination complaints, and by the applicant/employee name for reasonable accommodation requests.

SAFEGUARDS:

Records are protected from unauthorized access and improper use through administrative, technical and physical security measures. Technical security measures within CFTC include restrictions on computer access to authorized individuals, required use of strong passwords frequently changed, use of encryption for certain data types and transfers, and regular review of security procedures and best practices to enhance security. Physical measures include restrictions on building access and specifically to access of these records to authorized individuals and maintenance of records in lockable offices and filing cabinets.

RETENTION AND DISPOSAL:

Records are destroyed four years after resolution of the discrimination complaint. Reasonable accommodation records are maintained throughout employment; retired at employee's retirement; destroyed four years after retirement.

SYSTEM MANAGER(S) AND ADDRESS:

Director, Office of Equal Employment Opportunity, Commodity Futures Trading Commission, Three Lafayette Centre, 1155 21st Street, NW., Washington, DC 20581.

NOTIFICATION PROCEDURE:

Individuals seeking to determine whether the system of records contains information about themselves, seeking access to records about themselves in the system of records or contesting the content of records about themselves should address written inquiries to the Office of General Counsel, Paralegal Specialist, Commodity Futures Trading Commission, Three Lafayette Centre, 1155 21st Street, NW., Washington, DC 20581. Telephone (202) 418–5011.

RECORD SOURCE CATEGORIES:

Internal complaints, internal investigations, reports of activity which apparently violates the Commission's Sexual Harassment Policy or other employment discrimination prohibitions, proceedings, as relevant, under the EEOC's Federal Sector Complaint Processing rules, 29 CFR Part 1614.

CFTC–8

SYSTEM NAME:

Employment Applications.

SYSTEM LOCATION:

This system is located in the Office of Human Resources, Commodity Futures Trading Commission, Three Lafayette Centre, 1155 21st Street, NW., Washington, DC 20581.

CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

Applicants for positions with the Commission.

CATEGORIES OF RECORDS IN THE SYSTEM:

Contains the application and/or the resume of the applicant.

AUTHORITY FOR MAINTENANCE OF THE SYSTEM:

44 U.S.C. 3101.

ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND THE PURPOSES OF SUCH USES:

Information in this system may be disclosed in accordance with the blanket routine uses numbered 1 through 19 that appear at the beginning of the Commission's compilation of its systems of records notices.

POLICIES AND PRACTICES FOR STORING, RETRIEVING, ACCESSING, RETAINING, AND DISPOSING OF RECORDS IN THE SYSTEM:

STORAGE/RETRIEVABILITY:

Paper records are stored in file folders and electronic files submitted by applicants via *e-mail* to *Employment@cftc.gov*. The applicant tracking system is located on the CFTC Network. Summary information of applications is also available to staff of the Office of Human Resources through an automated applicant tracking system that can retrieve by announcement number or applicant name.

SAFEGUARDS:

Records are protected from unauthorized access and improper use through administrative, technical and physical security measures. Technical security measures within CFTC include restrictions on computer access to authorized individuals, required use of strong passwords frequently changed, use of encryption for certain data types and transfers, and regular review of security procedures and best practices to enhance security. Also, access to applicant tracking system granted only to appropriate personnel. Physical measures include restrictions on building access to authorized individuals and maintenance of records in lockable offices and filing cabinets.

RETENTION AND DISPOSAL:

Most applicant records are retained for two years, then destroyed. If a review is pending by the Office of Personnel Management (OPM) or other authority, the records are retained until that review is completed.

SYSTEM MANAGER(S) AND ADDRESS:

Director, Office of Human Resources, Commodity Futures Trading Commission, Three Lafayette Centre, 1155 21st Street, NW., Washington, DC 20581.

NOTIFICATION PROCEDURE:

Individuals seeking to determine whether this system of records contains information about themselves or seeking access to records about themselves in this system of records, or contesting the content of records about themselves contained in this system of records should address written inquiry to the Office of General Counsel, Paralegal Specialist, Commodity Futures Trading Commission, Three Lafayette Centre, 1155 21st Street, NW., Washington, DC 20581. Telephone (202) 418–5011.

RECORD SOURCE CATEGORIES:

The individual on whom the record is maintained.

CFTC–9

SYSTEM NAME:

Emergency Locator System.

SYSTEM LOCATION:

This system is located in the Office of Human Resources, Commodity Futures Trading Commission, Three Lafayette Centre, 1155 21st Street, NW., Washington, DC 20581.

CATEGORIES ON INDIVIDUALS COVERED BY THE SYSTEM:

Employees and contractors of the Commission.

CATEGORIES OF RECORDS IN THE SYSTEM:

This system contains information regarding the organizational and telephone number of individual Commission employees and contractors. The system also contains the home address, telephone numbers, and personal e-mail address of the individual, and the names, home addresses, personal e-mail address, and telephone numbers of the individual(s) to contact in the event of a medical or other emergency concerning the CFTC employee or contractor.

AUTHORITY FOR MAINTENANCE OF THE SYSTEM:

5 U.S.C. 301

PURPOSES:

The purpose of this system is to maintain emergency contact names and contact information for individuals for use in the event that a medical or other emergency involving the individual occurs while the individual is employed or providing services to the Commission through contract.

ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND THE PURPOSES OF SUCH USES:

Information in this system may be disclosed in accordance with the blanket routine uses numbered 1 through 19 that appear at the beginning of the Commission's compilation of its systems of records notices.

POLICIES AND PRACTICES FOR STORING, RETRIEVING, RETAINING, AND DISPOSING OF RECORDS IN THE SYSTEM:

STORAGE:

Paper records are stored in file folders; electronic records, including computer files, are stored on the Commission's network and in other electronic media as needed.

RETRIEVABILITY:

Records are retrieved by the name of the individual on whom they are maintained.

SAFEGUARDS:

Records are protected from unauthorized access and improper use through administrative, technical and physical security measures. Technical security measures within CFTC include restrictions on computer access to authorized individuals, required use of strong passwords frequently changed, use of encryption for certain data types and transfers, and regular review of security procedures and best practices to enhance security. Physical measures include restrictions on building access to authorized individuals and maintenance of records in lockable offices and filing cabinets. Also, these records are maintained in a secured area, available only to authorized personnel whose duties require access.

RETENTION AND DISPOSAL:

Records are maintained as long as the individual is an employee of, or providing services to, the Commission.

SYSTEM MANAGER AND ADDRESS:

Director, Office of Human Resources, Commodity Futures Trading Commission, Three Lafayette Centre, 1155 21st Street, NW., Washington, DC 20581. Telephone (202) 418–5013.

NOTIFICATION PROCEDURE:

Individuals seeking to determine whether this system of records contains information about themselves or seeking access to records about themselves in this system of records, or contesting the content of records about themselves contained in this system of records should address written inquiry to the Office of General Counsel, Paralegal Specialist, Commodity Futures Trading Commission, Three Lafayette Centre, 1155 21st Street, NW., Washington, DC 20581. Telephone (202) 418–5011.

RECORD SOURCE CATEGORIES:

Information is provided by the individual who is the subject of the record.

CFTC–10

SYSTEM NAME:

Investigatory Records (exempted).

SYSTEM LOCATION:

This system is located in the Office of General Counsel and the Division of Enforcement in the Commission's principal office at Commodity Futures Trading Commission, Three Lafayette Centre, 1155 21st Street, NW., Washington, DC 20581, and in the Division of Enforcement in the regional offices in Chicago at 525 West Monroe Street, Suite 1100 Chicago, IL 60661; in Kansas City at Two Emanuel Cleaver II Blvd., Suite 300, Kansas City, MO 64112; and New York at 140 Broadway, 19th Floor, New York, NY 10005.

CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

a. Individuals whom the Commission staff has reason to believe have violated, are violating, or are about to violate the Commodity Exchange Act and the rules, regulations and orders promulgated thereunder.

b. Individuals whom the Commission staff has reason to believe have violated, are violating or are about to violate a law or regulation or order of another Federal, State or foreign authority.

c. Individuals whom the Commission staff has reason to believe may have information concerning violations of the Commodity Exchange Act and the rules, regulations and orders promulgated thereunder.

d. Individuals involved in investigations authorized by the Commission concerning the activities of members of the Commission or its employees based upon formal complaint or otherwise.

e. Individuals whom the Commission staff has identified as relevant to an enforcement investigation, such as complainants, witnesses and counsel.

f. Individuals whom a foreign law enforcement authority has found or alleges to have, or suspects of having, violated foreign laws, rules, regulations or orders of such foreign law enforcement authority.

CATEGORIES OF RECORDS IN THE SYSTEM:

Investigatory materials compiled for law enforcement purposes whose disclosure the Commission staff has determined could impair the effectiveness and orderly conduct of the Commission's regulatory and enforcement program or compromise Commission investigations. This system may include all or any part of the records developed during the investigation or inquiry, including data from Commission reporting forms, account statements and other trading records, exchange records, bank records and credit information, business records, information available on the Internet or other electronic sources, reports of interviews, transcripts of testimony, exhibits to transcripts, affidavits, statements by witnesses, registration information, contracts and agreements. The system may also contain internal memoranda, reports of investigation, orders of investigation, subpoenas, warning letters, stipulations of compliance, correspondence, and other miscellaneous investigatory matters. The nature of the personal information contained in these files varies according to what is considered relevant by the attorney assigned based on the circumstances of the particular case under investigation, and may include personal background information about the individual involved, his education and employment history, information on prior violations, and a wide variety of financial information, as well as a detailed examination of the individual's activities during the period in question.

AUTHORITY FOR MAINTENANCE OF THE SYSTEM:

Commodity Exchange Act, 7 U.S.C. 1 *et seq.,* including 7 U.S.C. 13a–1, authorizing injunctive actions, various provisions in that Act authorizing administrative actions, and the rules and regulations promulgated thereunder.

ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND THE PURPOSES OF SUCH USES:

Information in this system may be disclosed in accordance with the blanket routine uses numbered 1 through 19 that appear at the beginning of the Commission's compilation of its systems of records notices.

POLICIES AND PRACTICES FOR STORING, RETRIEVING, ACCESSING, RETAINING, AND DISPOSING OF RECORDS IN THE SYSTEM:

STORAGE:

Paper records are stored in file folders, binders, computer files (eLaw) and computer disks. Electronic records, including computer files, are stored on the Commission's network and on various other electronic media as needed, such as encrypted hard drives.

RETRIEVABILITY:

By assigned file name, which may be the matter number or the name of the person or firm that is the principal subject of the investigation. A summary index of material is also stored on the computer.

SAFEGUARDS:

Records are protected from unauthorized access and improper use through administrative, technical and physical security measures. Technical security measures within CFTC include restrictions on computer access to authorized individuals, required use of strong passwords frequently changed, use of encryption for certain data types and transfers, and regular review of security procedures and best practices to enhance security. Physical measures include restrictions on building access to authorized individuals and maintenance of certain records in secured filing rooms and/or locked filing cabinets. Also, all employees are made aware of the sensitive nature of investigatory information.

RETENTION AND DISPOSAL:

If an investigatory matter is closed without institution of a case, the files are maintained in off site storage for five years, and then destroyed. When the Commission moves forward from an investigation to litigation:

(a) Investigatory records that are disclosed by the Commission in the administrative, court or other proceedings become part of non-exempt CFTC–16, Enforcement Case Files and/or CFTC–17, Litigation Files—OGC, and are retained and disposed of pursuant to CFTC–16 and/or CFTC–17; and

(b) Investigatory records not disclosed in such proceedings are retained in exempt CFTC–10, Investigatory Records, and disposed of on the same schedule as the related non-exempt records under CFTC–16 or CFTC–17.

All Investigatory Records remain exempt from disclosure under the Privacy Act.

SYSTEM MANAGER(S) AND ADDRESS:

Director, Division of Enforcement and/or General Counsel, Office of the General Counsel in the Commission's principal office at Commodity Futures Trading Commission, Three Lafayette Centre, 1155 21st Street, NW., Washington, DC 20581 and Regional Counsels in the regional offices: in Chicago at 525 West Monroe Street, Suite 1100, Chicago, IL 60661; in Kansas City at Two Emanuel Cleaver II Blvd., Suite 300, Kansas City, MO 64112; and in New York at 140 Broadway, 19th Floor, New York, NY 10005.

RECORD SOURCE CATEGORIES:

Reporting forms and other information filed with the Commission; self-regulatory organizations; individuals or firms covered by the Commission's registration requirements; Federal, *State* and local regulatory and law enforcement agencies; banks, credit organizations and other institutions; corporations; individuals having knowledge of the facts; attorneys; publications; courts; and miscellaneous sources.

SYSTEMS EXEMPTED FROM CERTAIN PROVISIONS OF THE ACT:

The records in this system have been exempted by the Commission from certain provisions of the Privacy Act of 1974 pursuant to the terms of the Privacy Act, 5 U.S.C. 552a(k)(2), and the Commission's rules promulgated thereunder, 17 CFR 146.12. These records are exempt from the notification procedures, records access procedures, and record contest procedures set forth in the system notices of other systems of records, and from the requirement that the sources of records in the system be described.

CFTC–12

SYSTEM NAME:

Fitness Investigations.

SYSTEM LOCATION:

Records for floor brokers and floor traders with respect to matters commenced prior to August 1, 1994 are located in the Division of Clearing and Intermediary Oversight, Commodity Futures Trading Commission, Three Lafayette Centre, 1155 21st Street, NW., Washington, DC 20581. Records for futures commission merchants, introducing brokers, commodity pool operators, commodity trading advisors, their respective associated persons and principals, with active registration status in any capacity on or after October 1, 1983; leverage transaction merchants and their associated persons and principals with active registration status as such on or after August 1, 1994; floor brokers and floor traders with active registration status as such on or after August 1, 1994; and agricultural trade option merchants (ATOMs) and their associated persons are located at the National Futures Association (NFA), 300 South Riverside, Suite 1800, Chicago, Illinois 60606.

CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

Individuals who have applied or who may apply for registration as futures commission merchants, introducing brokers, commodity pool operators, commodity trading advisors, leverage transaction merchants and ATOMs; individuals listed or who may be listed as principals (as defined in 17 CFR Part 3.1); individuals who have applied or who may apply for registration as associated persons of the foregoing firms; and floor brokers and floor traders.

CATEGORIES OF RECORDS IN THE SYSTEM:

Information pertaining to the fitness of the above-described individuals or firms to engage in business subject to the Commission's jurisdiction. The system contains information in computerized images or alpha-numeric format and hardcopy format including registration forms, schedules and supplements, fingerprint cards which are required for individual registrants except ATOMs, correspondence relating to registration, and reports and memoranda reflecting information developed from various sources. In addition, the system contains records of each fitness investigation.

AUTHORITY FOR MAINTENANCE OF THE SYSTEM:

The Commodity Exchange Act as amended, 7 U.S.C. 1 *et seq.,* including Sections 4f(a)(1) and (2), 4k(4), 4k(5), 4n(1), 8a(1)–(5), 8a(10), 8a(11), 17(o) and 19, at 7 U.S.C. 6f(1), 6k(4), 6k(5), 6n(1), 12a(1)–(5), 12a(10), 12a(11), 21(o) and 23, and the rules and regulations promulgated under the Commodity Exchange Act.

ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM INCLUDING CATEGORIES OF USERS AND THE PURPOSE OF SUCH USES:

a. Information contained in this system of records may be disclosed to any person with whom an applicant or registrant is or plans to be associated as an associated person or affiliated as a principal.

b. Information contained in this system of records may be disclosed to any registered futures commission merchant with whom an applicant or registered introducing broker has or plans to enter into a guarantee agreement in accordance with Commission regulation at 17 CFR Part 1.10.

Note: NFA may disclose information contained in those portions of this system of records, but any such disclosure must be made in accordance with NFA rules that have been approved by the Commission or permitted to become effective without Commission approval. The disclosure must be made under circumstances authorized by the Commission as consistent with the Commission's regulations and routine uses. No specific consent is required by an applicant or registered introducing broker to disclosure of information to the futures commission merchant with whom it has or plans to enter a guarantee agreement.

Information in this system may also be disclosed in accordance with the blanket routine uses numbered 1 through 19 that appear at the beginning of the Commission's compilation of its systems of records notices.

POLICIES AND PRACTICES FOR STORING, RETRIEVING, ACCESSING, RETAINING, AND DISPOSING OF RECORDS IN THE SYSTEM:

STORAGE:

Paper records are stored in file folders and binders. Electronic records, including computer files, are stored on the Commission's network, in the NFA Online Registration System (ORS), microfiche and various other electronic media as needed, such as encrypted hard drives.

RETRIEVABILITY:

By the name of the individual or firm, or by the assigned identification number. Where applicable, the NFA's computer cross-indexes the individual's file to the name of the futures commission merchant, introducing broker, commodity trading advisor, commodity pool operator, leverage transaction merchant or ATOMs with which the individual is associated or affiliated.

SAFEGUARDS:

Records are protected from unauthorized access and improper use through administrative, technical and physical security measures. Technical security measures within CFTC include restrictions on computer access to authorized individuals, required use of strong passwords frequently changed, use of encryption for certain data types and transfers, and regular review of security procedures and best practices to enhance security. Physical measures include restrictions on building access to authorized individuals, including limiting access to individuals whose official duties require access, and maintenance of records in lockable offices and filing cabinets.

RETENTION AND DISPOSAL:

Since 1991, when a fitness investigation is opened by NFA, applications, biographical supplements, other forms, related documents, correspondence and reports are immediately scanned, indexed and stored using computer imaging software so the information may be retrieved and printed. Imaged records are maintained indefinitely. Any hard copy originals are maintained by NFA for two years after imaged. Records retained by CFTC are held for ten years.

SYSTEM MANAGER(S) AND ADDRESS:

For records held by the Commission: Director, Division of Clearing and Intermediary Oversight, Commodity Futures Trading Commission, Three Lafayette Centre, 1155 21st Street, NW., Washington, DC 20581. For records held by NFA: Vice President for Registration, National Futures Association, 300 South Riverside, Suite 1800, Chicago, Illinois 60606.

NOTIFICATION PROCEDURE:

Individuals seeking to determine whether this system of records contains information about themselves or seeking access to records about themselves in this system of records, or contesting the content of records about themselves contained in this system of records should address written inquiry to the Office of General Counsel, Paralegal Specialist, Commodity Futures Trading Commission, Three Lafayette Centre, 1155 21st Street, NW., Washington, DC 20581. Telephone (202) 418–5011.

Individuals may also request registration information by telephone directly from the NFA information center at (800) 621–3570 or (312) 781–1410. Inquiries can also be made to NFA by fax at (312) 781–1459 or via the Internet at *information@nfa.futures.org.* NFA will query the ORS database system about current registration status and registration history, and will provide instructions on how to make written requests for copies of records. The Internet may be used to obtain information on current registration status and futures-related regulatory actions at *http://www.nfa.futures.org* by selecting "BASIC."

RECORDS SOURCE CATEGORIES:

The individual or firm on whom the record is maintained; the individual's employer; Federal, State and local regulatory and law enforcement agencies; commodities and securities exchanges; NFA; National Association of Securities Dealers; foreign futures and securities authorities and INTERPOL; and other miscellaneous sources.

CFTC–13

SYSTEM NAME:

Interpretive, Exemptive, and No-Action Files.

SYSTEM LOCATION:

Most files are prepared by the Division of Clearing and Intermediary

Oversight and are kept in that office. Public copies of the interpretative, exemptive and no-action letters, which may be redacted, are also kept in the Office of the Secretariat and the Office of Public Affairs, and are also available on the CFTC Web site (*http://www.cftc.gov*). All offices are located at the Commodity Futures Trading Commission, Three Lafayette Centre, 1155 21st Street, NW., Washington, DC 20581.

CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

Individuals who have requested the Commission or its staff to provide interpretations, exemptions or no-action positions regarding the provisions of the Commodity Exchange Act or the Commission's regulations there under. The requests may have been made directly by an individual, or through the individual's attorney or other representative. A request may also be made on behalf of a registrant or other party that contains information about individuals employed by or affiliated with the registrant or other party. Registrants include futures commission merchants, introducing brokers, commodity pool operators, commodity trading advisors, agricultural trade option merchants, leverage transaction merchants, associated persons, floor brokers and floor traders.

CATEGORIES OF RECORDS IN THE SYSTEM:

Requests for interpretative, exemptive and no-action letters, supplemental correspondence, any related internal memoranda, other supporting documents and the responses to the requests.

AUTHORITY FOR MAINTENANCE OF THE SYSTEM:

The Commodity Exchange Act, 7 U.S.C. 1 *et seq.,* and the rules and regulations promulgated thereunder, including 17 CFR Parts 140.98 and 140.99.

ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND THE PURPOSES OF SUCH USES:

a. Pursuant to the Commission's rules, 17 CFR Part 140.98, substantive interpretative, exemptive and no-action letters are made public and published by the Commission. Portions of such letters or information will be deleted or omitted to the extent necessary to prevent a clearly unwarranted invasion of personal privacy or to the extent they otherwise contain material considered nonpublic under the Freedom of Information Act and the Commission's rules implementing that Act.

b. Information in these files may be used as a reference in responding to later inquiries from the same party, in following up on earlier correspondence involving the same person, or when another person raises the same or similar issues.

Information in this system may also be disclosed in accordance with the blanket routine uses numbered 1 through 19 that appear at the beginning of the Commission's compilation of its systems of records notices.

POLICIES AND PRACTICES FOR STORING, RETRIEVING, ACCESSING, RETAINING AND DISPOSING OF RECORDS IN THE SYSTEM:

STORAGE:

Paper records in file folders. Electronic records, including computer files, are stored on the Commission's network, including desktop applications and e-mail files. The redacted outgoing letter is maintained electronically on a shared drive.

RETRIEVABILITY:

The Division of Clearing and Intermediary Oversight has tracking systems in place. A division-wide database maintains information on all projects, including requests for exemptive, no-action and interpretive letters, and is completely searchable. In addition, each section within the Division of Clearing and Intermediary Oversight may maintain its own tracking system for requests that preceded the implementation of the division-wide system. Public copy files in the Office of the Secretariat and the Office of Public Affairs are filed by the name of the requester, even if another party makes the request on behalf of the requester.

SAFEGUARDS:

Records are protected from unauthorized access and improper use through administrative, technical and physical security measures. Technical security measures within CFTC include restrictions on computer access to authorized individuals, required use of strong passwords frequently changed, use of encryption for certain data types and transfers, and regular review of security procedures and best practices to enhance security. Physical measures include restrictions on building access to authorized individuals and maintenance of records in lockable offices and filing cabinets.

RETENTION AND DISPOSAL:

Letters signed by the Commission and unique, precedent-setting letters signed by staff are maintained for 20 years, then transferred to the National Archives and Records Administration as permanent records. Other letters signed by staff are destroyed after 15 years.

SYSTEM MANAGER(S) AND ADDRESS:

Director, Division of Clearing and Intermediary Oversight; Secretary to the Commission, Office of the Secretariat; and Director, Office of Public Affairs at Commodity Futures Trading Commission, Three Lafayette Centre, 1155 21st Street, NW., Washington, DC 20581.

NOTIFICATION PROCEDURE:

Individuals seeking to determine whether this system of records contains information about themselves or seeking access to records about themselves in this system of records, or contesting the content of records about themselves contained in this system of records should address written inquiry to the Office of General Counsel, Paralegal Specialist, Commodity Futures Trading Commission, Three Lafayette Centre, 1155 21st Street, NW., Washington, DC 20581. Telephone (202) 418–5011.

RECORD SOURCE CATEGORIES:

Individuals, corporations, limited liability companies, other business organizations, or representatives seeking interpretations of, exemptions from, or no-action opinions on the provisions of the Commodity Exchange Act or Commission rules.

CFTC–14

SYSTEM NAME:

Commodity Futures Trading Commission Alumni Records.

SYSTEM LOCATION:

This system is located in the Office of Human Resources, Commodity Futures trading Commission, Three Lafayette Centre, 1155 21st Street, NW., Washington, DC 20581.

CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

Former employees of the Commission, and those who worked as contractors or were engaged in duties at the Commission.

CATEGORIES OF RECORDS IN THE SYSTEM:

This system contains information regarding former employees of the Commission including their names, position titles, office address and telephone number, and with the approval of the individual, home and/or business address, home and/or business telephone number, e-mail address, and other relevant data needed to keep in contact with the individual. This system will also contain similar information regarding contractors and other who were engaged in duties at the Commission.

AUTHORITY FOR MAINTENANCE OF THE SYSTEM:

5 U.S.C. 301.

PURPOSE:

The records are used by Commission staff to maintain contact with former Commission employees and others involved in Commission business. These records may be used to notify individuals of Commission events.

ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM:

Information in this system may be disclosed in accordance with the blanket routine uses numbered 1 through 19 that appear at the beginning of the Commission's compilation of its systems of records notices.

POLICIES AND PRACTICES FOR STORING, RETRIEVING, AND DISPOSING OF RECORDS IN THE SYSTEM:

STORAGE:

Paper records are stored in file folders; electronic records, including computer files, are stored on the Commission's network and other electronic media as needed.

RETRIEVABILITY:

Records may be retrieved by the name or e-mail address of the individual.

SAFEGUARDS:

Records are protected from unauthorized access and improper use through administrative, technical and physical security measures. Technical security measures within CFTC include restrictions on computer access to authorized individuals, required use of strong passwords frequently changed, use of encryption for certain data types and transfers, and regular review of security procedures and best practices to enhance security. Physical measures include restrictions on building access to authorized individuals and maintenance of records in lockable offices and filing cabinets.

RETENTION AND DISPOSAL:

Information is retained until revised or deleted in accordance with General Records Schedule 13, Item 4b.

SYSTEM MANAGER AND ADDRESS:

Deputy Director, Office of Management Operations, Three Lafayette Centre, 1155 21st Street, NW., Washington, DC 20581.

NOTIFICATION PROCEDURE:

Individuals seeking to determine whether this system of records contains information about themselves or seeking access to records about themselves in this system of records, or contesting the content of records about themselves contained in this system of records should address written inquiry to the Office of General Counsel, Paralegal Specialist, Commodity Futures Trading Commission, Three Lafayette Centre, 1155 21st Street, NW., Washington, DC 20581. Telephone (202) 418–5011.

RECORD SOURCE CATEGORIES:

Individuals about whom the records are maintained. Information will predominately be obtained directly from the individual in response to the Commission's request to have alumni respond regarding Commission events.

CFTC–15

SYSTEM NAME:

Large Trader Report Files (Integrated Surveillance System).

SYSTEM LOCATION:

This system is located in the Division of Market Oversight, in the Commission's principal office at Commodity Futures Trading Commission, Three Lafayette Centre, 1155 21st Street, NW., Washington, DC 20581; and in the regional offices at in Chicago at 525 West Monroe Street, Suite 1100 Chicago, IL 60661; and New York at 140 Broadway, 19th Floor, New York, NY 10005.

CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

Individuals holding reportable positions as defined in 17 CFR Parts 17, 18 and 19.

CATEGORIES OF RECORDS IN THE SYSTEM:

1. Reports filed by the individual holding the reportable position:

a. Statements of Reporting Trader (CFTC Form 40) contains information described in part 18 of the Commission's rules and regulations, including the name, address, number, and principal occupation of the reporting trader, financial interest in and control of commodity futures accounts, and information about the trader's business associations;

b. Large trader reporting contains information described in part 18 of the Commission's rules and regulations, including the trader's identifying number, previous open contracts, trades and deliveries that day, open contracts at the end of the day, and classification as to speculation or hedging (available on a non-routine basis by special call);

c. Large trader reporting form (Series 04 Form). Contains information described in part 19 of the Commission's rules and regulations, to be filed by merchants, processors and dealers in commodities that have Federally imposed speculative position limits. Includes trader's identifying number, stocks owned, fixed price sale and purchase commitments. These reports are filed in the Commission office in the city where the reporting trader is located. If there is no Commission office in that city, the reports are filed according to specific instructions of the Commission.

2. Reports to be filed by futures commission merchants, members of contract markets, foreign brokers and, for large option traders, by contract markets.

a. Identification of "Special Accounts" (CFTC Form 102). Contains material described in part 17 of the Commission's rules and regulations. Includes the name, address, and the occupation of a customer whose accounts have reached the reporting level. Also includes the account number that the futures commission merchant uses to identify this customer on the firm's 01 report (*see* next paragraph), and whether the customer has control of or financial interest in accounts of other traders.

b. Large trader reporting form (Series 01 Form). Contains material described in part 17 of the Commission's rules and regulations, for each "special account." Shows customer account number, reportable position held in each commodity future and option, and information concerning deliveries and exchanges of futures for physicals by individuals with reportable positions.

3. Computer records prepared from information on the forms described in items (1) and (2) above.

4. Correspondence and memoranda of telephone conversations between the Commission and the individual or between the Commission and other agencies dealing with matters of official business concerning the individual.

5. Other miscellaneous information, including intra-agency correspondence and memoranda concerning the individual and documents relating to official actions taken by the Commission against the individual.

6. Reports of Positions and Transactions of Clearing Member Firms. Information is provided in electronic transmission and is readable on the Internet and contains the data prescribed in section 16 of the Commission's regulations. The information includes an identification number for each clearing member, open contracts at the firm for proprietary and customer accounts and transactions such as trades, exchanges of futures for physicals, delivery notices issued and received, and transfers and option exercises. The information is filed in the

city where the exchange is located or as instructed by the Commission.

AUTHORITY FOR MAINTENANCE OF THE SYSTEM:

The Commodity Exchange Act, 7 U.S.C. 1 *et seq.,* including Sections 4g, 4i, and 8 of that Act, at 7 U.S.C. 6g, 6i and 12, and the rules and regulations promulgated thereunder.

ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND THE PURPOSES OF SUCH USES:

a. Information concerning traders and their activities may be disclosed and made public by the Commission to the extent permitted by law when deemed appropriate to further the practices and policies of the Commodity Exchange Act.

Information in this system may also be disclosed in accordance with the blanket routine uses numbered 1 through 19 that appear at the beginning of the Commission's compilation of its systems of records notices.

POLICIES AND PRACTICES FOR STORING, RETRIEVING, ACCESSING, RETAINING, AND DISPOSING OF THE RECORDS IN THE SYSTEM:

STORAGE:

Paper records are stored in file folders, loose-leaf binders and similar paper filing methods, and electronic records, including computer files and the Integrated Surveillance System, are stored on Commission's network and other electronic media as needed.

RETRIEVABILITY:

CFTC Form 40, CFTC Form 102, correspondence and other miscellaneous information are maintained directly under the name of the reporting trader. The series 01 and 04 forms are maintained by identifying code number. However, information from these forms is included in the computer and retrievable by individual identifier.

SAFEGUARDS:

Records are protected from unauthorized access and improper use through administrative, technical and physical security measures. Technical security measures within CFTC include restrictions on computer access to authorized individuals, strong passwords frequently changed, use of encryption for certain data types and transfers, and regular review of security procedures and best practices to enhance security. Further, access to these records is limited to those individuals whose official duties require access, through security features built into the Integrated Surveillance System. Physical measures include restrictions on building access to authorized individuals and maintenance of records in lockable offices and filing cabinets.

RETENTION AND DISPOSAL:

CFTC Form 40, CFTC Form 102, correspondence, memoranda, *etc.* are retained on the premises until the account has been inactive for five years and are then destroyed. Form 01 and 04 reports are maintained for six months on the premises and then held in offsite storage for five years before being destroyed. The computer file is maintained for ten years for Form 01 and 04. Clearing member positions and transactions are maintained for three years. Trader code numbers and related information are maintained for five years after a trader becomes non-reportable. Account numbers assigned by an futures commission merchant are maintained on the system for one year after the account is no longer reported.

SYSTEM MANAGER(S) AND ADDRESS:

Chief, Market Surveillance Section, Division of Market Oversight, Commodity Futures Trading Commission, Three Lafayette Centre, 1155 21st Street, NW., Washington, DC 20581; and Surveillance Branch Chiefs in the regional offices in Chicago at 525 West Monroe Street, Suite 1100 Chicago, IL 60661; and New York at 140 Broadway, 19th Floor, New York, NY 10005.

NOTIFICATION PROCEDURE:

Individuals seeking to determine whether this system of records contains information about themselves or seeking access to records about themselves in this system of records, or contesting the content of records about themselves contained in this system of records should address written inquiry to the Office of General Counsel, Paralegal Specialist, Commodity Futures Trading Commission, Three Lafayette Centre, 1155 21st Street, NW., Washington, DC 20581. Telephone (202) 418–5011.

RECORD SOURCE CATEGORIES:

The individual on whom the record is maintained and futures commission merchants through whom the individual trades. Correspondence and memoranda prepared by the Commission or its staff. Correspondence from firms, agencies, or individuals requested to provide information on the individual.

CFTC–16

SYSTEM NAME:

Enforcement Case Files.

SYSTEM LOCATION:

This system is located in the Division of Enforcement in the Commission's principal office at Commodity Futures Trading Commission, Three Lafayette Centre, 1155 21st Street, NW., Washington, DC 20581, and in the Division of Enforcement in the regional offices in Chicago at 525 West Monroe Street, Suite 1100 Chicago, IL 60661; in Kansas City at Two Emanuel Cleaver II Blvd., Suite 300, Kansas City, MO 64112; and New York at 140 Broadway, 19th Floor, New York, NY 10005.

CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

a. Individuals or firms against whom the Commission has taken enforcement action based on violations of the Commodity Exchange Act or the rules and regulations promulgated thereunder.

b. Individuals whom the Commission staff has identified as relevant to an enforcement investigation, such as complainants, witnesses and counsel.

CATEGORIES OF RECORDS IN THE SYSTEM:

Copies of various public papers filed by or with the Commission or the courts in connection with administrative proceedings or injunctive actions brought by the Commission. Records include, at a minimum, a copy of the complaint, motions filed, exhibits and the final decision, and order.

AUTHORITY FOR MAINTENANCE OF THE SYSTEM:

These files are necessary for the orderly and effective conduct of litigation authorized under the Commodity Exchange Act and other Federal statutes. The Commodity Exchange Act, 7 U.S.C. 1 *et seq.,* including section 6c of that Act at 7 U.S.C. 13a–1, section 6(c) of that Act at 7 U.S.C. 9, and the rules and regulations promulgated thereunder.

ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND THE PURPOSES OF SUCH USES:

Information in this system may be disclosed in accordance with the blanket routine uses numbered 1 through 19 that appear at the beginning of the Commission's compilation of its systems of records notices.

POLICIES AND PRACTICES FOR STORING, RETRIEVING, ACCESSING, RETAINING, AND DISPOSING OF RECORDS IN THE SYSTEM:

STORAGE:

Paper records are stored in file folders, binders, computer files (eLaw) and computer disks. Electronic records, including computer files, are stored on the Commission's network and on various other electronic media as needed, such as encrypted hard drives. A summary index of material is also stored on the computer network.

RETRIEVABILITY:

By case title or in some instances by docket number.

SAFEGUARDS:

Records are protected from unauthorized access and improper use through administrative, technical and physical security measures. Technical security measures within CFTC include restrictions on computer access to authorized individuals, strong passwords frequently changed, use of encryption for certain data types and transfers, and regular review of security procedures and best practices to enhance security. Physical measures include restrictions on building access to authorized individuals and maintenance of records in lockable offices and filing cabinets.

RETENTION AND DISPOSAL:

After an action is complete, the complaint and any final decision or dispositive orders are kept indefinitely at the headquarters office. Most case files are destroyed after 15 years; unique, precedent-setting cases are offered to the National Archives and Records Administration for permanent retention after 20 years.

SYSTEM MANAGER AND ADDRESS:

Director, Division of Enforcement, Commodity Futures Trading Commission, Three Lafayette Centre, 1155 21st Street, NW., Washington, DC 20581 and Regional Counsels in the regional offices: in Chicago at 525 West Monroe Street, Suite 1100 Chicago, IL 60661; in Kansas City at Two Emanuel Cleaver II Blvd., Suite 300, Kansas City, MO 64112; and in New York at 140 Broadway, 19th Floor, New York, NY 10005.

NOTIFICATION PROCEDURE:

Individuals seeking to determine whether this system of records contains information about themselves or seeking access to records about themselves in this system of records, or contesting the content of records about themselves contained in this system of records should address written inquiry to the Office of General Counsel, Paralegal Specialist, Commodity Futures Trading Commission, Three Lafayette Centre, 1155 21st Street, NW., Washington, DC 20581. Telephone (202) 418–5011.

RECORD SOURCE CATEGORIES:

The parties, their attorneys, the Commission's Office of Proceedings, the relevant court, and miscellaneous sources.

CFTC–17

SYSTEM NAME:

Litigation Files—OGC.

SYSTEM LOCATION:

This system is located in the Office of the General Counsel, Commodity Futures Trading Commission, Three Lafayette Centre, 1155 21st Street, NW., Washington, DC 20581.

CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

Parties involved in litigation with the Commission or litigation in which the Commission has an interest including, but not limited to:

a. Administrative proceedings before the Commission, including appeals from staff determinations of requests made under FOIA and the Privacy Act;

b. Federal court cases to which the Commission is a party;

c. Litigation in which the Commission is participating as amicus curiae; and

d. Other cases involving issues of concern to the Commission, including those brought by other law enforcement and regulatory agencies and those brought by private parties.

CATEGORIES OF RECORDS IN THE SYSTEM:

Public papers filed in litigation as described above, including appellate and amicus curiae briefs, motions, and final decisions and orders.

AUTHORITY FOR MAINTENANCE OF THE SYSTEM:

The Commodity Exchange Act, 7 U.S.C. 1, *et seq.,* and the rules and regulations promulgated pursuant to the Commodity Exchange Act, entrust the Commission with broad regulatory responsibilities over commodity futures transactions. In this connection, the Commission is authorized to bring both administrative proceedings and injunctive actions where there appear to have been violations of the Act. Furthermore, to effectuate the purposes of the Act, it is necessary that the Commission staff be familiar with developments in other actions brought by others that have implications in the commodity law areas.

ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND THE PURPOSES OF SUCH USES:

The information in these files is generally a matter of public record and may be disclosed without restriction. Information in this system may be disclosed in accordance with the blanket routine uses numbered 1 through 19 that appear at the beginning of the Commission's compilation of its systems of records notices.

POLICIES AND PRACTICES FOR STORING, RETRIEVING, ACCESSING, RETAINING, AND DISPOSING OF RECORDS IN THE SYSTEM:

STORAGE:

Paper records are stored in file folders, binders, computer files (eLaw) and computer disks. Electronic records, including computer files, are stored on the Commission's network and on various other electronic media as needed, such as encrypted hard drives.

RETRIEVABILITY:

Alphabetically by caption of the case.

SAFEGUARDS:

Records are protected from unauthorized access and improper use through administrative, technical and physical security measures. Technical security measures within CFTC include restrictions on computer access to authorized individuals, strong passwords frequently changed, use of encryption for certain data types and transfers, and regular review of security procedures and best practices to enhance security. Physical measures include restrictions on building access to authorized individuals and maintenance of records in lockable offices and filing cabinets.

RETENTION AND DISPOSAL:

Maintained in the active files until the action is completed, including final review at the appellate level. Thereafter, transferred to the inactive case files, where a skeletal record of pleadings, briefs, findings, and opinions and other particularly relevant papers may be maintained. These records are maintained on premises for five years, and then transferred to off-site storage. Most case files are destroyed after 15 years; unique precedent-setting cases are transferred to the National Archives for permanent retention. A copy of some of the documents may be kept in precedent files for use in later legal research or preparation of filings in other matters.

SYSTEM MANAGER AND ADDRESS:

Deputy General Counsel for Litigation, Office of the General Counsel, Commodity Futures Trading Commission, Three Lafayette Centre, 1155 21st Street, NW., Washington, DC 20581.

NOTIFICATION PROCEDURE:

Individuals seeking to determine whether this system of records contains information about themselves or seeking access to records about themselves in this system of records, or contesting the content of records about themselves contained in this system of records

should address written inquiry to the Office of General Counsel, Paralegal Specialist, Commodity Futures Trading Commission, Three Lafayette Centre, 1155 21st Street, NW., Washington, DC 20581. Telephone (202) 418–5011.

RECORD SOURCE CATEGORIES:

The court or regulatory authority before which the action is pending, the attorneys for one of the named parties, and miscellaneous sources.

CFTC–18

SYSTEM NAME:

Logbook on Speculative Limit Violations.

SYSTEM LOCATION:

This system is located in the Division of Market Oversight, in the Commission's principal office at Commodity Futures Trading Commission, Three Lafayette Centre, 1155 21st Street, NW., Washington, DC 20581; and is accessible in the regional offices in Chicago at 525 West Monroe Street, Suite 1100, Chicago, IL 60661; and New York at 140 Broadway, 19th Floor, New York, NY 10005.

CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

Individuals who have exceeded and who have potentially exceeded speculative limits in a particular fiscal year.

CATEGORIES OF RECORDS IN THE SYSTEM:

The records consist of a sequential listing, by year, of the possible violations and confirmed violations of speculative limits imposed by the Commission and the exchanges. The logbook records the date notification is sent to traders and/or exchanges, the due date for reply and the date the response is received. It includes the trader's name and assigned trader ID, the commodity (code) involved, and the type of violation. Copies of referral letters, warning letters and replies pertaining to the violation listed are scanned and become part of the electronic record.

AUTHORITY FOR MAINTENANCE OF THE SYSTEM:

The Commodity Exchange Act, 7 U.S.C. 1 *et seq.,* including Sections 4i and 8 of that Act at 7 U.S.C. 6i and 12, and the rules and regulations promulgated thereunder.

ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND THE PURPOSES OF SUCH USES:

Information in this system may be disclosed in accordance with the blanket routine uses numbered 1 through 19 that appear at the beginning of the Commission's compilation of its systems of records notices.

POLICIES AND PRACTICES FOR STORING, RETRIEVING, ACCESSING, RETAINING, AND DISPOSING OF RECORDS IN THE SYSTEM:

STORAGE:

Paper records are stored in file folders. Electronic records, including computer files, are stored on the Commission's network and in other electronic media as needed.

RETRIEVABILITY:

By any of the available data fields as noted above under "Categories of Records in the System," *e.g.,* trader's name and assigned trader ID, the commodity (code) involved, the type of violation, and dates for tracking referral letters, other correspondence and reports.

SAFEGUARDS:

Records are protected from unauthorized access and improper use through administrative, technical and physical security measures. Technical security measures within CFTC include restrictions on computer access to authorized individuals, strong passwords frequently changed, use of encryption for certain data types and transfers, and regular review of security procedures and best practices to enhance security. Physical measures include restrictions on building access to authorized individuals and maintenance of records in lockable offices and filing cabinets.

RETENTION AND DISPOSAL:

Files are destroyed five years after the end of the fiscal year that the records covered.

SYSTEM MANAGER(S) AND ADDRESS:

Market Surveillance Market Information Group Management in the regional offices in Chicago at 525 West Monroe Street, Suite 1100 Chicago, IL 60661; and New York at 140 Broadway, 19th Floor, New York, NY 10005.

NOTIFICATION PROCEDURE:

Individuals seeking to determine whether this system of records contains information about themselves or seeking access to records about themselves in this system of records, or contesting the content of records about themselves contained in this system of records should address written inquiry to the Office of General Counsel, Paralegal Specialist, Commodity Futures Trading Commission, Three Lafayette Centre, 1155 21st Street, NW., Washington, DC 20581. Telephone (202) 418–5011.

RECORD SOURCE CATEGORIES:

Large Trader reports filed by reporting firms and reporting markets. Correspondence prepared by the Commission or by the individual or individual's representative.

CFTC–20

SYSTEM NAME:

Registration (Registration of Floor Brokers, Floor Traders, Futures Commission Merchants, Introducing Brokers, Commodity Trading Advisors, Commodity Pool Operators, Leverage Transaction Merchants, Agricultural Trade Option Merchants and Associated Persons).

SYSTEM LOCATION:

This system is located at the National Futures Association (NFA), 300 South Riverside, Suite 1800, Chicago, IL 60606.

CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

Individuals who have applied or who may apply for registration as futures commission merchants, introducing brokers, commodity pool operators, commodity trading advisors, leverage transaction merchants and agricultural trade option merchants (ATOMs); individuals listed or who may be listed as principals (as defined in 17 Part CFR 3.1); individuals who have applied or who may apply for registration as associated persons of the foregoing firms; and floor brokers and floor traders.

CATEGORIES OF RECORDS IN THE SYSTEM:

Information pertaining to the registration and fitness of the above-described individuals, except ATOMs, to engage in business subject to the Commission's jurisdiction. Information on ATOMs includes only the names and registration status of ATOMs and their associated persons. The system includes registration forms, schedules, and supplements; correspondence relating to registration; and reports and memoranda reflecting information developed from various sources.

Computerized systems, consisting primarily of information taken from the registration forms, are maintained by NFA. Computer records include the name, date and place of birth, social security number (optional), exchange trading privileges (floor brokers and floor traders only), firm affiliation, and the residence or business address, or both, of each associated person, floor broker, floor trader and principal. Computer records also include information relating to name, trade name, principal office address, records

address, names of principals and branch managers of futures commission merchants, introducing brokers, commodity pool operators, commodity trading advisors, leverage transaction merchants, and ATOMs.

Firm directories, business address, telephone number, registration category, and effective date of registration of futures commission merchants, introducing brokers, commodity pool operators and commodity trading advisors may be sold to the public by the NFA. These directories provide registration forms and biographical supplements, except for any confidential information on supplementary attachments to the forms, are publicly available for disclosure, inspection and copying.

AUTHORITY FOR MAINTENANCE OF THE SYSTEM:

The Commodity Exchange Act, 7 U.S.C. 1 *et seq.,* including Sections 4f(a)(1) and (2), 4k(4), 4k(5), 4n(1), 8a(1), 8a(5), 8a(10) and 19 of the Commodity Exchange Act as amended, at 7 U.S.C. 6f(1), 6k(4), 6k(5), 6n(1), 12a(1), 12a(5), 12a(10), and 23, and the rules and regulations promulgated thereunder.

ROUTINE USES OF THE RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND THE PURPOSES OF SUCH USES:

a. Information contained in this system of records may be disclosed to any person with whom an applicant or registrant is or plans to be associated as an associated person or affiliated as a principal.

b. Information contained in this system of records may be disclosed to any registered futures commission merchant with whom an applicant or registered introducing broker has entered or plans to enter into a guarantee agreement in accordance with Commission regulation at 17 CFR Part 1.10.

Information in this system may also be disclosed in accordance with the blanket routine uses numbered 1 through 19 that appear at the beginning of the Commission's compilation of its systems of records notices.

Note: NFA may disclose information contained in those portions of this system of records maintained by NFA, but any such disclosure must be made in accordance with NFA rules that have been approved by the Commission or permitted to become effective without Commission approval. Disclosures must be made under circumstances authorized by the Commission as consistent with the Commission's regulations and routine uses. No specific consent is required by an applicant or registered introducing broker for disclosure of information to the futures commission merchant with whom it has or plans to enter a guarantee agreement.

POLICIES AND PRACTICES FOR STORING, RETRIEVING, ACCESSING, RETAINING, AND DISPOSING OF RECORDS IN THE SYSTEM:

STORAGE:

Paper records are stored in file folders and binders. Electronic information, including computer files, are stored on the Commission's network, in the NFA Online Registration System (ORS)), microfiche and various other electronic media as needed.

RETRIEVABILITY:

By the name of the individual or firm, or by assigned identification number. Where applicable, the NFA's computer cross-indexes the individual's primary registration file to the name of the futures commission merchant, introducing broker, commodity trading advisor, commodity pool operator, leverage transaction merchant or ATOM with whom the individual is associated or affiliated.

SAFEGUARDS:

Records are protected from unauthorized access and improper use through administrative, technical and physical security measures. Technical security measures within CFTC include restrictions on computer access to authorized individuals, strong passwords frequently changed, use of encryption for certain data types and transfers, and regular review of security procedures and best practices to enhance security. Physical measures include restrictions on building access to authorized individuals and maintenance of records in lockable offices and filing cabinets.

RETENTION AND DISPOSAL:

Since 2002, registration application records have primarily been managed electronically through ORS. ORS electronic records are maintained indefinitely, and are updated periodically as long as the individual has a registration application pending, is registered in any capacity, or is affiliated with any registrant in any capacity. ORS records on individuals who may apply are maintained indefinitely.

Hard copy records generated prior to 2002 are also maintained indefinitely, as is an electronic index and summary of these hard copy records.

SYSTEM MANAGER(S) AND ADDRESS:

Vice President for Registration, National Futures Association (NFA), 300 South Riverside, Suite 1800, Chicago, IL 60606.

NOTIFICATION PROCEDURE:

Individuals may also request registration information by telephone from the NFA information center at (800) 621–3570 or (312) 781–1410. Inquiries can also be made to NFA by fax at (312) 781–1459 or via *e-mail* at *information@nfa.futures.org.* NFA will query the ORS system about current registration status and registration and disciplinary history, and will provide instructions on how to make written requests for copies of records. The Internet may be used to obtain information on current registration status and futures-related regulatory actions at *http://www.nfa.futures.org* by selecting "BASIC."

RECORD SOURCE CATEGORIES:

The individual or firm on whom the record is maintained; the individual's employer; and other miscellaneous sources. The computer records are prepared from the forms, supplements, attachments and related documents submitted to the NFA.

CFTC–28

SYSTEM NAME:

Self-Regulatory Organization Disciplinary Action Files.

SYSTEM LOCATION:

This system is located in the Division of Market Oversight, Commodity Futures Trading Commission, Three Lafayette Centre, 1155 21st Street NW., Washington, DC 20581; in the regional offices in Chicago at Chicago at 525 West Monroe Street, Suite 1100 Chicago, IL 60661 and New York at 140 Broadway, 19th Floor, New York, NY 10005; and at the National Futures Association (NFA), 300 South Riverside, Suite 1800, Chicago, IL 60606.

CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

Individuals who have been suspended, expelled, disciplined, or denied access to or by a self-regulatory organization (SRO).

CATEGORIES OF RECORDS IN THE SYSTEM:

Information pertaining to a disciplinary or other adverse action taken by an SRO, including the name of the person against whom such action was taken, the action taken, and the reasons therefore. The information is maintained on a computerized system, the Background Affiliation Status Information Center (BASIC), and consists primarily of data furnished by NFA and other SROs.

AUTHORITY FOR MAINTENANCE OF THE SYSTEM:

44 U.S.C. 3101; the Commodity Exchange Act, 7 U.S.C. 1 *et seq.,* including Section 8c(a)(1) of the Commodity Exchange Act, at 7 U.S.C.

12c(a)(1), and the rules and regulations promulgated thereunder.

ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND THE PURPOSES OF SUCH USES:

Information in this system may be disclosed in accordance with the blanket routine uses numbered 1 through 19 that appear at the beginning of the Commission's compilation of its systems of records notices.

POLICIES AND PRACTICES FOR STORING, RETRIEVING, ACCESSING, RETAINING, AND DISPOSING OF RECORDS IN THE SYSTEM:

STORAGE:

Paper records are stored in file folders and binders. Electronic information, including computer files, is stored on the Commission's network, the NFA Website/BASIC, and other electronic media as needed.

RETRIEVABILITY:

By the name of the individual or firm, or by an NFA identification number.

SAFEGUARDS:

Records are protected from unauthorized access and improper use through administrative, technical and physical security measures. Technical security measures within CFTC include restrictions on computer access to authorized individuals, strong passwords frequently changed, use of encryption for certain data types and transfers, and regular review of security procedures and best practices to enhance security. Physical measures include restrictions on building access to authorized individuals and maintenance of records in lockable offices and filing cabinets.

RETENTION AND DISPOSAL:

Records are retained indefinitely.

SYSTEM MANAGER(S) AND ADDRESS:

Deputy Director, Division of Market Oversight, Commodity Futures Trading Commission, Three Lafayette Centre, 1155 21st Street, NW., Washington, DC 20581; Surveillance Branch Chiefs in the regional offices in Chicago at 525 West Monroe Street, Suite 1100 Chicago, IL 60661 and New York at 140 Broadway, 19th Floor, New York, NY 10005; and Vice President for Registration, National Futures Association, 300 South Riverside, Suite 1800, Chicago, IL 60606.

NOTIFICATION PROCEDURE:

Individuals seeking to determine whether this system of records contains information about themselves or seeking access to records about themselves in this system of records, or contesting the content of records about themselves contained in this system of records should address written inquiry to the Office of General Counsel, Paralegal Specialist, Commodity Futures Trading Commission, Three Lafayette Centre, 1155 21st Street, NW., Washington, DC 20581. Telephone (202) 418–5011.

RECORD SOURCE CATEGORIES:

Self-regulatory organizations notifying the Commission of disciplinary or other adverse actions taken.

CFTC–29

SYSTEM NAME:

Reparations Cases Closed in the Complaints Section.

SYSTEM LOCATION:

This system is located in the Office of Proceedings, Commodity Futures Trading Commission, Three Lafayette Centre, 1155 21st Street, NW., Washington, DC 20581.

CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

Individuals filing reparations complaints, as well as the firms and individuals named in the complaints.

CATEGORIES OF RECORDS IN THE SYSTEM:

Reparations complaints, answers, supporting documentation and correspondence filed with the Office of Proceedings. If the complaint is forwarded for decision by an administrative law judge or judgment officer, records become part of CFTC–3, Docket Files for Reparations and Administrative Adjudication.

AUTHORITY FOR MAINTENANCE OF THE SYSTEM:

The Commodity Exchange Act, 7 U.S.C. 1 *et seq.,* including Section 14 of the Commodity Exchange Act, at 7 U.S.C. 18; 44 U.S.C. 3101, and the rules and regulations promulgated thereunder.

ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND THE PURPOSES OF SUCH USES:

Information in this system may be disclosed in accordance with the blanket routine uses numbered 1 through 19 that appear at the beginning of the Commission's compilation of its systems of records notices.

POLICIES AND PRACTICES FOR STORING, RETRIEVING, ACCESSING, RETAINING, AND DISPOSING OF RECORDS IN THE SYSTEM:

STORAGE:

Paper records are stored in file folders, manual and paper docket cards; electronic records, including computer files, are stored on the Commission's network and other electronic media as needed.

RETRIEVABILITY:

By docket number and cross-indexed by the name of the complainant and respondent.

SAFEGUARDS:

Records are protected from unauthorized access and improper use through administrative, technical and physical security measures. Technical security measures within CFTC include restrictions on computer access to authorized individuals, strong passwords frequently changed, use of encryption for certain data types and transfers, and regular review of security procedures and best practices to enhance security. Physical measures include restrictions on building access to authorized individuals and maintenance of records in lockable offices and filing cabinets.

RETENTION AND DISPOSAL:

The records are maintained for ten years after the case is closed, except that complaints, decisions, and Commission opinions and orders, are retained permanently. Records concerning reparations complaints that are not accepted are maintained for three years.

SYSTEM MANAGER(S) AND ADDRESS:

Futures Trading Specialist, Complaints Section, Office of Proceedings, Commodity Futures Trading Commission, Three Lafayette Centre, 1155 21st Street, NW., Washington, DC 20581.

NOTIFICATION PROCEDURE:

Individuals seeking to determine whether this system of records contains information about themselves or seeking access to records about themselves in this system of records, or contesting the content of records about themselves contained in this system of records should address written inquiry to the Office of General Counsel, Paralegal Specialist, Commodity Futures Trading Commission, Three Lafayette Centre, 1155 21st Street, NW., Washington, DC 20581. Telephone (202) 418–5011.

RECORD SOURCE CATEGORIES:

Individuals filing reparations complaints or answers.

CFTC–30

SYSTEM NAME:

Open Commission Meetings.

SYSTEM LOCATION:

This system is located in the Office of the Secretariat, Commodity Futures Trading Commission, Three Lafayette Centre, 1155 21st Street, NW., Washington, DC 20581.

CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

Individuals who are the subject of discussion at a Commission meeting open for public observation.

CATEGORIES OF RECORDS IN THE SYSTEM:

Information pertaining to the individuals who are the subject of discussion at an open Commission meeting.

AUTHORITY FOR MAINTENANCE OF THE SYSTEM:

Government in the Sunshine Act, 5 U.S.C. 552b(f); the Commodity Exchange Act, 7 U.S.C. 1 *et seq.,* and rules and regulations promulgated thereunder, including Commission regulations at 17 CFR Part 147.7.

ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND THE PURPOSES OF SUCH USES:

The information in these files is a matter of public record and may be disclosed without restriction. Information in this system may also be disclosed in accordance with the blanket routine uses numbered 1 through 19 that appear at the beginning of the Commission's compilation of its systems of records notices.

POLICIES AND PRACTICES FOR STORING, RETRIEVING, ACCESSING, RETAINING AND DISPOSING OF RECORDS IN THE SYSTEM:

STORAGE:

Paper records are stored in file folders; electronic records, including computer files, are stored on the Commission's network, in desktop applications and CommMinutes. Information is also stored on microfiche, in audiocassette tapes, CDs and DVDs.

RETRIEVABILITY:

These records that include recordings, transcripts, and minutes of all Commission meetings are organized and retrieved either by year in chronological order or by the names of the individuals, firms, exchanges, or other topics that are discussed at the meetings.

SAFEGUARDS:

Records are protected from unauthorized access and improper use through administrative, technical and physical security measures. Technical security measures within CFTC include restrictions on computer access to authorized individuals, strong passwords frequently changed, use of encryption for certain data types and transfers, and regular review of security procedures and best practices to enhance security. Physical measures include restrictions on building access to authorized individuals and maintenance of records in lockable offices and filing cabinets.

RETENTION AND DISPOSAL:

Maintained on the Commission premises for at least the statutory period required by the Sunshine Act and Commission regulations (at least two years after each meeting or at least one year after the conclusion of any agency proceeding with respect to which the meeting or portion of the meeting was held, whichever is later); transferred to the National Archives as permanent records when 20 years old.

SYSTEM MANAGER(S) AND ADDRESS:

Secretary of the Commission, Office of the Secretariat, Commodity Futures Trading Commission, Three Lafayette Centre, 1155 21st Street, NW., Washington, DC 20581.

NOTIFICATION PROCEDURES:

Individuals seeking to determine whether this system of records contains information about themselves, seeking access to records about themselves in this system of records, or contesting the content of records about themselves contained in this system of records should address written inquiry to the Office of General Counsel, Paralegal Specialist, Commodity Futures Trading Commission, Three Lafayette Centre, 1155 21st Street, NW., Washington, DC 20581. Telephone (202) 418–5011.

RECORD SOURCE CATEGORIES:

The staff in one or more Divisions generates the information recorded during Commission meetings concerning individuals who are the subject of discussion at the meetings. The indices are prepared from the recordings, transcripts and/or minutes.

CFTC–31

SYSTEM NAME:

Closed Commission Meetings (exempted).

SYSTEM LOCATION:

This system is located in the Office of the Secretariat, Commodity Futures Trading Commission, Three Lafayette Centre, 1155 21st Street, NW., Washington, DC 20581.

CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

Individuals who are the subject of discussion at a closed Commission meeting.

CATEGORIES OF RECORDS IN THE SYSTEM:

Information pertaining to individuals who are the subject of discussion at a closed Commission meeting. This information consists of (a) investigatory materials compiled for law enforcement purposes whose disclosure the Commission has determined could impair the effectiveness and orderly conduct of the Commission's regulatory, enforcement and contract market surveillance programs or compromise Commission investigations, or (b) investigatory materials compiled solely for the purpose of determining suitability, eligibility, or qualifications for employment with the Commission to the extent that it identifies a confidential source.

AUTHORITY FOR MAINTENANCE OF THE SYSTEM:

Government in the Sunshine Act, 5 U.S.C. 552b(f); the Commodity Exchange Act, 7 U.S.C. 1 *et seq.,* and the rules and regulations promulgated thereunder, including Commission regulations at 17 CFR Part 147.7.

ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND THE PURPOSES OF SUCH USES:

Information in this system may be disclosed in accordance with the blanket routine uses numbered 1 through 19 that appear at the beginning of the Commission's compilation of its systems of records notices.

POLICIES AND PRACTICES FOR STORING, RETRIEVING, ACCESSING, RETAINING AND DISPOSING OF RECORDS IN THE SYSTEM:

STORAGE:

Paper records are stored in file folders; electronic records, including computer files, are stored on the Commission's network, in desktop applications and CommMinutes, and other electronic media as needed. Information is also stored on microfiche, in audiocassette tapes, CDs and DVDs.

RETRIEVABILITY:

These records that include recordings, transcripts, and minutes of all Commission meetings are organized and retrieved either by year in chronological order or by the name of the individuals, firms, exchanges, or other topics discussed at the meetings.

SAFEGUARDS:

Records are protected from unauthorized access and improper use through administrative, technical and physical security measures. Technical security measures within CFTC include restrictions on computer access to authorized individuals, strong passwords frequently changed, use of encryption for certain data types and transfers, and regular review of security procedures and best practices to enhance security. Physical measures include restrictions on building access to authorized individuals and

maintenance of records in lockable offices and filing cabinets.

RETENTION AND DISPOSAL:

Maintained on the Commission premises for at least the statutory period required by the Sunshine Act and Commission regulations (at least two years after each meeting or at least one year after the conclusion of any agency proceeding with respect to which meeting was held, whichever is later); transferred to the National Archives as permanent records when 20 years old.

SYSTEM MANAGER(S) AND ADDRESS:

Secretary of the Commission, Office of the Secretariat, Commodity Futures Trading Commission, Three Lafayette Centre, 1155 21st Street, NW., Washington, DC 20581.

SYSTEM EXEMPTED FROM CERTAIN PROVISIONS OF THE ACT:

The records in this system have been exempted by the Commission from certain provisions of the Privacy Act of 1974 pursuant to the terms of the Privacy Act, 5 U.S.C. 552a, and the Commission's rules promulgated thereunder, 17 CFR Part 146.12. These records are exempted from the notification procedures, record access procedures and record contest procedures set forth in the system notices of other record systems, and from the requirement that the source of records in the system be described.

CFTC–32

SYSTEM NAME:

Office of the Inspector General Investigative Files (exempted).

SYSTEM LOCATION:

This system is located in the Office of the Inspector General, Commodity Futures Trading Commission, Three Lafayette Centre, 1155 21st Street NW., Washington, DC 20581.

CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

Individuals who are part of an investigation of fraud and abuse concerning Commission programs or operations.

CATEGORIES OF RECORDS IN THE SYSTEM:

All correspondence relevant to the investigation; all internal staff memoranda, copies of all subpoenas issued during the investigation, affidavits, statement from witnesses, transcripts of testimony taken in the investigation and accompanying exhibits; documents and records or copies obtained during the investigation; opening reports, progress reports and closing reports; and an index of individuals investigated.

AUTHORITY FOR MAINTENANCE OF THE SYSTEM:

Commodity Exchange Act, 7 U.S.C. 1 *et seq.,* and regulations, rules or orders issued thereunder; Public Law 95–452, as amended, 5 U.S.C. App. 3.

ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND THE PURPOSES OF SUCH USES:

a. The information in the system may be disclosed by the Commission in any administrative proceeding before the Commission, in any injunctive action, or in any other action or proceeding authorized under the Commodity Exchange Act or the Inspector General Act of 1978 in which the Commission or any member of the Commission or its staff participates as a party or the Commission participates as amicus curiae.

b. In any case in which records in the system indicates a violation or potential violation of law, whether civil, criminal or regulatory in nature, whether arising by general statute or particular program statute, or by regulation, rule or order issued pursuant thereto, the relevant records may be referred to the appropriate agency, whether Federal, foreign, State or local, charged with enforcing or implementing the statute, regulation, rule or order.

c. In any case in which records in the system indicate a violation or potential violation of law, whether civil, criminal or regulatory in nature, the relevant records may be referred to the appropriate board of trade designated as a contract market by the Commission or to the appropriate futures association registered with the Commission, if the Office of the Inspector General has reason to believe this will assist the contract market or registered futures association in carrying out its self-regulatory responsibilities under the Commodity Exchange Act, 7 U.S.C. 1 *et seq.,* and regulations, rules or orders issued pursuant thereto, and such records may also be referred to any national securities exchange or national securities association registered with the Securities and Exchange Commission, to assist those organizations in carrying out their self-regulatory responsibilities under the Securities Exchange Act of 1934, 15 U.S.C. 78a *et seq.,* and regulations, rules or orders issued pursuant thereto.

d. The information may be given or shown to anyone during the course of an Office of the Inspector General (OIG) investigation if the staff has reason to believe that disclosure to the person will further the investigation. Information may also be disclosed to Federal, foreign, State or local authorities in order to obtain information or records relevant to an OIG investigation.

e. The information may be given to independent auditors or other private firms with which the OIG has contracted to carry out an independent audit, or to collate, aggregate or otherwise refine data collected in the system of records. These contractors will be required to maintain Privacy Act safeguards with respect to such records.

f. The information may be disclosed to a Federal, foreign, State or local government agency where records in either system of records pertain to an applicant for employment, or to a current employer of that agency where the records are relevant and necessary to an agency decision concerning the hiring or retention of an employee or disciplinary or other administrative action concerning an employee.

g. The information may be disclosed to a Federal, foreign, State, or local government agency in response to its request in connection with the issuance of a security clearance, the letting of a contract, or the issuance of a license, grant or other benefit by the requesting agency, to the extent that the information is relevant and necessary to the requesting agency's decision in the matter.

h. The information may be disclosed to the Department of Justice or other counsel to the Commission for legal advice or to pursue claims and to government counsel when the defendant in litigation is (a) any component of the Commission or any member or employee of the Commission in his or her official capacity, or (b) the United States or any agency thereof.

Information in this system may also be disclosed in accordance with the blanket routine uses numbered 1 through 19 that appear at the beginning of the Commission's compilation of its systems of records notices.

POLICIES AND PRACTICES FOR STORING, RETRIEVING, ACCESSING, RETAINING, AND DISPOSING OF RECORDS IN THE SYSTEM:

STORAGE:

Paper records are stored in file folders; electronic records, including computer files, are stored on the Commission's network, including desktop applications, and other electronic media as needed.

RETRIEVABILITY:

Investigative files are retrieved by the subject matter of the investigation or by case file number. An index provides a

cross-reference on individuals investigated.

SAFEGUARDS:

Records are protected from unauthorized access and improper use through administrative, technical and physical security measures. Technical security measures within CFTC include restrictions on computer access to authorized individuals, strong passwords frequently changed, use of encryption for certain data types and transfers, and regular review of security procedures and best practices to enhance security. Physical measures include restrictions on building access to authorized individuals and maintenance of records in lockable offices and filing cabinets. These records are kept in limited access areas during duty hours and in file cabinets in locked offices at all other times. These records are available only to those individuals whose official duties require such access.

RETENTION AND DISPOSAL:

The Office of the Inspector General Investigative Files and the index to the files are destroyed 20 years after the case is closed.

SYSTEM MANAGER(S) AND ADDRESS:

Inspector General, Office of the Inspector General, Commodity Futures Trading Commission, Three Lafayette Centre, 1155 21st Street, NW., Washington, DC 20581.

NOTIFICATION PROCEDURE:

Individuals seeking to determine whether this system of records contains information about themselves or seeking access to records about themselves in this system of records, or contesting the content of records about themselves contained in this system of records should address written inquiry to the Office of General Counsel, Paralegal Specialist, Commodity Futures Trading Commission, Three Lafayette Centre, 1155 21st Street, NW., Washington, DC 20581. Telephone (202) 418–5011.

RECORD SOURCE CATEGORIES:

Information in these records is supplied by: Individuals including, where practicable, those to whom the information relates; witnesses, corporations and other entities; records of individuals and of the Commission; records of other entities; Federal, foreign, State or local bodies and law enforcement agencies; documents, correspondence relating to litigation, and transcripts of testimony; and miscellaneous other sources.

SYSTEM EXEMPTIONS FROM CERTAIN PROVISIONS OF THE PRIVACY ACT:

Under 5 U.S.C. 552a(j)(2), the Office of the Inspector General Investigative Files are exempted from 5 U.S.C. 552a except subsections (b), (c)(1), and (2), (e)(4)(A) through (F), (e)(6), (7), (9), (10), and (11), and (i) to the extent the system of records pertains to the enforcement of criminal laws. Under 5 U.S.C. 552(k)(2), the Office of the Inspector General Investigative Files are exempted from 5 U.S.C. 552a(c)(3), (d), (e)(1), (e)(4)(G), (H), and (I) and (f) to the extent the system of records consists of investigatory material compiled for law enforcement purposes. These exemptions are contained at 17 CFR 146.13.

CFTC–33

SYSTEM NAME:

Electronic Access Card.

SYSTEM LOCATION:

This system is located in the Office of Management Operations, Commodity Futures Trading Commission, Three Lafayette Centre, 1155 21st Street, NW., Washington, DC 20581, and regional offices in New York, Chicago, and Kansas City.

CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

Authorized access cardholders in headquarters and regional offices, including Commission employees, onsite contractors, visitors, or representatives of landlords.

CATEGORIES OF RECORDS IN THE SYSTEM:

Records showing name of assigned user, electronic access card number and card status (*i.e.,* whether the card is active or inactive) are directly accessible by the Office of Management Operations ("OMO") in the New York and Chicago regional offices, and by OMO upon request to the landlord in the headquarters and Kansas City regional office. These records are used to verify that cards have been activated and deactivated correctly.

Records showing name of assigned user, electronic access card number, card status and card activity (*i.e.,* the time and location of access card use by access card user) are directly accessible by OMO in the New York and Chicago regional offices, and by OMO upon request to the landlord in the headquarters and Kansas City regional office. Such records are only accessed and used by the Commission to investigate security incidents, such as thefts or inappropriate access to secure files.

AUTHORITY FOR MAINTENANCE OF THE SYSTEM:

The Commodity Exchange Act, 7 U.S.C. 1 *et seq.,* including Section 12(b)(3) of the Act, at 7 U.S.C. 16(b)(3), and rules and regulations promulgated thereunder.

ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND THE PURPOSES OF SUCH USES:

a. Information contained in this system may be disclosed by the Commission to any person in connection with architectural, security or other surveys concerning use of office space.

b. Information contained in this system may be disclosed to any person for their use of maintenance or service of data processing systems.

Information in this system may also be disclosed in accordance with the blanket routine uses numbered 1 through 19 that appear at the beginning of the Commission's compilation of its systems of records notices.

POLICIES AND PRACTICES FOR STORING, RETRIEVING, ACCESSING, RETAINING AND DISPOSING OF RECORDS IN THE SYSTEM:

STORAGE:

Paper records are stored in file folders; electronic records, including computer files, are stored on the Commission's network, including desktop applications, and other electronic media as needed. Various reports are generated from the computer system.

RETRIEVABILITY:

By name of the subject, by assigned access card number, by time period and by entry point.

SAFEGUARDS:

Records are protected from unauthorized access and improper use through administrative, technical and physical security measures. Technical security measures within CFTC include restrictions on computer access to authorized individuals, strong passwords frequently changed, use of encryption for certain data types and transfers, and regular review of security procedures and best practices to enhance security. Physical measures include restrictions on building access to authorized individuals and maintenance of records in lockable offices and filing cabinets. In the headquarters office, these records may be requested from the Commission's landlords' databases only by the Director of the Office of Management Operations, or his/her designee, and the CFTC maintains all access card usage records in limited access areas at all

times. In the regional offices, access card information is maintained in a locked area, with access restricted to staff members of the Office of Management Operations.

RETENTION AND DISPOSAL:

In accordance with the General Record Schedules, the records in the system are considered temporary and are destroyed six months after the user turns in the access card. Paper records are destroyed when no longer required or after two years, whichever is shorter.

SYSTEM MANAGER(S) AND ADDRESS:

Director, Office of Management Operations, Commodity Futures Trading Commission, Three Lafayette Centre, 1155 21st Street, NW., Washington, DC 20581.

NOTIFICATION PROCEDURES:

Individuals seeking to determine whether the system of records contains information about themselves, seeking access to records about themselves in the system of records or contesting the content of records about themselves should address written inquiry to the Office of General Counsel, Paralegal Specialist, Commodity Futures Trading Commission, Three Lafayette Centre, 1155 21st Street, NW., Washington, DC 20581. Telephone (202) 418–5011. The system of records and the notification, access and challenge procedures apply only to records of access card usage in the Commission's actual possession. None of these applies to any information solely in a landlord's possession.

RECORD RESOURCE CATEGORIES:

The Commission's landlords in headquarters and the regional offices provide information on name of assigned user, access card number, access level, and status on a weekly basis or as needed.

CFTC–34

SYSTEM NAME:

Telecommunications Services (BlackBerry or Calling Card).

SYSTEM LOCATION:

This system is located in the Office of Information and Technology Services, Commodity Futures Trading Commission, Three Lafayette Centre, 1155 21st Street, NW., Washington, DC 20581.

CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

Commission employees and contractor personnel who are issued either a Blackberry or Calling Card.

CATEGORIES OF RECORDS IN THE SYSTEM:

Calling Card numbers, BlackBerry numbers and the individuals to whom they are assigned.

AUTHORITY FOR MAINTENANCE OF THE SYSTEM:

5 U.S.C. 301 and 41 CFR Part 101–35.

ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM INCLUDING CATEGORIES OF USERS AND THE PURPOSES OF SUCH USES:

Information in this system may be disclosed in accordance with the blanket routine uses numbered 1 through 19 that appear at the beginning of the Commission's compilation of its systems of records notices.

POLICIES AND PRACTICES FOR STORING, RETRIEVEING, ACCESSING, RETAINING, AND DISPOSING OF RECORDS IN THE SYSTEM:

STORAGE:

Calling Card records are stored in a spreadsheet file. BlackBerry records are stored in a database file. Both files are located on a file server on the Commission's network in the headquarters office.

RETRIEVABILITY:

Records are retrievable by employee name, BlackBerry telephone number, or calling card number.

SAFEGUARDS:

Records are protected from unauthorized access and improper use through administrative, technical and physical security measures. Technical security measures within CFTC include restrictions on computer access to authorized individuals, strong passwords frequently changed, use of encryption for certain data types and transfers, and regular review of security procedures and best practices to enhance security. Physical measures include restrictions on building access to authorized individuals and maintenance of records in lockable offices and filing cabinets.

RETENTION AND DISPOSAL:

A BlackBerry record is cancelled when a device is reassigned to another user. A Calling Card and its record are cancelled when the card is returned to the Office of Information and Technology Services.

SYSTEM MANAGER(S) AND ADDRESS:

Telecommunications Manager, Office of Information and Technology Services, Commodity Futures Trading Commission, Three Lafayette Centre, 1155 21st Street, NW., Washington, DC 20581.

NOTIFICATION PROCEDURE:

Individuals seeking to determine whether the system of records contains information about themselves, seeking access to records about themselves in the system of records or contesting the content of records about themselves should address written inquiries to the Office of General Counsel, Paralegal Specialist, Commodity Futures Trading Commission, Three Lafayette Centre, 1155 21st Street, NW., Washington, DC 20581. Telephone (202) 418–5011.

RECORD SOURCE CATEGORIES:

BlackBerry and Calling Card assignment records.

CFTC–35

SYSTEM NAME:

Interoffice and Internet E-mail.

SYSTEM LOCATION:

This system is located in the Office of Information Technology Services, Commodity Futures Trading Commission, Three Lafayette Centre, 1155 21st Street, NW., Washington, DC 20581.

CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

All Commission employees and authorized contractors.

CATEGORIES OF RECORDS IN THE SYSTEM:

Records on the use of the interoffice and Internet e-mail system, including the mailbox name, number of objects in the mailbox, and aggregate size of the mailbox.

AUTHORITY FOR MAINTENANCE OF THE SYSTEM:

5 U.S.C. 301; Commodity Exchange Act, 7 U.S.C. 1 *et seq.,* including Section 12(b)(3) of the Commodity Exchange Act, at 7 U.S.C. 16(b)(3), and rules and regulations promulgated thereunder.

ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM INCLUDING CATEGORIES OF USER AND THE PURPOSES OF SUCH USES:

Information in this system may be disclosed in accordance with the blanket routine uses numbered 1 through 19 that appear at the beginning of the Commission's compilation of its systems of records notices.

POLICIES AND PRACTICES FOR STORING, RETRIEVING, ACCESSING, RETAINING AND DISPOSING OF RECORDS IN THE SYSTEM:

STORAGE:

Records are stored on the mail servers on the computer network in each Commission location. Records also may be stored on other electronic media as needed, such as encrypted hard drives.

RETRIEVABILITY:

The information can be retrieved by assigned interoffice or Internet mail address.

SAFEGUARDS:

Records are protected from unauthorized access and improper use through administrative, technical and physical security measures. Technical security measures within CFTC include restrictions on computer access to authorized individuals, strong passwords frequently changed, use of encryption for certain data types and transfers, and regular review of security procedures and best practices to enhance security. Physical measures include restrictions on building access to authorized individuals and maintenance of records in lockable offices and filing cabinets.

Network administrators have access to the e-mail information, including the "header" information described under "Categories of Records." In addition, the mailbox owner can grant access to objects in the mailbox to others.

RETENTION AND DISPOSAL:

Records are retained on the Commission's computer mail servers until the sender and receiver delete the information from the e-mail system, except to the extent the records are archived for back-up or disaster recovery purposes. Archived records are retained on the Commission's network file servers or other electronic media as needed until overwritten through standard archive/back-up and deletion procedures. Internet e-mail information that is received by the postmaster due to an error in delivery is considered temporary and is destroyed after the problem is corrected. When an employee leaves the Commission, the employee's mailbox is deleted unless the employee or the employee's administrative officer requests that the mailbox be retained in order to recover work-related information, or unless the employee's e-mail is relevant to pending or anticipated litigation or an investigation.

SYSTEM MANAGER(S) AND ADDRESS:

Network Manager, Office of Information and Technology Services, Commodity Futures Trading Commission, Three Lafayette Centre, 1155 21st Street, NW., Washington, DC 20581.

NOTIFICATION PROCEDURES:

Individuals seeking to determine whether the system of records contains information about themselves, seeking access to records about themselves in the system of records, or contesting the content of records about themselves should address written inquiries to the Office of General Counsel, Paralegal Specialist, Commodity Futures Trading Commission, Three Lafayette Centre, 1155 21st Street, NW., Washington, DC 20581. Telephone (202) 418–5011.

RECORD SOURCE CATEGORIES:

Internet e-mail, interoffice e-mail.

CFTC–36

SYSTEM NAME:

Internet Security Gateway Systems (Firewall, Web Content Filter, and E-mail Filter).

SYSTEM LOCATION:

This system is located in the Office of Information and Technology Services, Commodity Futures Trading Commission, Three Lafayette Centre, 1155 21st Street, NW., Washington, DC 20581 and in the Chicago Regional Office, 525 West Monroe Street, Suite 1100, Chicago, IL 60661.

CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

All CFTC employees and onsite contractors who are users of the Internet.

CATEGORIES OF RECORDS IN THE SYSTEM:

Records on the Web sites accessed and inbound e-mail received, as identified by the Internet protocol address assigned to each computer, as well as information on the date and time of the Web site that was accessed or e-mail that was received, including a record of the sender of the e-mail.

AUTHORITY FOR MAINTENANCE OF THE SYSTEM:

5 U.S.C. 301; Commodity Exchange Act, 7 U.S.C. 1 *et seq.,* including Section 12(b)(3) of the Commodity Exchange Act, at 7 U.S.C. 16(b)(3), and rules and regulations promulgated thereunder.

ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND THE PURPOSES OF SUCH USES:

Information in this system may be disclosed in accordance with the blanket routine uses numbered 1 through 19 that appear at the beginning of the Commission's compilation of its systems of records notices.

POLICIES AND PRACTICES FOR STORING, RETRIEVING, ACCESSING, RETAINING AND DISPOSING OF RECORDS IN THE SYSTEM:

STORAGE:

Records are kept and maintained on the Internet Security Gateway Systems servers in the DC headquarters and Chicago Regional Office computer rooms.

RETRIEVABILITY:

The information can be retrieved by Internet protocol address. The network administrators have access to information about the office location and individuals assigned to each computer, as identified by Internet protocol address.

SAFEGUARDS:

Records are protected from unauthorized access and improper use through administrative, technical and physical security measures. Technical security measures within CFTC include restrictions on computer access to authorized individuals, strong passwords frequently changed, use of encryption for certain data types and transfers, and regular review of security procedures and best practices to enhance security. Access to the Internet Security Gateway Systems is password-protected information that is stored on servers in the DC headquarters and Chicago Regional Office computer rooms. Physical measures include restrictions on building access to authorized individuals and maintenance of records in lockable offices and filing cabinets.

Access to the computer room is limited to certain employees of the Office of Information and Technology Services.

RETENTION AND DISPOSAL:

Because these records are routinely overwritten through standard procedures, the length of time of storage on the Internet Security Gateway Systems servers is governed by available disk space on the server. Records are generally overwritten in less than one (1) year.

SYSTEM MANAGER(S) AND ADDRESS:

Network Manager, Commodity Futures Trading Commission, Three Lafayette Centre, 1155 21st Street, NW., Washington, DC 20581.

NOTIFICATION PROCEDURE:

Individuals seeking to determine whether the system of records contains information about themselves, seeking access to records about themselves in the system of records, or contesting the content of records about themselves should address written inquiries to the Office of General Counsel, Paralegal Specialist, Commodity Futures Trading Commission, Three Lafayette Centre, 1155 21st Street, NW., Washington, DC 20581. Telephone (202) 418–5011.

RECORD SOURCE CATEGORIES:

Internet, Web site and news group browsing, Web site access.

CFTC–37

SYSTEM NAME:

Lexis/Westlaw Billing Information System.

SYSTEM LOCATION:

This system is located in the Library, Commodity Futures Trading Commission, Three Lafayette Centre, 1155 21st Street, NW., Washington, DC 20581.

CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

All Commission employees and onsite contractors who are users of the Lexis/Westlaw research system.

CATEGORIES OF RECORDS IN THE SYSTEM:

Records on the name, search subject, database searched, date, elapsed time, type of charge, and total charge for a search in the Lexis/Westlaw automated research system.

AUTHORITY FOR MAINTENANCE OF THE SYSTEM:

5 U.S.C. 301; Commodity Exchange Act, 7 U.S.C. 1 *et seq.,* including Section 12(b)(3) of the Commodity Exchange Act, 7 U.S.C. 16(b)(3), and rules and regulations promulgated thereunder.

ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM INCLUDING CATEGORIES OF USERS AND THE PURPOSES OF SUCH USES:

Information in this system may be disclosed in accordance with the blanket routine uses numbered 1 through 19 that appear at the beginning of the Commission's compilation of its systems of records notices.

POLICIES AND PRACTICES FOR STORING, RETRIEVING, ACCESSING, RETAINING AND DISPOSING OF RECORDS IN THE SYSTEM:

STORAGE:

Records are accessed by Commission staff through the Commission's network, including its electronic billing system (MarkView), and may be copied by authorized Commission staff to the Commission's computer network. The records are stored on the network of the Department of Transportation, the organization contractually obligated to support the Commission's electronic billing system. When printed, the records are stored in a lockable file cabinets.

RETRIEVABILITY:

By division, by month of use, by database accessed, by user name and user identification number.

SAFEGUARDS:

Records are protected from unauthorized access and improper use through administrative, technical and physical security measures. Technical security measures within CFTC include restrictions on computer access to authorized individuals, strong passwords frequently changed, use of encryption for certain data types and transfers, and regular review of security procedures and best practices to enhance security. Physical measures include restrictions on building access to authorized individuals and maintenance of records in lockable offices and filing cabinets.

RETENTION AND DISPOSAL:

Records are retained indefinitely in electronic form, while hard copies are destroyed when no longer useful to the Commission employee reviewing them.

SYSTEM MANAGER(S) AND ADDRESS:

Supervisory Librarian, Commodity Futures Trading Commission, Three Lafayette Centre, 1155 21st Street, NW., Washington, DC 20581.

NOTIFICATION PROCEDURE:

Individuals seeking to determine whether the system of records contains information about themselves, seeking access to records about themselves in the system of records, or contesting the content of records about themselves should address written inquiries to the Office of General Counsel, Paralegal Specialist, Commodity Futures Trading Commission, Three Lafayette Centre, 1155 21st Street, NW., Washington, DC 20581. Telephone (202) 418–5011.

RECORD SOURCE CATEGORIES:

Lexis/Westlaw billing information.

CFTC–38

SYSTEM NAME:

Automated Library Circulation System.

SYSTEM LOCATION:

This system is located in the Library, Commodity Futures Trading Commission, Three Lafayette Centre, 1155 21st Street, NW., Washington, DC 20581.

CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

Individual Commission employees who check out books and periodicals from the Commission Library.

CATEGORIES OF RECORDS IN THE SYSTEM:

Records showing the bar code assigned to employees who use the library, title, due date, and hold information on library materials checked-out by individual CFTC employees; records of overdue materials and of employee notification of overdue materials.

AUTHORITY FOR MAINTENANCE OF THE SYSTEM:

5 U.S.C. 301 and 41 CFR Part 101–27.

ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM INCLUDING CATEGORIES OF USERS AND THE PURPOSES OF SUCH USES:

Information in this system may be disclosed in accordance with the blanket routine uses numbered 1 through 19 that appear at the beginning of the Commission's compilation of its systems of records notices.

POLICIES AND PRACTICES FOR STORING, RETRIEVING, ACCESSING, RETAINING AND DISPOSING OF RECORDS IN THE SYSTEM:

STORAGE:

Records are stored on the Commission network (Horizon Integrated Library System [ILS]). Records on the identifying bar codes assigned to individuals are also stored on the network.

RETRIEVABILITY:

Records are retrievable by employee name, by the employee's bar code number, or by employee's office telephone number.

SAFEGUARDS:

Records are protected from unauthorized access and improper use through administrative, technical and physical security measures. Technical security measures within CFTC include restrictions on computer access to authorized individuals, strong passwords frequently changed, use of encryption for certain data types and transfers, and regular review of security procedures and best practices to enhance security. Physical measures include restrictions on building access to authorized individuals and maintenance of records in lockable offices and filing cabinets. Employees may access their own records. Only authorized Commission staff members, who are principally staff of the Library or the Office of Information and Technology Services, may access records of all employees.

RETENTION AND DISPOSAL:

Records in the system are considered temporary. The records of library transactions are destroyed when an item on loan is returned or reimbursement is made for replacement of the item.

SYSTEM MANAGER(S) AND ADDRESS:

Supervisory Librarian, Commodity Futures Trading Commission, Three Lafayette Centre, 1155 21st Street NW., Washington, DC 20581.

NOTIFICATION PROCEDURES:

Individuals seeking to determine whether the system of records contains information about themselves, seeking access to records about themselves in the system of records, or contesting the

content of records about themselves should address written inquiries to the Office of General Counsel, Paralegal Specialist, Commodity Futures Trading Commission, Three Lafayette Centre, 1155 21st Street, NW., Washington, DC 20581. Telephone (202) 418–5011.

RECORD SOURCE CATEGORIES:

Library user bar code identifiers; library materials use; overdue notices.

CFTC–39

SYSTEM NAME:

Freedom of Information Act Requests.

SYSTEM LOCATION:

This system is located in the Office of General Counsel, Commodity Futures Trading Commission, Three Lafayette Centre, 1155 21st Street, NW., Washington, DC 20581. Other offices involved in the processing of requests may also maintain copies of the requests and any related internal administrative records.

CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

Individuals requesting information from the Commission pursuant to provisions of the Freedom of Information Act (FOIA), 5 U.S.C. 552, and individuals who are the subjects of FOIA requests.

CATEGORIES OF RECORDS IN THE SYSTEM:

Requests, internal memoranda, response letters, appeals of denials, appeal determinations and electronic tracking data.

AUTHORITY FOR MAINTENANCE OF THE SYSTEM:

5 U.S.C. 552, 5 U.S.C. 301.

ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND THE PURPOSES OF SUCH USES:

Information in this system may be disclosed in accordance with the blanket routine uses numbered 1 through 19 that appear at the beginning of the Commission's compilation of its systems of records notices.

POLICIES AND PRACTICES FOR STORING, RETRIEVING, ACCESSING, RETAINING, AND DISPOSING OF RECORDS IN THE SYSTEM:

STORAGE:

Paper records are stored in file folders and on microfiche; electronic records, including computer files, are stored on the Commission's network, *e.g.,* desktop applications and RequestTracking, and on other electronic media as needed.

RETRIEVABILITY:

By assigned control number, by name of requester, or by subject of request.

SAFEGUARDS:

Records are protected from unauthorized access and improper use through administrative, technical and physical security measures. Technical security measures within CFTC include restrictions on computer access to authorized individuals, strong passwords frequently changed, use of encryption for certain data types and transfers, and regular review of security procedures and best practices to enhance security. Physical measures include restrictions on building access to authorized individuals and maintenance of records in lockable offices and filing cabinets.

RETENTION AND DISPOSAL:

FOIA requests are retained in accordance with General Records Schedule 14 of the National Archives and Records Administration.

SYSTEM MANAGER(S) AND ADDRESS:

Paralegal Specialist, Office of General Counsel, Commodity Futures Trading Commission, Three Lafayette Centre, 1155 21st Street, NW., Washington, DC 20581.

NOTIFICATION PROCEDURE:

Individuals seeking to determine whether this system of records contains information about themselves or seeking access to records about themselves in this system of records, or contesting the content of records about themselves contained in this system of records should address written inquiry to the Office of General Counsel, Paralegal Specialist, Commodity Futures Trading Commission, Three Lafayette Centre, 1155 21st Street, NW., Washington, DC 20581. Telephone (202) 418–5011.

RECORD SOURCE CATEGORIES:

Individuals requesting information from the Commission pursuant to the FOIA and employees processing the requests.

CFTC–40

SYSTEM NAME:

Privacy Act Requests.

SYSTEM LOCATION:

This system is located in the Office of General Counsel, Commodity Futures Trading Commission, Three Lafayette Centre, 1155 21st Street, NW., Washington, DC 20581. Telephone (202) 418–5011. Copies of the requests and any related internal administrative records may also be maintained by other offices involved in the processing of requests.

CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

Individuals filing requests for access to, correction of, or an accounting of disclosures of personal information contained in system of records maintained by the Commission, pursuant to the Privacy Act of 1974. 5 U.S.C. 552a.

CATEGORIES OF RECORDS IN THE SYSTEM:

Requests, internal memoranda, response letters, appeals of denials, appeal determinations and electronic tracking data.

AUTHORITY FOR MAINTENANCE OF THE SYSTEM:

5 U.S.C. 552a, 5 U.S.C. 301.

ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND THE PURPOSES OF SUCH USES:

Information in this system may be disclosed in accordance with the blanket routine uses numbered 1 through 19 that appear at the beginning of the Commission's compilation of its systems of records notices.

POLICIES AND PRACTICES FOR STORING, RETRIEVING, ACCESSING, RETAINING, AND DISPOSING OF RECORDS IN THE SYSTEM:

STORAGE:

Paper records are stored in file folders and on microfiche; electronic records, including computer files, are stored on the Commission's network, *e.g.,* desktop applications and RequestTracking, and on other electronic media as needed.

RETRIEVABILITY:

By assigned control number or by name of requester.

SAFEGUARDS:

Records are protected from unauthorized access and improper use through administrative, technical and physical security measures. Technical security measures within CFTC include restrictions on computer access to authorized individuals, strong passwords frequently changed, use of encryption for certain data types and transfers, and regular review of security procedures and best practices to enhance security. Physical measures include restrictions on building access to authorized individuals and maintenance of records in lockable offices and filing cabinets.

RETENTION AND DISPOSAL:

Privacy Act requests are retained in accordance with General Records Schedule 14 of the National Archives and Records Administration.

SYSTEM MANAGER(S) AND ADDRESS:

Paralegal Specialist, Office of General Counsel, Commodity Futures Trading

Commission, Three Lafayette Centre, 1155 21st Street, NW., Washington, DC 20581.

NOTIFICATION PROCEDURE:

Individuals seeking to determine whether this system of records contains information about themselves or seeking access to records about themselves in this system of records, or contesting the content of records about themselves contained in this system of records should address written inquiry to the Office of General Counsel, Paralegal Specialist, Commodity Futures Trading Commission, Three Lafayette Centre, 1155 21st Street, NW., Washington, DC 20581. Telephone (202) 418–5011.

RECORD SOURCE CATEGORIES:

Individuals requesting information from the Commission pursuant to the Privacy Act and employees processing the requests.

CFTC–41

SYSTEM NAME:

Requests for Confidential Treatment.

SYSTEM LOCATION:

This system is located in the Office of General Counsel, Commodity Futures Trading Commission, Three Lafayette Centre, 1155 21st Street, NW., Washington, DC 20581. A copy of the request may also be kept by the office receiving the document for which confidential treatment is being requested.

CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

Individuals requesting confidential treatment of, and individuals who are the subjects of, documents filed with the Commission.

CATEGORIES OF RECORDS IN THE SYSTEM:

Requests for confidential treatment, the documents for which confidential treatment is requested and electronic tracking data.

AUTHORITY FOR MAINTENANCE OF THE SYSTEM:

5 U.S.C. 552, 5 U.S.C. 301.

ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND THE PURPOSES OF SUCH USES:

Information in this system may be disclosed in accordance with the blanket routine uses numbered 1 through 19 that appear at the beginning of the Commission's compilation of its systems of records notices.

POLICIES AND PRACTICES FOR STORING, RETRIEVING, ACCESSING, RETAINING, AND DISPOSING OF RECORDS IN THE SYSTEM:

STORAGE:

Paper records are stored in file folders and on microfiche; electronic records, including computer files, are stored on the Commission's network, *e.g.,* desktop applications and Contreat2003, and on other electronic media as needed.

RETRIEVABILITY:

By name of requester or by subject of request.

SAFEGUARDS:

Records are protected from unauthorized access and improper use through administrative, technical and physical security measures. Technical security measures within CFTC include restrictions on computer access to authorized individuals, strong passwords frequently changed, use of encryption for certain data types and transfers, and regular review of security procedures and best practices to enhance security. Physical measures include restrictions on building access to authorized individuals and maintenance of records in lockable offices and filing cabinets.

RETENTION AND DISPOSAL:

Records are retained for 20 years then destroyed.

SYSTEM MANAGER(S) AND ADDRESS:

Paralegal Specialist, Office of General Counsel, Commodity Futures Trading Commission, Three Lafayette Centre, 1155 21st Street, NW., Washington, DC 20581.

NOTIFICATION PROCEDURE:

Individuals seeking to determine whether this system of records contains information about themselves or seeking access to records about themselves in this system of records, or contesting the content of records about themselves contained in this system of records should address written inquiry to the Office of General Counsel, Paralegal Specialist, Commodity Futures Trading Commission, Three Lafayette Centre, 1155 21st Street, NW., Washington, DC 20581. Telephone (202) 418–5011.

RECORD SOURCE CATEGORIES:

Individuals submitting documents to the Commission.

CFTC–42

SYSTEM NAME:

Debt Collection Files.

SYSTEM LOCATION:

This system is located in the Office of Financial Management, Commodity Futures Trading Commission, Three Lafayette Centre, 1155 21st St. NW., Washington, DC 20581.

CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

Individuals who owe a civil monetary penalty to the Commodity Futures Trading Commission or who have not complied with an order of restitution or disgorgement resulting from an administrative or injunctive enforcement action.

CATEGORIES OF RECORDS IN THE SYSTEM:

The files will generally contain information including the name and address of the debtor, the taxpayer's identification number (which may be the social security number); records of each collection made; and notice(s) to the debtor demanding payment and describing the consequences of non-payment. The files may also contain credit reports; reports of asset searches; copies of income tax returns; financial statements reflecting the net worth of the debtor; if applicable, date by which the debt must be referred to the Department of the Treasury or Department of Justice for further collection action; documentation of judgments or liens; and citation or basis on which the debt was terminated or compromised.

AUTHORITY FOR MAINTENANCE OF THE SYSTEM:

31 U.S.C. 3701, *et seq.*

ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND THE PURPOSES OF SUCH USERS:

a. Information regarding the debt and the actions taken to collect the monies may be disclosed to the Department of the Treasury or the Department of Justice for further collection action. Once the records are forwarded to the Department of the Treasury, they are covered by the Treasury/Financial Management Services System 014, Debt Collection Operations. If the records are forwarded to the Department of Justice, they are covered by the Department's system JMD–006, Debt Collection Management System.

b. Information about the delinquent debt may be disclosed to consumer or commercial reporting agencies as required by 31 U.S.C. 3711(e). Reporting may be done directly by the Commission or through the Department of the Treasury upon referral of the delinquent debt for further collection action.

Information in this system may also be disclosed in accordance with the blanket routine uses numbered 1 through 19 that appear at the beginning

of the Commission's compilation of its systems of records notices.

POLICIES AND PRACTICES FOR STORING, RETRIEVING, ACCESSING, RETAINING AND DISPOSING OF RECORDS IN THE SYSTEM:

STORAGE:

Paper records are stored in file folders. Electronic records, including computer files, are stored on the Commission's network and on various other electronic media as needed, including eLaw (Practice Manager) and DOT Delphi Financial System.

RETRIEVABILITY:

Records are retrievable by CFTC docket number and by the name of the debtor.

SAFEGUARDS:

Records are protected from unauthorized access and improper use through administrative, technical and physical security measures. Technical security measures within CFTC include restrictions on computer access to authorized individuals, strong passwords frequently changed, use of encryption for certain data types and transfers, and regular review of security procedures and best practices to enhance security. Physical measures include restrictions on building access to authorized individuals and maintenance of records in lockable offices and filing cabinets.

RETENTION AND DISPOSAL:

Records are retained and disposed in accordance with General Records Schedule 6 of the National Archives and Records Administration.

SYSTEM MANAGER(S) AND ADDRESS:

Office of Financial Management, Commodity Futures Trading Commission, Three Lafayette Centre, 1155 21st Street, NW., Washington, DC 20581.

NOTIFICATION PROCEDURE:

Individuals seeking to determine whether the system of records contains information about themselves, seeking access to records about themselves in the system of records or contesting the content of records about themselves should address written inquiries to the Office of General Counsel, Paralegal Specialist, Commodity Futures Trading Commission, Three Lafayette Centre, 1155 21st Street, NW., Washington, DC 20581. Telephone (202) 418–5011.

RECORD SOURCE CATEGORIES:

Commission orders, judicial orders, debtors, credit reports from commercial credit bureaus, asset search databases, Department of the Treasury, Department of Justice.

CFTC–43

SYSTEM NAME:

Visitor Information System.

SYSTEM LOCATION:

The system is located in the Office of the Executive Director, Office of Management Operations, Commodity Futures Trading Commission, Three Lafayette Centre, 1155 21st Street, NW., Washington, DC 20581.

CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

Visitors to the Commission.

CATEGORIES OF RECORDS IN THE SYSTEM:

Information from personal identity records, such as driver's license, passport, or Federal/Military ID; the number of the printed badge issued; location, date, and time of entry; company affiliation of visitor; name and phone number of the employee visited; and the purpose of the visit.

AUTHORITY FOR MAINTENANCE OF THE SYSTEM:

The Federal Property and Administrative Services Act of 1949 (63 Stat. 377), as amended; Homeland Security Presidential Directive 12 (HSPD–12), Policy for a Common Identification Standard for Federal Employees and Contractors, August 27, 2004.

PURPOSE:

The purpose of this information is to verify the identity of visitors in order to protect the employees and property of the Commission, verify that visitors entering the property are authorized to do so, and track the time, date, and location of the visitor so that, in the event of emergency, the agency can account for all the people in its space.

ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM:

Information in this system may be disclosed in accordance with the blanket routine uses numbered 1 through 19 that appear at the beginning of the Commission's compilation of its systems of records notices.

POLICIES AND PRACTICES FOR STORING, RETRIEVING, SAFEGUARDING ACCESS, RETAINING, AND DISPOSING OF RECORDS IN THE SYSTEM:

STORAGE:

Computer records are stored in a stand-alone database. Paper reports from the system are kept in a locked file.

RETRIEVABILITY:

By date and by visitor name.

SAFEGUARDS:

Records are protected from unauthorized access and improper use through administrative, technical and physical security measures. Technical security measures within CFTC include restrictions on computer access to authorized individuals, strong passwords frequently changed, use of encryption for certain data types and transfers, and regular review of security procedures and best practices to enhance security. The visitor database is a stand-alone database, not accessible through the CFTC network, and is password protected. Physical measures include restrictions on building access to authorized individuals and maintenance of records in lockable offices and filing cabinets. Written reports are kept in a locked file with limited key access.

RETENTION AND DISPOSAL:

Records will be retained for three months and then destroyed.

SYSTEM MANAGER(S) AND ADDRESS:

Deputy Director, Office of Management Operations, Commodity Futures Trading Commission, Three Lafayette Centre, 1155 21st Street, NW., Washington, DC 20581.

NOTIFICATION PROCEDURE:

Individuals seeking to determine whether this system of records contains information about themselves, or seeking access to records about themselves in the system of records, or contesting the content of records about themselves contained in this system of records should address written inquiry to the Office of General Counsel, Paralegal Specialist, Commodity Futures Trading Commission, Three Lafayette Centre, 1155 21st Street, NW., Washington, DC 20581. Telephone (202) 418–5011.

RECORD SOURCE CATEGORIES:

The individual on whom the record is maintained.

CFTC–44

SYSTEM NAME:

Personnel Security Files.

SYSTEM LOCATION:

This system is located in the Office of Human Resources, Commodity Futures Trading Commission, Three Lafayette Centre, 1155 21st Street, NW., Washington, DC 20581.

CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

Individuals who require regular, ongoing access to CFTC facilities, information technology systems, or information classified in the interest of national security, including applicants for Commission employment or

contracts, Commission employees, contractors of the Commission, students, interns, volunteers, individuals authorized to perform or use services provided in Commission facilities, and individuals formerly in any of these positions.

CATEGORIES OF RECORDS IN THE SYSTEM:

Records may include any or all of the following, depending on the individual and his or her position: Resume, OF 306, and "I–9" documents, such as copies of driver's license, passport, and birth certificate, and similar documents.

Note: This system of records does not include the Office of Personnel Management (OPM) background investigation report. An identical version of the investigation report is in the possession of the Commission, but is considered to be part of the OPM Central–9, Personnel Investigations Records. For information on how to request access to the OPM Central–9, Personnel Investigations Records, please *see* the Note in the Records Access Procedures section of this notice.

AUTHORITY FOR MAINTENANCE OF THE SYSTEM:

Depending on the purpose of the investigation, the U.S. government is authorized to ask for this information under Executive Orders 10450, 10865, 12333, 13526, and 13488; sections 3301 and 9101 of title 5, U.S. Code; sections 2165 and 2201 of title 42, U.S. Code; sections 781 to 887 of title 50, U.S. Code; parts 5, 731, 732, and 736 of title 5, Code of Federal Regulations; and Homeland Security Presidential Directive 12 (HSPD–12), Policy for a Common Identification Standard for Federal Employees and Contractors, August 27, 2004.

PURPOSE:

The records in this system are used to verify identity and to facilitate background investigations by OPM.

ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM:

Information in this system may be disclosed under the following conditions:

a. Except as noted on Forms SF 85, 85–P, and 86, when a record on its face, or in conjunction with other records, indicates a violation or potential violation of law, whether civil, criminal, or regulatory in nature, and whether arising by general statute or particular program statute, or by regulation, rule, or order issued pursuant thereto, disclosure may be made to the appropriate public authority, whether Federal, foreign, State, local, or Tribal, or otherwise, responsible for enforcing, investigating or prosecuting such violation or charged with enforcing or implementing the statute, or rule, regulation, or order issued pursuant thereto, if the information disclosed is relevant to any enforcement, regulatory, investigative or prosecutorial responsibility of the receiving entity.

b. Employment, Clearances, Contract, or Other Benefits Decision by an Organization other than the Commission—disclosure may be made to a Federal, State, local, foreign, or Tribal or other public authority of the fact that this system of records contains information relevant to the retention of an employee, the retention of a security clearance, or the letting of a contract. The other agency or licensing organization may then make a request supported by the written consent of the individual for the entire record if it so chooses. No disclosure will be made unless the information has been determined to be sufficiently reliable to support a referral to another office within the agency or to another Federal agency for criminal, civil, administrative, personnel, or regulatory action.

c. National Security and Intelligence Matters—these records may be disclosed to Federal, State, local agencies, or other appropriate entities or individuals, or through established liaison channels to selected foreign governments, in order to enable an intelligence agency to carry out its responsibilities under the National Security Act of 1947 as amended, the CIA Act of 1949 as amended, Executive Order 12333 or any successor order, applicable national security directives, or classified implementing procedures approved by the Attorney General and promulgated pursuant to such statutes, orders or directives.

Information in this system may also be disclosed in accordance with the blanket routine uses numbered 1 through 19 that appear at the beginning of the Commission's compilation of its systems of records notices.

POLICIES AND PRACTICES FOR STORING, RETRIEVING, SAFEGUARDING ACCESS, RETAINING, AND DISPOSING OF RECORDS IN THE SYSTEM:

STORAGE:

These records are maintained on paper. They are stored in a secure location in file folders and/or binders.

RETRIEVABILITY:

Files are retrieved by name.

SAFEGUARDS:

Records are protected from unauthorized access and improper use through administrative and physical security measures. Physical measures include restrictions on building access to authorized individuals and maintenance of records in lockable offices and filing cabinets. These records are kept in file folders in locked metal file cabinets in locked rooms at the headquarters office in the Office of Human Resources. Access to records is limited to approved security and administrative personnel who have a need for the information in the performance of their official duties.

RETENTION AND DISPOSAL:

These records are retained and disposed of in accordance with General Records Schedule 18, item 22b.

SYSTEM MANAGER(S) AND ADDRESS:

Manager of Employment and Compensation, Office of Human Resources, Commodity Futures Trading Commission, Three Lafayette Centre, 1155 21st Street, NW., Washington, DC 20581.

NOTIFICATION PROCEDURE:

An individual can determine if this system contains a record pertaining to him/her by sending a request in writing, signed, to the Office of General Counsel, Paralegal Specialist, Three Lafayette Centre, 1155 21st Street, NW., Washington, DC 20581. Telephone (202) 418–5011. When requesting notification of, or access to, records covered by this Notice, an individual should provide his/her full name, date of birth, agency name, and work location. An individual requesting notification of records in person must provide identity documents, such as a government-issue photo ID, sufficient to satisfy the custodian of the records that the requester is entitled to access. Individuals requesting notification via mail or telephone must furnish, at a minimum, name, date of birth, social security number, and home address in order to establish identity.

Note: For information on how to request access to the OPM Personnel Investigations Records which are part of the OPM Central–9 system of records, please *see* the Note in the Records Access Procedures section of this notice.

RECORDS ACCESS PROCEDURES:

Individuals wishing to request access to CFTC records about them should contact the system manager indicated above. Individuals must furnish their full name (first, middle, and last name) and birth date for their record to be located and identified. An individual requesting access must also follow CFTC Privacy Act requirements regarding verification of identity and amendment of records. Correspondence between the requester and OHR employees on the subject of any

background investigation and security adjudication may also be made available.

Note: The CFTC may not provide an individual with access to his/her OPM Personnel Investigations Records or to copies of OPM documentation of any background investigation conducted by OPM or contractors dealing with those investigations. These records, which are sent to the CFTC Personnel Security Office to allow adjudication of the request for security clearance, are owned by OPM and reside within the OPM Central–9 system of records. OPM is solely responsible for controlling access to, or amendment of, those records. Those seeking access to, or amendment, of those records owned by OPM should submit a request in writing to: FOI/P, Office of Personnel Management, Federal Investigative Services Division, P.O. Box 618, Boyers, PA 16018–0618. The signed request should be made under the Privacy Act of 1974 and include the requester's full name, home address, Social Security Number, and date and place of birth.

CONTESTING RECORD PROCEDURES:

Individuals wishing to request amendment of their CFTC records should contact the system manager indicated above. Individuals must furnish their full name (first, middle, and last name) and birth date for the record to be located and identified. An individual requesting amendment must also follow the CFTC Privacy Act requirements regarding verification of identity and amendment of records. (*Note:* Individuals who wish to request amendment of their OPM Personnel Investigations Records should follow the requirements of the OPM Central–9 system of records. For information on how to submit such a request, *please see* the Note in the Records Access Procedures section of this notice.)

RECORD SOURCE CATEGORIES:

Information is obtained from the individual.

Issued in Washington, DC, on January 25, 2011.

By the Commission.

David Stawick,

Secretary of the Commission.

[FR Doc. 2011–2133 Filed 2–1–11; 8:45 am]

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Part IV

Department of Defense

Defense Acquisition Regulations System

48 CFR Parts 245 and 252
Defense Federal Acquisition Regulation Supplements; Marking of Government-Furnished Property; Reporting of Government Property Lost, Stolen, Damaged, or Destroyed; Final Rules

DEPARTMENT OF DEFENSE

Defense Acquisition Regulations System

48 CFR Parts 245 and 252

[DFARS Case 2008–D050]

RIN 0750–AG44

Defense Federal Acquisition Regulation Supplement; Marking of Government-Furnished Property

AGENCY: Defense Acquisition Regulations System; Department of Defense (DoD).

ACTION: Final rule.

SUMMARY: DoD is issuing a final rule amending the Defense Federal Acquisition Regulation Supplement (DFARS) to require contractors to tag, label, or mark Government-furnished property items identified in the contract as subject to serialized item management.

DATES: *Effective Date:* February 2, 2011.

FOR FURTHER INFORMATION CONTACT: Ms. Clare Zebrowski, 703–602–0289.

SUPPLEMENTARY INFORMATION:

I. Background

This final rule provides a clause at DFARS 252.245–7001, Tagging, Labeling, and Marking of Government-Furnished Property, requiring contractors to tag, label, or mark Government-furnished property items identified in the contract when such items are subject to serialized item management. The final rule has been changed as follows—

- The proposed coverage in DFARS 211.274 has been relocated to DFARS subpart 245.1.
- DFARS 245.102(4) now provides the complete list of exceptions to the policy to require tagging, labeling, and marking of property, rather than including the exceptions in the clause, because the Government will identify to the contractor the items that require tagging, labeling, or marking. The list had been expanded to include exceptions based on determinations by the agency.
- Adds DFARS clause 252.245–7001, in lieu of proposed DFARS 252.211–70YY, to align with coverage being relocated from DFARS part 211 to part 245.
- The proposed definition of "Government-furnished property" has been deleted and replaced with a reference to the definition in FAR 52.245–1.

II. Discussion and Analysis

DoD published a proposed rule at 75 FR 25160 on May 7, 2010, and the public comment period closed on July 6, 2010. Three respondents submitted comments that are grouped into four categories. The following is a discussion of the comments and the changes included in this final rule as a result of those comments.

A. Location of Coverage

Comment: One respondent recommended that DFARS 211.274–5 should be redesignated as DFARS 245.102–70, as the mechanics for implementing this rule are not included at DFARS 211.274, but in FAR 52.245–1, Government Property.

DoD Response: The coverage has been relocated to DFARS part 245 from part 211.

Comment: One respondent recommended that the contract clause be placed in DFARS section 252.245, as opposed to DFARS 252.211.

DoD Response: DoD has made this change to coincide with the related recommendation to move the policy for marking Government-furnished property from DFARS part 211 to part 245.

B. Accountability

Comment: One respondent asked if the rule will require contractors to conduct periodic inventories, and if so, who is to receive the results of the inventories.

DoD Response: The rule does not contain a requirement for contractors to conduct physical inventories. However, the contractor is responsible under FAR 52.245–1, Government Property, paragraph (f)(1)(iv), to periodically perform, record, and disclose physical inventory results. Physical inventory results are generally provided to the assigned Government property administrator or other responsible Government official during a property management system analysis or audit.

Comment: One respondent asked if the contracting officer will be responsible for ensuring property accountability.

DoD Response: The contracting officer is responsible for ensuring that the contractor complies with all contract terms and conditions, to include Government property accountability.

Comment: One respondent asked if a chain of custody is feasible for property accountability or should accountability be delegated to a different Government official.

DoD Response: The contracting officer is responsible for ensuring compliance with the terms and conditions of the contract. However, the contracting officer may appoint a property administrator (FAR 45.101) to administer the contract requirements relating to Government property in the possession of a contractor.

Comment: One respondent recommended that the rule specifically detail a tracking procedure, which could mirror existing policy for tracking Government property throughout DoD.

DoD Response: The respondent's recommendation is outside the scope of the rule. It should be noted, however, that FAR 52.245–1, Government Property, paragraph (b)(1), already requires contractors to have a system to manage (control, use, preserve, protect, repair, and maintain) Government property in their possession.

Comment: One respondent recommended that the rule address who will be held responsible for lost, missing, or stolen property, and if contractors will be responsible for designating a responsible officer.

DoD Response: Contractor responsibility and liability requirements for lost, missing, or stolen property are provided under FAR 52.245–1, Government Property. Accordingly, it is neither necessary nor appropriate for the rule to require contractors to designate a responsible person, persons, or positions.

Comment: One respondent stated that the final rule should address the full cycle necessary to achieve the desired end-state of accountability and control.

DoD Response: The end-state to which the respondent refers is based on a variety of factors, many of which are beyond the scope of this rule. However, the tagging, labeling, and marking requirements contained in this rule are important enablers toward the desired end-state of accountability and control. Contractor responsibilities for accountability and control are provided under FAR 52.245–1, Government Property.

C. Policy

Comment: One respondent recommended a cross reference at 211.274–5 to policy at 245.102–70, with addition of policy at DFARS 245.102–70 regarding the requirement for contractors to tag, label, or mark items of Government-furnished property identified in the contract when the Government-furnished material and Government-furnished property are subject to serialized item management.

DoD Response: DoD has moved the entire discussion of policy to 245.102(4).

Comment: One respondent recommended that the rule address potential conflicts with related sections of the CFR.

DoD Response: DoD is unable to respond in detail to the comment as the respondent did not identify any specific potential conflicts.

Comment: One respondent asked if marked items will be annotated in the initial contract documents. Another respondent recommended that the Government provide drawings and instructions to the contractor on how and where to mark the Government-furnished property.

DoD Response: The rule requires identification in the contract of all Government-furnished property subject to serialized item management, in accordance with Procedures, Guidance, and Information 245.201–71, GFP attachments to solicitations and awards.

Comment: One respondent recommended that the rule include a reference to 48 CFR (DFARS) 245.105.

DoD Response: The requirements of DFARS 245.105 are not directed at contractors. Rather, they are directed at the Government agency responsible for contract administration. Contractor responsibilities for accountability and control are provided under FAR 52.245–1, Government Property.

D. Exceptions

Comment: One respondent asked what the impact of the rule is on the exceptions listed in 48 CFR (DFARS) 211.274–2(b).

DoD Response: The exceptions at 211.274–2 are exceptions to the requirement that the contractor be required to provide DoD unique item identification for delivered items based on determinations by the agency. The impact to the rule of not including the exceptions at DFARS 211.274–2(b) would be to create inconsistency in application of contractor requirements for marking, tagging, and labeling. While the exceptions at DFARS 211.274–2(b) apply to new deliverables, the principle applies to Government-furnished property as well. In recognition of this, DoD has addressed the potential inconsistent application by including these exceptions in the final rule. The exceptions listed at DFARS 211.274–2(b) have been added to DFARS 245.102(4).

Comment: One respondent asked if the exceptions to UID reporting for Government-furnished equipment at DFARS 211.274–4 are to remain unchanged, or will the section now only apply to non-Government-furnished contractor property.

DoD Response: The exceptions cited in DFARS 211.274–4 apply to the reporting requirements under DFARS 252.211–7007, Reporting of Government-Furnished Equipment in the DoD Item Unique Identification Registry. The exceptions do not apply to the requirements of this rule.

Comment: One respondent recommended that the rule include specific language assuring that contractor-acquired special tooling and special test equipment, having been physically marked by the contractor, and subsequently transferred in-place, does not have to be retagged, relabeled, or remarked until the tooling or test equipment leaves the contractor's possession or accountability.

DoD Response: The exception provided at paragraph (c)(1) of the proposed clause was sufficient to cover this concern. This statement has been retained in paragraph (c) of the final clause, to ensure that the contractor does not need to tag, label, or mark Government-furnished property that has already been tagged, labeled, or marked.

E. Definition

Comment: One respondent recommended that the definition of "Government-furnished property" not be repeated in the rule since it appears in both FAR part 45 and 52.245–1.

DoD Response: The final rule has been changed to reference the FAR definition.

F. Clause Prescription

Comment: One respondent recommended deleting the proposed reference at DFARS 211.274–6 to FAR 52.245–2, Government Property Installation Operation Services, as a condition for use of DFARS 252.245–70YY.

DoD Response: Use of the clause at 252.245–7001, Tagging, Labeling, and Marking of Government-Furnished Property, is not dependent on the presence of FAR 52.252–2. The new clause prescription at DFARS 245.107 now refers only to the presence of the FAR clause 52.245–1, Government Property.

G. Applicability to international and FMS contracts

Comment: One respondent asked if the rule applies to foreign Government and international contracts under 48 CFR (DFARS) 245.3.

DoD Response: The rule applies to contracts with foreign Governments and international organizations under DFARS 245.3.

Comment: One respondent asked about the impact on FMS sales.

DoD Response: The security assistance community will derive the same tagging, labeling, and marking benefits of this rule. The new DFARS clause is mandatory for all DoD contracts that contain the FAR clause 52.245–1, Government Property, including those for foreign customers.

H. Applicability to existing contracts

Comment: One respondent noted that on-going contracts were not priced to consider the implementation of this rule. Therefore, there may be a need for pricing adjustments for those contracts.

DoD Response: The clause does not apply to existing contracts unless the contracting officer executes a bilateral contract modification, consistent with FAR 1.108(d), which would require consideration.

III. Executive Order 12866

This is not a significant regulatory action and, therefore, was not subject to review under Section 6(b) of Executive Order 12866, Regulatory Planning and Review, dated September 30, 1993. This rule is not a major rule under 5 U.S.C. 804.

IV. Regulatory Flexibility Act

DoD has prepared a final regulatory flexibility analysis consistent with 5 U.S.C. 604. A copy of the analysis may be obtained from the individual specified herein. The analysis is summarized as follows:

The objective of the rule is to improve the accountability and control of DoD assets. The tagging, labeling, and marking requirements are consistent with DoD's use of unique identifiers to track and trace property items throughout their lifecycle. Three respondents provided twenty-three comments on the proposed rule. None of the comments was in response to the initial regulatory flexibility analysis. Therefore, there is no change to the rule in this regard.

The rule will apply to DoD contractors provided with Government-furnished property that is subject to serialized item management. The clause at DFARS 252.211–7001, Tagging, Labeling, and Marking of Government-Furnished Property, requires the contractor to tag, label, or mark Government-furnished property items identified in the contract when the requiring activity determines that such items are subject to serialized item management (serially-managed items).

This final rule is not expected to have a significant economic impact on a substantial number of small entities within the meaning of the Regulatory Flexibility Act, 5 U.S.C. 601, *et seq.,*

because any start-up costs that contractors will incur to comply with the rule are expected to be minimal.

Moreover, the rule excludes items, as determined by the head of the agency, that are to be used to support a contingency operation; or to facilitate defense against or recovery from nuclear, biological, chemical, or radiological attack; or for which a determination and findings has been executed concluding that it is more cost effective for the Government requiring activity to assign, mark, and register the unique item identification after delivery of an item acquired from a small business concern or a commercial item acquired under FAR part 8 or part 12.

The rule does not duplicate, overlap, or conflict with any other Federal rules. DoD considers the approach described in the rule to be the most practical and beneficial for both Government and industry.

V. Paperwork Reduction Act

The Paperwork Reduction Act (Pub. L. 96–511) does not apply because the rule does not impose additional information collection requirements that require the approval of the Office of Management and Budget under 44 U.S.C. 3501, *et seq.*

List of Subjects in 48 CFR Parts 245 and 252

Government procurement.

Ynette R. Shelkin,

Editor, Defense Acquisition Regulations System.

Therefore, 48 CFR parts 245 and 252 are amended as follows:

■ 1. The authority citation for 48 CFR parts 245 and 252 continues to read as follows:

Authority: 41 U.S.C. 421 and 48 CFR chapter 1.

PART 245—GOVERNMENT PROPERTY

■ 2. In section 245.102, paragraph (4) is added to read as follows:

245.102 Policy.

* * * * *

(4) *Government-furnished property identification.*

(i) It is DoD policy that Government-furnished property be tagged, labeled, or marked based on DoD marking standards (MIL Standard 130) or other standards, when the requiring activity determines that such items are subject to serialized item management (serially-managed items). The list of Government-furnished property subject to serialized item management will be identified in the contract in accordance with PGI 245.201–71, GFP attachments to solicitations and awards.

(ii) *Exceptions.* The Contractor will not be required to tag, label, or mark—

(A) Government-furnished property that was previously tagged, labeled, or marked;

(B) Items, as determined by the head of the agency, that are to be used to support a contingency operation; or to facilitate defense against or recovery from nuclear, biological, chemical, or radiological attack;

(C) Items for which a determination and findings has been executed concluding that it is more cost effective for the Government requiring activity to assign, mark, and register the unique item identification after delivery of an item acquired from a small business concern or a commercial item acquired under FAR part 12 or part 8.

(*1*) The determination and findings shall be executed by—

(*i*) The Component Acquisition Executive for an Acquisition Category (ACAT) I program; or

(*ii*) The head of the contracting activity for all other programs.

(*2*) A copy of the executed determination and findings shall be provided to the DoD Unique Item Identification Policy Office at this address: OUSD (AT&L) DPAP/Program Development and Implementation, Room 3B855, 3060 Defense Pentagon, Washington, DC 20301–3060; or by facsimile to 703–602–6047.

(D) Items that are contractor-acquired property;

(E) Property under any statutory leasing authority;

(F) Property to which the Government has acquired a lien or title solely because of partial, advance, progress, or performance-based payments;

(G) Intellectual property or software; or

(H) Real property.

245.107–70 [Redesignated as 245.107]

■ 3. Section 245.107–70 is redesignated as 245.107 and revised to read as follows:

245.107 Contract clauses.

(a) Use the clause at 252.245–7000, Government-Furnished Mapping, Charting, and Geodesy Property, in solicitations and contracts when mapping, charting, and geodesy property is to be furnished.

(b) Use the clause at 252.245–7001, Tagging, Labeling, and Marking of Government-Furnished Property, in solicitations and contracts that contain the clause at FAR 52.245–1, Government Property.

PART 252—SOLICITATION PROVISIONS AND CONTRACT CLAUSES

■ 4. In section 252.245–7000, the introductory text is amended by removing "245.107–70" and adding in its place "245.107(a)".

■ 5. Add section 252.245–7001 to read as follows:

252.245–7001 Tagging, Labeling, and Marking of Government-Furnished Property

As prescribed in 245.107(b), use the following clause:

TAGGING, LABELING, AND MARKING OF GOVERNMENT-FURNISHED PROPERTY (FEB 2011)

(a) *Definitions.* As used in this clause—

Government-furnished property is defined in the clause at FAR 52.245–1, Government Property.

Serially-managed item means an item designated by DoD to be uniquely tracked, controlled, or managed in maintenance, repair, and/or supply systems by means of its serial number.

(b) The Contractor shall tag, label, or mark Government-furnished property items identified in the contract as subject to serialized item management (serially-managed items).

(c) The Contractor is not required to tag, label, or mark Government-furnished property previously tagged, labeled, or marked.

(End of clause)

[FR Doc. 2011–2043 Filed 2–1–11; 8:45 am]

BILLING CODE 5001–08–P

DEPARTMENT OF DEFENSE

Defense Acquisition Regulations System

48 CFR Parts 245 and 252

[DFARS Case 2008–D049]

RIN 0750–AG64

Defense Federal Acquisition Regulation Supplement; Reporting of Government Property Lost, Stolen, Damaged, or Destroyed

AGENCY: Defense Acquisition Regulations System; Department of Defense (DoD).

ACTION: Final rule.

SUMMARY: DoD is issuing a final rule amending the Defense Federal Acquisition Regulation Supplement (DFARS) to require contractors to report loss of Government property to the Defense Contract Management Agency (DCMA) eTools application.

DATES: *Effective Date:* February 2, 2011.

FOR FURTHER INFORMATION CONTACT: Ms. Clare Zebrowski, 703–602–0289.

SUPPLEMENTARY INFORMATION:

I. Background

This final rule provides a clause at DFARS 252.245–7002, Reporting Loss of Government Property, that requires DoD contractors to report the loss, theft, damage, and destruction of Government property to the DCMA eTools application. The final rule changes—

- DFARS 245.102(4), Policy, to make editorial changes to remove subparagraphs that unnecessarily duplicate language contained in the clause at 252.245–7002, Reporting Loss of Government Property. This paragraph has been redesignated as 245.102(5).
- DFARS 245.107(2), Contract clauses, to correct the prescription for use of the clause at 252.245–7002, Reporting Loss of Government Property, by removing the reference to FAR 52.245–2, Government Property Installation Operation Services. This paragraph has been redesignated as 245.107(c).
- Clause 252.245–7002, Reporting Loss of Government Property, to—
  - Revise the clause title;
  - Change the defined term "acquisition cost" to "unit acquisition cost" and expand the definition to include contractor-acquired property;
  - Revise the definition for "Government property" to state that the term is defined in the clause at FAR 52.245–1, Government Property;
  - Add a new definition for "loss of Government property";
  - Revise the paragraph (b) title and (b)(1) to accommodate the new definition of "Loss of Government property".
  - Revise paragraph (b)(1) to add the word "unit" to reflect that reporting value shall be at "unit acquisition cost," and to provide an updated Web page for accessing the eTools application;
- Revise paragraph (b)(3) to make editorial and format changes;
- Revise paragraph (b)(4) to make editorial changes and to delete reference to two specific property clauses and instead state that the reporting requirements do not change any other liability or other reporting requirement that may exist under the contract.

II. Discussion and Analysis

Three respondents submitted four comments on the proposed rule, which was published at 75 FR 22729 on April 30, 2010. Comments were due June 29, 2010. A discussion of the comments received follows:

A. Clause Prescription

Comment: One respondent recommended revising paragraph 245.107(2) to remove the reference to FAR 52.245–2, Government Property Installation Operation Services, as the loss of property reporting requirement stems directly from FAR 52.245–1 and not from 52.245–2.

DoD Response: DoD has revised the language accordingly.

B. Definition of "Government Property"

Comment: One respondent recommended that the definition of "Government property" in the proposed clause should make clear that it includes all property acquired by the contractor through indirect cost accounts.

DoD Response: The recommendation is outside the scope of the rule. The rule does not seek to alter or modify the definition of Government property as prescribed in the Federal Acquisition Regulations (FAR 52.245–1). However, in order to clarify the Government property definition, DoD has replaced the definition of "Government property" in the clause with a reference to the definition of "Government property" in FAR 52.245–1.

C. Use of Term "Losses"

Comment: One respondent recommended modifying the clause language in paragraph (b) to replace the term "lost, stolen, damaged, or destroyed" with "losses" to maintain simplicity and consistency.

DoD Response: A new definition for "loss of Government property" has been added to the clause at 252.245–7002, Reporting Loss of Government Property.

D. Definition of "Estimated Harm"/ "Acquisition Cost"

Comment: One respondent recommended adding a new definition of "estimated harm" to the proposed clause at 252.245–70XX and stated that estimated harm should consider other factors such as residual value, replacement cost, and care and handling cost. The respondent stated that the estimated harm should be expressed as a numeric value, and that providing only the acquisition cost without providing estimated harm to the Government is misleading and may result in poor decisions. According to the respondent, industry experience has proven that there typically is minimal or no harm to the Government and, even though the Government is self insured, replacement of lost items rarely occurs.

Similarly, a respondent stated the need to address the materiality of the loss and that without this information, decision makers may be misled and losses may be overstated. Further, according to the respondent, the rule should then explain how to compensate the Government for losses when the "indirect costs used to buy the property" have been partially allocated to Government contracts and partially allocated to commercial work or firm-fixed-price contracts.

DoD Response: These recommendations are outside the scope of the rule. The clause seeks only to require the electronic reporting of data pertaining to Government property losses. It does not require reporting of the estimated harm or materiality of such losses to the Government.

However, in order to clarify the reporting value, the clause definition of "acquisition cost" has been revised to a definition of "unit acquisition cost." The new definition clarifies that for Government-furnished property, the unit acquisition cost is the dollar value assigned by the Government and identified in the contract; and adds the method for determining the reporting value for contractor-acquired property. The revised definition is more comprehensive and clarifies the property values to be reported.

The final rule also revises paragraph (b)(4) of the clause to remove the references to 52.245–1 and 52.245–2, since the contract may contain other liability or other reporting requirements. This change clarifies that the new clause does not impact any other contractual reporting or liability requirements.

III. Executive Order 12866

This rule was not subject to Office of Management and Budget review under Executive Order 12866, dated September 30, 1993. This rule is not a major rule under 5 U.S.C. 804.

IV. Regulatory Flexibility Act

DoD has prepared a final regulatory flexibility analysis consistent with 5 U.S.C. 604. A copy of the analysis may be obtained from the individual specified herein. The analysis is summarized as follows:

The objective of this rule is to provide DoD with a single repository for reporting loss of Government property to improve accountability and control of DoD assets and contractor oversight.

None of the comments from the three respondents was in response to the initial regulatory flexibility analysis. Therefore, there is no change to the rule in this regard.

The rule applies to DoD contractors provided with Government property. The clause at 252.245–7002, Reporting Loss of Government Property, requires the contractor to use the Defense Contract Management Agency eTools software application for reporting loss of

Government property. The eTools software can be accessed from the DCMA homepage External Web Access Management application at *http://www.dcma.mil/aboutetools.cfm*.

Unless otherwise provided for in the contract, these requirements do not apply to normal and reasonable inventory adjustments, *i.e.,* losses of low-risk consumable material such as common hardware, as agreed to by the contractor and the Government property administrator. Such losses are typically a product of normal process variation. The contractor shall ensure that its property management system provides adequate management control measures, *e.g.,* statistical process controls, as a means of managing such variation.

Reporting requirements apply to losses of Government property outside normal process variation, *e.g.,* because of—

(1) Theft;

(2) Inadequate storage;

(3) Inadequate security; or

(4) "Acts of God."

This rule is not expected to have a significant economic impact on a substantial number of small entities within the meaning of the Regulatory Flexibility Act, 5 U.S.C. 601, *et seq.,* because any start-up costs that contractors will incur to comply with the rule are expected to be minimal. The rule is expected to have a positive or beneficial impact on small entities by making available a Government-provided software application to use for reporting purposes. The rule does not duplicate, overlap, or conflict with any other Federal rules.

V. Paperwork Reduction Act

This final rule does not significantly increase the information collection requirements set forth under FAR 52.245–1(f)(vi), approved by the Office of Management and Budget under OMB clearance number 9000–0075. The rule will have a minimal impact on contractors, as such reporting is already common practice and is on an exception basis, *i.e.,* only when reportable property is lost. There were no comments received on the proposed rule concerning information collection.

List of Subjects in 48 CFR Parts 245 and 252

Government procurement.

Ynette R. Shelkin,

Editor, Defense Acquisition Regulations System.

Therefore, 48 CFR parts 245 and 252 are amended as follows:

■ 1. The authority citation for 48 CFR parts 245 and 252 continues to read as follows:

Authority: 41 U.S.C. 421 and 48 CFR chapter 1.

PART 245—GOVERNMENT PROPERTY

245.102 Policy.

■ 2. Section 245.102 is amended by adding paragraph (5) to read as follows:

* * * * *

(5) *Reporting loss of Government property.* The Defense Contract Management Agency (DCMA) eTools software application is the DoD data repository for reporting loss of Government property in the possession of contractors. The requirements and procedures for reporting loss of Government property to eTools are set forth in the clause at 252.245–7002, Reporting Loss of Government Property, prescribed at 245.107.

■ 3. Section 245.107 is amended by adding paragraph (c) to read as follows:

245.107 Contract clauses.

* * * * *

(c) Use the clause at 252.245–7002, Reporting Loss of Government Property, in solicitations and contracts that contain the clause at FAR 52.245–1, Government Property.

PART 252—SOLICITATION PROVISIONS AND CONTRACT CLAUSES

■ 4. Add section 252.245–7002 to read as follows:

252.245–7002 Reporting Loss of Government Property.

As prescribed in 245.107(c), use the following clause:

REPORTING LOSS OF GOVERNMENT PROPERTY (FEB 2011)

(a) *Definitions.* As used in this clause—

Government property is defined in the clause at FAR 52.245–1, Government Property.

Loss of Government property means unintended, unforeseen, or accidental loss, damage, or destruction of Government property that reduces the Government's expected economic benefits of the property. Loss of Government property does not include purposeful destructive testing, obsolescence, normal wear and tear, or manufacturing defects. Loss of Government property includes, but is not limited to—

(1) Items that cannot be found after a reasonable search;

(2) Theft;

(3) Damage resulting in unexpected harm to property requiring repair to restore the item to usable condition; or

(4) Destruction resulting from incidents that render the item useless for its intended purpose or beyond economical repair.

Unit acquisition cost means—

(1) For Government-furnished property, the dollar value assigned by the Government and identified in the contract; and

(2) For Contractor-acquired property, the cost derived from the Contractor's records that reflect consistently applied, generally acceptable accounting principles.

(b) *Reporting loss of Government property.* (1) The Contractor shall use the Defense Contract Management Agency (DCMA) eTools software application for reporting loss of Government property. Reporting value shall be at unit acquisition cost. The eTools "LTDD of Government Property" toolset can be accessed from the DCMA home page External Web Access Management application at *http://www.dcma.mil/aboutetools.cfm.*

(2) Unless otherwise provided for in this contract, the requirements of paragraph (b)(1) of this clause do not apply to normal and reasonable inventory adjustments, *i.e.,* losses of low-risk consumable material such as common hardware, as agreed to by the Contractor and the Government Property Administrator. Such losses are typically a product of normal process variation. The Contractor shall ensure that its property management system provides adequate management control measures, *e.g.,* statistical process controls, as a means of managing such variation.

(3) The Contractor shall report losses of Government property outside normal process variation, *e.g.,* losses due to—

(i) Theft;

(ii) Inadequate storage;

(iii) Lack of physical security; or

(iv) "Acts of God."

(4) This reporting requirement does not change any liability provisions or other reporting requirements that may exist under this contract.

(End of clause)

[FR Doc. 2011–2044 Filed 2–1–11; 8:45 am]

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Part V

Securities and Exchange Commission

17 CFR 229, 240, and 249

Shareholder Approval of Executive Compensation and Golden Parachute Compensation; Final Rule

SECURITIES AND EXCHANGE COMMISSION

17 CFR Parts 229, 240 and 249

[Release Nos. 33–9178; 34–63768; File No. S7–31–10]

RIN 3235–AK68

Shareholder Approval of Executive Compensation and Golden Parachute Compensation

AGENCY: Securities and Exchange Commission.

ACTION: Final rule.

SUMMARY: We are adopting amendments to our rules to implement the provisions of the Dodd-Frank Wall Street Reform and Consumer Protection Act relating to shareholder approval of executive compensation and "golden parachute" compensation arrangements. Section 951 of the Dodd-Frank Act amends the Securities Exchange Act of 1934 by adding Section 14A, which requires companies to conduct a separate shareholder advisory vote to approve the compensation of executives, as disclosed pursuant to Item 402 of Regulation S–K or any successor to Item 402. Section 14A also requires companies to conduct a separate shareholder advisory vote to determine how often an issuer will conduct a shareholder advisory vote on executive compensation. In addition, Section 14A requires companies soliciting votes to approve merger or acquisition transactions to provide disclosure of certain "golden parachute" compensation arrangements and, in certain circumstances, to conduct a separate shareholder advisory vote to approve the golden parachute compensation arrangements.

DATES: *Effective Date:* April 4, 2011.

Compliance Date: April 4, 2011, except that issuers must comply with Exchange Act Section 14A(b) and Rule 14a–21(c) and the amendments to Item 5 of Schedule 14A, Item 3 of Schedule 14C, Item 1011 of Regulation M–A, Item 11 of Schedule TO, Item 15 of Schedule 13E–3, and Item 8 of Schedule 14D–9 for initial preliminary proxy and information statements, Schedules TO, 13E–3, and 14D–9 and Forms S–4 and F–4 filed on or after April 25, 2011.

Companies that qualify as "smaller reporting companies" (as defined in 17 CFR 240.12b–2) as of January 21, 2011, including newly public companies that qualify as smaller reporting companies after January 21, 2011, will not be subject to Exchange Act Section 14A(a) and Rule 14a–21(a) and (b) until the first annual or other meeting of shareholders at which directors will be elected and for which the rules of the Commission require executive compensation disclosure pursuant to Item 402 of Regulation S–K (17 CFR 229.402) occurring on or after January 21, 2013.

FOR FURTHER INFORMATION CONTACT: Scott Hodgdon, Attorney-Adviser, at (202) 551–3430, Anne Krauskopf, Senior Special Counsel, at (202) 551–3500, or Perry Hindin, Special Counsel, at (202) 551–3440, Division of Corporation Finance, U.S. Securities and Exchange Commission, 100 F Street, NE., Washington, DC 20549–3628.

SUPPLEMENTARY INFORMATION: We are adopting new Rule 14a–21 and amendments to Rules 14a–4,[1] 14a–6,[2] 14a–8[3] and a new Item 24 and amendments to Item 5 of Schedule 14A[4] and amendments to Item 3 of Schedule 14C[5] under the Securities Exchange Act of 1934 ("Exchange Act").[6] We are also adopting amendments to Item 402[7] of Regulation S–K,[8] Item 1011[9] of Regulation M–A,[10] Item 15 of Schedule 13E–3,[11] Item 8 of Schedule 14D–9,[12] Item 11 of Schedule TO,[13] and amendments to Item 5.07 of Form 8–K.[14]

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[1] 17 CFR 240.14a–4.
[2] 17 CFR 240.14a–6.
[3] 17 CFR 240.14a–8.
[4] 17 CFR 240.14a–101.
[5] 17 CFR 240.14c–101.
[6] 15 U.S.C. 78a *et seq.*
[7] 17 CFR 229.402.
[8] 17 CFR 229.10 *et seq.*
[9] 17 CFR 229.1011.
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I. Background and Summary

On October 18, 2010, we proposed a number of amendments to our rules relating to the shareholder approval of executive compensation and golden parachute compensation.[15] We proposed these rules to implement Section 951 of the Dodd-Frank Wall Street Reform and Consumer Protection Act (the "Act").[16] As discussed in detail below, we have taken into consideration the comments received on the proposed amendments and are adopting several amendments to our rules.[17]

The Act amends the Exchange Act by adding new Section 14A. New Section 14A(a)(1) requires that "[n]ot less frequently than once every 3 years, a proxy or consent or authorization for an annual or other meeting of the shareholders for which the proxy solicitation rules of the Commission require compensation disclosure shall include a separate resolution subject to shareholder vote to approve the compensation of executives,"[18] as disclosed pursuant to Item 402 of Regulation S–K, or any successor to Item 402 (a "say-on-pay vote"). The shareholder vote to approve executive compensation required by Section 14A(a)(1) "shall not be binding on the issuer or the board of directors of an issuer."[19]

Section 951 of the Act also adds new Section 14A(a)(2) to the Exchange Act, requiring that, "[n]ot less frequently than once every 6 years, a proxy or consent or authorization for an annual or other meeting of the shareholders for which the proxy solicitation rules of the Commission require compensation disclosure shall include a separate resolution subject to shareholder vote to determine whether [the say-on-pay vote] will occur every 1, 2, or 3 years."[20] As discussed below, this shareholder vote "shall not be binding on the issuer or the board of directors of an issuer."[21]

In addition, Section 951 of the Act amends the Exchange Act by adding new Section 14A(b)(1), which requires that, in any proxy or consent solicitation material for a meeting of shareholders "at which shareholders are asked to approve an acquisition, merger, consolidation, or proposed sale or other disposition of all or substantially all the assets of an issuer, the person making such solicitation shall disclose in the proxy or consent solicitation material, in a clear and simple form in accordance with regulations to be promulgated by the Commission, any agreements or understandings that such person has with any named executive officers of such issuer (or of the acquiring issuer, if such issuer is not the acquiring issuer) concerning any type of compensation (whether present, deferred, or contingent) that is based on or otherwise relates to the acquisition, merger, consolidation, sale or other disposition of all or substantially all of the assets of the issuer[* * *]."[22] These compensation arrangements are often referred to as "golden parachute" compensation. Such disclosure must include the aggregate total of all such compensation that may be paid or become payable to or on behalf of such named executive officer, and the conditions upon which it may be paid or become payable.[23] Under Section 14A(b)(2), "unless such agreements or understandings have been subject to [the periodic shareholder vote described in Section 14A(a)(1)]," [24] a separate shareholder vote to approve such agreements or understandings and compensation as disclosed is also required.[25] As with the say-on-pay vote and the shareholder vote on the frequency of such votes, this shareholder vote "shall not be binding on the issuer or the board of directors of an issuer."[26]

In addition to their non-binding status, none of the shareholder votes required pursuant to Section 14A is to be construed "as overruling a decision by such issuer or board of directors."[27] These shareholder votes also do not "create or imply any change to the fiduciary duties of such issuer or board of directors"[28] nor do they "create or imply any additional fiduciary duties for such issuer or board of directors."[29] Further, these votes will not be construed "to restrict or limit the ability of shareholders to make proposals for inclusion in proxy materials related to executive compensation."[30] Section 14A also provides that "the Commission may, by rule or order, exempt an issuer or class of issuers" from the shareholder

[15] See Release No. 33–9153 (October 18, 2010) [75 FR 66590] (the "Proposing Release").

[16] Public Law 111–203 (July 21, 2010).

[17] The public comments we received on the Proposing Release are available on our Web site at *http://www.sec.gov/comments/s7-31-10/s73110.shtml.* In addition, to facilitate public input on the Act, the Commission provided a series of e-mail links, organized by topic, on its Web site at *http://www.sec.gov/spotlight/regreformcomments.shtml.* The public comments we received on Section 951 of the Act are available on our Web site *at http://www.sec.gov/comments/df-title-ix/executive-compensation/executive-compensation.shtml.*

[18] Exchange Act Section 14A(a)(1). Section 951 of the Act includes the language "or other meeting of the shareholders," which is similar to corresponding language in Section 111(e)(1) of the Emergency Economic Stabilization Act of 2008, or EESA, 12 U.S.C. 5221. As noted in the Proposing Release, we have previously considered this language in connection with companies required to provide a separate shareholder vote on executive compensation so long as the company has outstanding obligations under the Troubled Asset Relief Program, or TARP. *See Shareholder Approval of Executive Compensation of TARP Recipients,* Release No. 34–61335 (Jan. 12, 2010) [75 FR 2789] (hereinafter, the "TARP Adopting Release"). We continue to view this provision to require a separate shareholder vote on executive compensation only with respect to an annual meeting of shareholders for which proxies will be solicited for the election of directors, or a special meeting in lieu of such annual meeting. Similarly, Rules 14a–21(a) and (b) are intended to result in issuers conducting the required advisory votes in connection with the election of directors, the proxy materials for which are required to include disclosure of executive compensation.

[19] Exchange Act Section 14A(c).

[20] Exchange Act Section 14A(a)(2).

[21] Exchange Act Section 14A(c).

[22] Exchange Act Section 14A(b)(1).

[23] Exchange Act Section 14A(b)(1).

[24] Exchange Act Section 14A(b)(2).

[25] Exchange Act Section 14A(b)(2).

[26] Exchange Act Section 14A(c).

[27] Exchange Act Section 14A(c)(1).

[28] Exchange Act Section 14A(c)(2).

[29] Exchange Act Section 14A(c)(3).

[30] Exchange Act Section 14A(c)(4). In addition, Exchange Act Section 14A(d) provides that every institutional manager subject to Exchange Act Section 13(f) [15 U.S.C. 78m(f)] shall report at least annually how it voted on any shareholder vote required by Section 951 of the Act, including the shareholder vote on executive compensation, the shareholder vote on the frequency of shareholder votes on executive compensation, and the golden parachute compensation vote, unless such vote is otherwise required to be reported publicly by rule or regulation of the Commission. Amendments to our rules to implement this requirement were proposed in a separate rulemaking. *See Reporting of Proxy Votes on Executive Compensation and Other Matters,* Release No. 34–63123 (Oct. 18, 2010) [75 FR 66622].

advisory votes required by Section 14A.[31] In determining whether to make an exemption, the Commission is directed to take into account, among other considerations, whether the requirements of Section 14A(a) and (b) disproportionately burden small issuers.[32]

Section 14A(a)(3) requires that both the initial shareholder vote on executive compensation and the initial vote on the frequency of votes on executive compensation be included in proxy statements "for the first annual or other meeting of the shareholders occurring after the end of the 6-month period beginning on the date of enactment" of the Act.[33] Thus, the statute requires separate resolutions subject to shareholder vote to approve executive compensation and to approve the frequency of say-on-pay votes for proxy statements relating to an issuer's first annual or other meeting of the shareholders occurring on or after January 21, 2011, whether or not the Commission has adopted rules to implement Section 14A(a). Because Section 14A(a) applies to shareholder meetings taking place on or after January 21, 2011, any proxy statement that is required to include executive compensation disclosure pursuant to Item 402 of Regulation S–K, whether in preliminary or definitive form, even if filed prior to this date, for meetings taking place on or after January 21, 2011, must include the separate resolutions for shareholders to approve executive compensation and the frequency of say-on-pay votes required by Section 14A(a) without regard to whether the amendments in this release are in effect by that time.[34]

With respect to the disclosure of golden parachute arrangements in accordance with Commission regulations in merger proxy statements required by Section 14A(b)(1), we note that the statute similarly references a 6-month period beginning on the date of enactment of the Act. However, because the statute requires such disclosure to be "in accordance with regulations to be promulgated by the Commission,"[35] the golden parachute compensation arrangements disclosure under proposed new Item 402(t) and a separate resolution to approve golden parachute compensation arrangements pursuant to Rule 14a–21(c) will not be required for merger proxy statements relating to a meeting of shareholders until the effective date of our rules implementing Section 14A(b)(1). The rule amendments we adopt today with respect to new Rule 14a–21(c) and the amendments to the disclosure requirements in Item 5 of Schedule 14A, Item 3 of Schedule 14C, Item 1011 of Regulation M–A, Item 11 of Schedule TO, Item 15 of Schedule 13E–3, and Item 8 of Schedule 14D–9, are effective for initial filings on or after April 25, 2011.

We received over 60 comment letters in response to the proposed amendments. In addition, we received over a dozen letters relating to Section 951 of the Act.[36] These letters came from corporations, pension funds, professional associations, trade unions, law firms, consultants, academics, individual investors, and other interested parties. In general, the commentators supported the proposed amendments that would implement Section 951 of the Act. Some commentators, however, opposed some of the proposed amendments and suggested modifications or alternatives to the proposals.

We have reviewed and considered all of the comments that we received relating to the proposed amendments. The adopted rules reflect changes made in response to many of these comments. We discuss our revisions with respect to each proposed rule amendment in more detail throughout this release.

We are adopting Rule 14a–21 to provide a separate shareholder vote to approve executive compensation, to approve the frequency of such votes on executive compensation and to approve golden parachute compensation arrangements in connection with certain extraordinary business transactions. We are also adopting a new Item 24 of Schedule 14A to provide disclosure regarding the effect of the shareholder votes required by Rule 14a–21, such as whether each vote is non-binding. In addition, our amendments to Item 5 of Schedule 14A, Item 3 of Schedule 14C, Item 1011 of Regulation M–A, Item 8 of Schedule 14D–9, and Item 15 of Schedule 13E–3 will require additional disclosure regarding golden parachute arrangements in connection with certain extraordinary business transactions, Rule 13e–3[37] going-private transactions and tender offers.

We are also adopting amendments to Item 402 of Regulation S–K to require disclosure of an issuer's consideration of the say-on-pay vote in its Compensation Discussion and Analysis, and to prescribe disclosure about golden parachute compensation arrangements in new Item 402(t). In addition, we are adopting an instruction to Rule 14a–8 to clarify the treatment of shareholder proposals relating to the shareholder advisory votes required by Rule 14a–21. Finally, we are adopting amendments to Form 8–K to facilitate disclosure of the results of the shareholder advisory vote on the frequency of say-on-pay votes, and to require disclosure about whether and how the issuer will implement the results of the shareholder advisory vote on the frequency of say-on-pay votes.

II. Discussion of the Amendments

A. Shareholder Approval of Executive Compensation

1. Rule 14a–21(a)

Proposed Rule 14a–21(a) would require issuers,[38] not less frequently than once every three years, to include in their proxy statements a separate shareholder advisory vote to approve the compensation of executives. We are adopting the rule substantially as proposed with some changes in response to comments.

a. Proposed Rule

Under our proposed rule, an issuer would be required, not less frequently than once every three years, to provide a separate shareholder advisory vote in proxy statements to approve the compensation of its named executive officers, as defined in Item 402(a)(3)[39] of Regulation S–K. Rule 14a–21(a), as proposed, would specify that the separate shareholder vote on executive compensation is required only when proxies are solicited for an annual or other meeting of security holders for which our rules require the disclosure of executive compensation pursuant to Item 402 of Regulation S–K. Proposed Rule 14a–21(a) would require a separate shareholder vote to approve the compensation of executives for the first annual or other such meeting of shareholders occurring on or after January 21, 2011, the first day after the end of the 6-month period beginning on the date of enactment of the Act.

In accordance with Section 14A(a)(1), shareholders would vote to approve the compensation of the issuer's named

[31] Exchange Act Section 14A(e).

[32] Exchange Act Section 14A(e).

[33] Exchange Act Section 14A(a)(3).

[34] See Section II.E below for a discussion of a temporary exemption for smaller reporting companies.

[35] Exchange Act Section 14A(b)(1).

[36] These comment letters were received prior to publication of the Proposing Release. See note 17 above.

[37] 17 CFR 240.13e–3.

[38] Our rules as adopted apply to issuers who have a class of equity securities registered under Section 12 [15 U.S.C. 78*l*] of the Exchange Act and are subject to our proxy rules. Foreign private issuers, as defined in Rule 3b–4(c) [17 CFR 240.3b–4(c)], are not required under Section 14A or the rules we are adopting today to conduct a shareholder advisory vote on executive compensation nor a shareholder advisory vote on the frequency of such votes.

[39] 17 CFR 229.402(a)(3).

executive officers, as such compensation is disclosed pursuant to Item 402 [40] of Regulation S–K, including the Compensation Discussion and Analysis ("CD&A"), the compensation tables and other narrative executive compensation disclosures required by Item 402. We also proposed an instruction to Rule 14a–21 to specify that the rule does not change the scaled disclosure requirements for smaller reporting companies and that smaller reporting companies would not be required to provide a CD&A in order to comply with Rule 14a–21.

b. Comments on the Proposed Rule

Commentators were generally supportive of the proposal. Many commentators agreed with the approach, as proposed, not to designate specific language to be used or require issuers to frame the shareholder vote to approve executive compensation in the form of a standard resolution.[41] Some commentators indicated that issuers should have flexibility in drafting the resolution.[42] Commentators noted that flexibility would permit issuers to tailor the resolution to the issuer's individual circumstances.[43] Others stated that we should designate specific language for the resolution [44] or at least establish clear, minimum guidelines,[45] principles-based guidelines,[46] or model language,[47] while other commentators suggested we include language for a resolution in the form of non-exclusive examples [48] or a safe harbor.[49] Commentators indicated that it would be helpful to have an example of resolution language that would comply with the rule [50] and that sample language would simplify the drafting process for issuers and promote efficiency.[51]

Many commentators agreed with our proposed approach not to exempt smaller reporting companies from Rule 14a–21(a) and Exchange Act Section 14A(a)(1).[52] Some commentators did suggest that smaller reporting companies should be exempt from the say-on-pay vote [53] or required to conduct a say-on-pay vote on a triennial basis beginning in 2013.[54]

Some commentators suggested that we clarify the relationship between the federally created right and state law voting rights.[55] Most commentators, however, indicated there was no need for the Commission to adopt rules as to which shares are entitled to vote.[56] One commentator asserted that the issue as to which shares are entitled to vote is traditionally a state law matter that we do not need to address in our rulemaking.[57]

c. Final Rule

After considering the comments, we are adopting Rule 14a–21(a) substantially as proposed with some modifications. Under the final rule, issuers will be required, not less frequently than once every three years, to provide a separate shareholder advisory vote in proxy statements to approve the compensation of their named executive officers, as defined in Item 402(a)(3) of Regulation S–K. Rule 14a–21(a) specifies that the separate shareholder vote on executive compensation is required only when proxies are solicited for an annual or other meeting of security holders for which our rules require the disclosure of executive compensation pursuant to Item 402 of Regulation S–K. We have modified the proposal to clarify in the rule that the shareholder vote on executive compensation required by Exchange Act Section 14A(a)(1) and Rule 14a–21(a) is required with respect to an annual meeting of shareholders at which proxies will be solicited for the election of directors, or a special meeting in lieu of such annual meeting.[58] In addition, we have modified the rule to clarify that a say-on-pay vote is required at least once every three calendar years. Commentators expressed the view that as proposed, the rule would have required a say-on-pay vote within three years of the date of the most recent say-on-pay vote, which in some cases could have required a say-on-pay vote more frequently than once every three calendar years.[59]

As adopted, Rule 14a–21(a) requires a separate shareholder vote to approve the compensation of executives for the first annual or other meeting of shareholders occurring on or after January 21, 2011, the first day after the end of the 6-month period beginning on the date of enactment of the Act. In accordance with Section 14A(a)(1), shareholders would vote to approve the compensation of the issuer's named executive officers, as such compensation is disclosed pursuant to Item 402 [60] of Regulation S–K, including the CD&A, the compensation tables and other narrative executive compensation disclosures required by Item 402.[61] We have included an instruction to Rule 14a–21 to specify that Rule 14a–21 does not change the scaled disclosure requirements for smaller reporting companies and that smaller reporting companies will not be required to provide a CD&A in order to comply with Rule 14a–21. We understand that smaller reporting companies may wish to include supplemental disclosure to facilitate shareholder understanding of

[40] We proposed that if disclosure of golden parachute compensation arrangements pursuant to proposed Item 402(t) is included in an annual meeting proxy statement, such disclosure would be included in the disclosure subject to the shareholder advisory vote under Rule 14a–21(a). Such disclosure under Item 402(t), however, would not be required to be included in annual meeting proxy statements.

[41] *See, e.g.,* letters from American Federation of State, County and Municipal Employees ("AFSCME"), Center on Executive Compensation ("Center on Exec. Comp."), Compensia ("Compensia"), Davis Polk & Wardwell LLP ("Davis Polk"), the Financial Services Roundtable ("FSR"), Pfizer Inc. ("Pfizer"), Protective Life Corporation ("Protective Life"), and United Brotherhood of Carpenters ("UBC").

[42] *See, e.g.,* letters from Business Roundtable ("Business Roundtable") and Towers Watson ("Towers Watson").

[43] *See* letter from Business Roundtable.

[44] *See, e.g.,* letters from National Association of Corporate Directors ("NACD"), PGGM Investments ("PGGM"), Public Citizen ("Public Citizen"), and WorldatWork ("WorldatWork").

[45] *See, e.g.,* letters from Boston Common Asset Management ("Boston Common"), First Affirmative Financial Network, LLC ("First Affirmative"), Glass Lewis & Co. ("Glass Lewis"), Social Investment Forum ("Social Investment"), and Walden Asset Management ("Walden").

[46] *See, e.g.,* letters from International Corporate Governance Network ("ICGN") and Teachers Insurance and Annuities Association of America and College Retirement Equities Fund ("TIAA–CREF").

[47] *See, e.g.,* letter from Calvert Group, Ltd. ("Calvert").

[48] *See, e.g.,* letters from Society of Corporate Secretaries and Governance Professionals ("Society of Corp. Sec.") and Sullivan & Cromwell LLP ("Sullivan").

[49] *See, e.g.,* letters from The Boeing Company ("Boeing") and Pearl Meyer & Partners ("PM&P").

[50] *See* letter from Society of Corp. Sec.

[51] *See* letter from Sullivan.

[52] *See, e.g.,* letters from California Public Employees Retirement System ("CalPERS"), Council of Institutional Investors ("CII"), Glass Lewis, ICGN, PGGM, and the State Board of Administration of Florida ("SBA of Florida").

[53] *See, e.g.,* letters from NACD and UBC.

[54] *See* letter from the Committee on Federal Regulation of Securities, Section of Business Law of the American Bar Association ("ABA").

[55] *See, e.g.,* letter from the ABA.

[56] *See, e.g.,* letters from Business Roundtable, FSR, Pfizer, PGGM, and Protective Life.

[57] *See* letter from Business Roundtable.

[58] See the discussion in Note 18 above.

[59] *See* letter from ABA.

[60] If disclosure of golden parachute compensation arrangements pursuant to Item 402(t) is included in an annual meeting proxy statement, such disclosure would be included in the disclosure subject to the shareholder advisory vote under Rule 14a–21(a). Such disclosure under Item 402(t), however, is not required to be included in all annual meeting proxy statements.

[61] While not required, our rules "would not preclude an issuer from seeking more specific shareholder opinion through separate votes on cash compensation, golden parachute policy, severance or other aspects of compensation." *See* Report of the Senate Committee on Banking, Housing, and Urban Affairs regarding The Restoring American Financial Stability Act of 2010, S. Rep. No. 111–176 at 133 (2010).

their compensation arrangements in connection with say-on-pay votes.[62] We do not believe, however, that this possibility supports exempting smaller reporting companies from the say-on-pay votes. As more fully discussed in Section II.E below, in order to ease compliance burdens for smaller reporting companies, we are adopting a two-year temporary exemption before these companies are required to conduct a shareholder advisory vote to approve executive compensation to permit these companies additional time to prepare for the new shareholder advisory votes.

As noted in the Proposing Release, consistent with Section 14A, the compensation of directors, as disclosed pursuant to Item 402(k)[63] or Item 402(r)[64] is not subject to the shareholder advisory vote. In addition, if an issuer includes disclosure pursuant to Item 402(s)[65] of Regulation S–K about the issuer's compensation policies and practices as they relate to risk management and risk-taking incentives, these policies and practices will not be subject to the shareholder advisory vote required by Section 14A(a)(1) as they relate to the issuer's compensation for employees generally. We note, however, that to the extent that risk considerations are a material aspect of the issuer's compensation policies or decisions for named executive officers, the issuer is required to discuss them as part of its CD&A,[66] and therefore such disclosure would be considered by shareholders when voting on executive compensation.

Though we have considered the views of commentators that prescribed language would be helpful, the final rule does not require issuers to use any specific language or form of resolution to be voted on by shareholders. This is consistent with the approach taken by the Commission in adopting Rule 14a–20 to implement the shareholder advisory vote on executive compensation for companies subject to the Emergency Economic Stabilization Act of 2008, or EESA. We believe that issuers should retain flexibility to craft the resolution language. As we noted in the Proposing Release, however, the shareholder advisory vote must relate to all executive compensation disclosure disclosed pursuant to Item 402 of Regulation S–K. Section 14A(a)(1) of the Exchange Act requires that the shareholder advisory vote must be "to approve the compensation of executives, as disclosed pursuant to [Item 402 of Regulation S–K] or any successor thereto."[67] We have added an instruction to Rule 14a–21(a) to indicate that this language from Section 14A(a)(1) should be included in an issuer's resolution for the say-on-pay vote and to provide a non-exclusive example of a resolution that would satisfy the applicable requirements.[68] A vote to approve a proposal on a different subject matter, such as a vote to approve only compensation policies and procedures, would not satisfy the requirement of Section 14A(a)(1) or final Rule 14a–21(a). We note that issuers are not limited to the required shareholder advisory vote under Rule 14a–21(a) and may solicit shareholder votes on a range of compensation matters to obtain more specific feedback on the issuer's compensation policies and programs.

2. Item 24 to Schedule 14A

We proposed a new Item 24 to Schedule 14A, to require disclosure in any proxy statement in which an issuer is providing a separate shareholder vote on executive compensation to briefly explain the general effect of the vote, such as whether the vote is non-binding. We are adopting this amendment to Schedule 14A as proposed with some modifications.

a. Proposed Amendments

Pursuant to proposed new Item 24 of Schedule 14A, issuers would be required to disclose in a proxy statement for an annual meeting (or other meeting of shareholders for which our rules require executive compensation disclosure) that they are providing a separate shareholder vote on executive compensation and to briefly explain the general effect of the vote, such as whether the vote is non-binding.[69] This was similar to the approach taken by the Commission in connection with disclosure requirements about the shareholder vote on executive compensation for companies subject to the EESA.[70]

b. Comments on the Proposed Amendments

Commentators were generally supportive of proposed Item 24 of Schedule 14A. We requested comment regarding whether any additional disclosures should be provided by issuers that would be useful to shareholders. Two commentators indicated that we should amend the proposal to require disclosure of the results of previous votes on executive compensation.[71] Another commentator suggested that we should remove the reference to the "general effect" of the vote as it would lead to boilerplate disclosure and remove the word "whether" from the rule given the non-binding nature of the vote.[72]

c. Final Rule

After considering the comments, we are adopting Item 24 to Schedule 14A as proposed with some modifications.[73] Though we agree that the disclosure of previous results would be useful to shareholders, these results are required to be disclosed pursuant to Item 5.07 of Form 8–K immediately following the votes. Consequently, we do not believe it is necessary to mandate such disclosure in Item 24 of Schedule 14A. As discussed below, we have modified the proposal to require disclosure of the current frequency of say-on-pay votes and to require disclosure of when the next say-on-pay vote will occur.

Item 24 is consistent with the approach taken by the Commission in Item 20 of Schedule 14A in connection with disclosure requirements about the shareholder advisory vote on executive compensation for companies subject to EESA. Based on our experience with these votes, we believe that such requirements will lead to disclosure of useful information about the nature and effect of the vote for shareholders to consider, such as whether the vote is non-binding. We note that although not required, issuers may choose to provide additional disclosure in their proxy materials.

3. Amendments to Item 402(b) of Regulation S–K

Item 402 requires the disclosure of executive compensation and includes

[62] *See* letter from Society of Corp. Sec., which notes that smaller reporting companies may "feel compelled to include CD&A to provide additional disclosure so as to reduce the potential for an unfavorable shareholder vote."

[63] 17 CFR 229.402(k).

[64] 17 CFR 229.402(r).

[65] 17 CFR 229.402(s).

[66] *See Proxy Disclosure Enhancements,* Release No. 33–9089 (Dec. 16, 2009) [74 FR 68334] at note 38.

[67] Exchange Act Section 14A(a)(1).

[68] Instruction to Rule 14a–21(a) provides the following non-exclusive example that would satisfy Rule 14a–21(a): "RESOLVED, that the compensation paid to the company's named executive officers, as disclosed pursuant to Item 402 of Regulation S–K, including the Compensation Discussion and Analysis, compensation tables and narrative discussion, is hereby APPROVED."

[69] Section 14A(a) does not require additional disclosure with respect to the non-binding nature of the vote. We proposed to require additional disclosure so that information about the advisory nature of the vote is available to shareholders before they vote. We continue to believe this information should be available to shareholders.

[70] *See* Item 20 of Schedule 14A; TARP Adopting Release, *supra* note 18, at 75 FR 2790.

[71] *See* letters from ICGN and PGGM.

[72] *See* letter from ABA.

[73] See discussion of the modification to the proposed Item 24 relating to the frequency of say-on-pay votes below at Section II.B.2.c.

requirements prescribing narrative and tabular disclosure, as well as separate scaled disclosure requirements for smaller reporting companies.[74] Item 402(b)[75] contains the requirement for CD&A, which is intended to be a narrative overview that puts into context the executive compensation disclosure provided elsewhere in response to the requirements of Item 402. The CD&A disclosure requirement is principles-based, in that it identifies the disclosure concept and provides several non-exclusive examples. Under Item 402(b)(1), issuers must explain all material elements of their named executive officers' compensation by addressing mandatory principles-based topics in their CD&A.[76] Item 402(b)(2) of Regulation S–K sets forth certain non-exclusive examples of the kind of information that an issuer should address in its CD&A, depending upon the facts and circumstances.

In connection with our implementation of Section 14A(a)(1), we proposed amendments to require disclosure in CD&A regarding how issuers have considered the results of previous say-on-pay votes required by Section 14A and Rule 14a–20.[77] After reviewing comments on this proposal, we are adopting amendments to Item 402(b)(1) as proposed, with some modifications in response to concerns raised by commentators.

a. Proposed Amendments

We proposed to amend Item 402(b)(1) to add to the mandatory CD&A topics whether, and if so, how an issuer has considered the results of previous shareholder votes on executive compensation required by Section 14A or Rule 14a–20 in determining compensation policies and decisions and, if so, how that consideration has affected its compensation policies and decisions. We did not propose to add a specific requirement for smaller reporting companies to provide disclosure about how previous votes pursuant to Section 14A or Rule 14a–20 affected compensation policies and decisions because in our view such information would not be as valuable outside the context of a complete CD&A covering the full range of matters required to be addressed by Item 402(b), which smaller reporting companies are not required to provide.

b. Comments on the Proposed Amendments

Comments on the proposal were mixed. Several commentators expressed support for an amendment to Item 402(b)(1) to require that issuers discuss the results of the shareholder vote and its effect, if any, on executive compensation decisions and policies.[78] Many of these commentators agreed with the proposal that discussion of say-on-pay vote results in CD&A should be mandatory,[79] in some cases noting that this would provide shareholders a better understanding of how the board of directors considered the results of shareholder advisory votes[80] and encourage a dialogue between issuers and shareholders on the topic of compensation.[81] Commentators also indicated that a mandatory discussion of the consideration of say-on-pay votes will aid transparency of issuers' disclosures on compensation[82] and will help investors better understand compensation decisions made by issuers.[83]

A number of commentators stated that it would be more appropriate instead to include consideration of say-on-pay votes among the non-exclusive examples of the kind of information that should be addressed in CD&A, only if material given the issuer's individual facts and circumstances[84] because this approach would avoid boilerplate disclosure and require discussion only when material,[85] and that discussion on a mandatory basis may lead to awkward and non-substantive disclosure if the issuer has not made changes to its compensation program in response to the shareholder vote.[86]

Other commentators stated that no amendment to CD&A is required[87] because the Act does not require additional CD&A disclosure and it should not be required by rule,[88] the proposed amendment would add length to CD&A without providing meaningful information to shareholders,[89] and the amendment would deem the consideration of say-on-pay votes material whether such consideration is material or not.[90] Similarly a number of commentators who asserted that amending Item 402(b) is not required also expressed the view that if the Commission does adopt an amendment, such CD&A disclosure should be required only if material under the issuer's individual facts and circumstances.[91]

Commentators also disagreed with respect to which say-on-pay votes should be covered by the CD&A discussion. Some favored only the most recent say-on-pay vote,[92] indicating that mandating discussion of prior votes would result in extraneous discussion[93] and little benefit.[94] Other commentators indicated that prior votes should also be required to be addressed.[95] These commentators noted that such disclosure of prior votes is appropriate given the long-term process of determining compensation[96] and that it would permit investors to evaluate any trends in the results of say-on-pay votes.[97] One commentator stated that if CD&A disclosure with respect to say-on-pay votes is mandatory, it should be limited to the most recent vote, but if not mandatory should not be so limited.[98] Although there was little response to our request for comment regarding whether smaller reporting companies should be required to disclose their consideration of

[74] Item 402 also includes requirements to disclose director compensation (Items 402(k) and 402(r)) and the issuer's compensation policies as they relate to risk management (Item 402(s)).

[75] 17 CFR 229.402(b).

[76] These mandatory principles-based topics require the company to disclose the objectives of the company's compensation programs; what the compensation program is designed to reward; each element of compensation; why the company chooses to pay each element; how the company determines the amount (and, where applicable, the formula) for each element; and how each element and the company's decisions regarding that element fit into the company's overall compensation objectives and affect decisions regarding other elements.

[77] 17 CFR 240.14a–20. Pursuant to the EESA, issuers that have received financial assistance under the Troubled Asset Relief Program, or TARP, are required to conduct a separate annual shareholder vote to approve executive compensation during the period in which any obligation arising from the financial assistance provided under the TARP remains outstanding.

[78] *See, e.g.,* letters from CalPERS, Calvert, CII, Colorado Public Employees' Retirement Association ("COPERA"), ICGN, Meridian Compensation Partners ("Meridian"), PGGM, Pensions Investment Research Consultants ("PIRC"), SBA of Florida, Sullivan, and TIAA–CREF.

[79] *See, e.g.,* letters from CalPERS, Calvert, CII, PGGM, PIRC, SBA of Florida, and TIAA–CREF.

[80] *See* letter from CalPERS.

[81] *See* letter from TIAA–CREF.

[82] *See* letter from PIRC.

[83] *See* letter from SBA of Florida.

[84] *See, e.g.,* letters from ABA, Boeing, Business Roundtable, Eaton Corporation ("Eaton"), FSR, PM&P, Sullivan, and UnitedHealth Group ("UnitedHealth").

[85] *See, e.g.,* letter from UnitedHealth.

[86] *See* letter from PM&P.

[87] *See, e.g.,* letters from Center on Exec. Comp., Compensia, Davis Polk, Pfizer, Society of Corp. Sec., and UBC.

[88] *See, e.g.,* letter from Center on Exec. Comp.

[89] *See* letter from Davis Polk.

[90] *See, e.g.,* letter from Society of Corp. Sec.

[91] *See, e.g.,* letters from Compensia, Davis Polk, and Society of Corp. Sec.

[92] *See, e.g.,* letters from ABA, Boeing, Eaton, FSR, McGuireWoods ("McGuireWoods"), Meridian, NACD, Pfizer, Protective Life, and Sullivan.

[93] *See* letter from Sullivan.

[94] *See* letter from McGuireWoods.

[95] *See, e.g.,* letters from Chris Barnard ("Barnard"), Calvert, PGGM, PIRC, PM&P, and SBA of Florida.

[96] *See, e.g.,* letter from PGGM.

[97] *See, e.g.,* letter from SBA of Florida.

[98] *See* letter from Boeing.

shareholder advisory votes on executive compensation, one commentator stated that our existing disclosure requirements for these companies are sufficient.[99]

c. Final Rule

After considering the comments, we are adopting amendments to the disclosure requirements of Item 402(b)(1) substantially as proposed, with a modification to clarify that this mandatory topic relates to the issuer's consideration of the most recent say-on-pay vote. As discussed below, issuers should address their consideration of the results of earlier say-on-pay votes, to the extent material.

The final rule amends Item 402(b)(1) to require issuers to address in CD&A whether and, if so, how their compensation policies and decisions have taken into account the results of the most recent shareholder advisory vote on executive compensation. Although it is not mandated by Section 951 of the Act, we continue to believe that including this mandatory topic in CD&A will facilitate better investor understanding of issuers' compensation decisions. Because the shareholder advisory vote will apply to all issuers, we view information about how issuers have responded to such votes as more in the nature of a mandatory principles-based topic than an example. The manner in which individual issuers may respond to such votes in determining executive compensation policies and decisions will likely vary depending upon facts and circumstances. We expect that this variation will be reflected in the CD&A disclosures.

Following consideration of the comments received, we have decided to limit the mandatory topic to whether, and if so, how the issuer has considered the results of the most recent say-on-pay vote in determining compensation policies and decisions, and if so, how that consideration has affected the issuer's executive compensation policies and decisions.[100] This modification reflects that, in making voting and investment decisions, shareholders will benefit from understanding what consideration the issuer has given to the most recent say-on-pay vote. Limiting the mandatory topic to the most recent shareholder vote should also focus the disclosure so there should not be lengthy boilerplate discussions of all previous votes. Although we have added issuer consideration of the most recent say-on-pay vote to the mandatory topics, we believe that, consistent with the principles-based nature of CD&A, issuers should address their consideration of the results of earlier say-on-pay votes to the extent such consideration is material to the compensation policies and decisions discussed.

Because companies with outstanding indebtedness under the TARP will continue to have an annual say-on-pay vote until they repay all such indebtedness, these votes should be addressed by issuers in CD&A as well. To reflect our treatment of companies subject to EESA with outstanding obligations under TARP, we have also modified the amendment to Item 402(b)(1) as adopted to address issuer consideration of the results of the most recent shareholder advisory vote on executive compensation required by Section 14A *or* Rule 14a–20. This reflects that the vote required pursuant to the EESA and 14a–20 is effectively the same vote that would be required under Section 14A(a)(1).[101]

Smaller reporting companies are subject to scaled disclosure requirements in Item 402 of Regulation S–K and are not required to include a CD&A. We are not adding a specific requirement for smaller reporting companies to provide disclosure about how previous votes pursuant to Section 14A affected compensation policies and decisions because we believe such information would not be as valuable outside the context of a complete CD&A covering the full range of matters required to be addressed by Item 402(b). However, we note that pursuant to Item 402(o) of Regulation S–K, [102] smaller reporting companies are required to provide a narrative description of any material factors necessary to an understanding of the information disclosed in the Summary Compensation Table. If consideration of prior say-on-pay votes is such a factor for a particular issuer, disclosure would be required pursuant to Item 402(o).

B. Shareholder Approval of the Frequency of Shareholder Votes on Executive Compensation

1. Rule 14a–21(b)

We proposed Rule 14a–21(b) pursuant to which issuers would be required, not less frequently than once every six years, to provide a separate shareholder advisory vote in proxy statements to determine the frequency of the shareholder vote on the compensation of executives required by Section 14A(a)(1). We are adopting this amendment substantially as proposed with slight modifications in response to comments.

a. Proposed Rule

Under proposed Rule 14a–21(b), issuers would be required, not less frequently than once every six years, to provide a separate shareholder advisory vote in proxy statements for annual meetings to determine whether the shareholder vote on the compensation of executives required by Section 14A(a)(1) "will occur every 1, 2, or 3 years." [103] As proposed, Rule 14a–21(b) would also clarify that the separate shareholder vote on the frequency of shareholder votes on executive compensation would be required only in a proxy statement for an annual or other meeting of shareholders for which our rules require compensation disclosure. Consistent with Section 14A, issuers would be required to provide the separate shareholder vote on the frequency of the say-on-pay vote for the first annual or other such meeting of shareholders occurring on or after January 21, 2011.

b. Comments on the Proposed Rule

Comments on the proposal were generally favorable. Many commentators agreed that the rule did not need to specify the required language to be used for the shareholder vote on the frequency of shareholder votes to approve executive compensation.[104] Some commentators, however, recommended that the Commission should specify language or provide non-exclusive examples of resolutions so issuers would know how the requirement may be satisfied.[105] A number of commentators also requested that the Commission clarify whether the vote should be presented in the form of a resolution given that shareholders will have a choice among three frequencies

[99] *See* letter from ICGN.

[100] Reporting companies are currently required to disclose, pursuant to Item 5.07 of Form 8–K [17 CFR 249.208a], the preliminary results of a shareholder vote within four business days after the end of the meeting at which the vote is held and final voting results within four business days after the final voting results are known. We are adopting amendments to require additional disclosure on Form 8–K regarding the company's determination of the frequency of say-on-pay votes. See Section II.B.5 below.

[101] The treatment of companies subject to EESA with outstanding obligations under TARP is discussed in Section II.C.3 below.

[102] 17 CFR 229.402(o).

[103] Exchange Act Section 14A(a)(2).

[104] *See, e.g.,* letters from AFSCME, Business Roundtable, FSR, Protective Life, and Towers Watson.

[105] *See, e.g.,* letters from Boeing, Pfizer, PGGM, Society of Corp. Sec., and Sullivan.

or abstaining from the frequency vote.[106] Although some commentators suggested that we specify which shares are entitled to vote in the shareholder vote on the frequency of say-on-pay votes,[107] most commentators indicated there was no need for the Commission to address this question.[108]

We also requested comment regarding whether a new issuer should be permitted to disclose the frequency of its say-on-pay votes in the registration statement for its initial public offering and be exempted from conducting say-on-pay votes and frequency votes at its annual meetings until the annual meeting for the year disclosed in its registration statement. Most commentators indicated that newly public companies should not be exempt from the say-on-pay and frequency votes and should be required to conduct say-on-pay and frequency votes at their first annual shareholders meeting after the initial public offering.[109] However, some commentators expressed support for such an exemption as it would provide these issuers additional time to formulate their compensation policies as a public company before conducting the shareholder votes required by Section 14A.[110]

c. Final Rule

After reviewing and considering the comments, we are adopting Rule 14a–21(b) as proposed with slight modifications to clarify that the frequency vote is required at least once during the six calendar years following the prior frequency vote.[111] Under Rule 14a–21(b), issuers will be required, not less frequently than once every six calendar years, to provide a separate shareholder advisory vote in proxy statements for annual meetings to determine whether the shareholder vote on the compensation of executives required by Section 14A(a)(1) "will occur every 1, 2, or 3 years."[112] After considering and reviewing comments on the proposed rule, we do not believe it is necessary to provide a form of resolution for the vote required by Rule 14a–21(b). In response to concerns raised by commentators and discussed below, we are also adopting a temporary exemption under which smaller reporting companies will not be required to conduct a shareholder advisory vote on the frequency of say-on-pay votes until meetings on or after January 21, 2013.[113]

Rule 14a–21(b) will also clarify that the separate shareholder vote on the frequency of shareholder votes on executive compensation will be required only in a proxy statement for an annual or other meeting of shareholders at which directors will be elected and that such vote is required only once every six calendar years. Under Rule 14a–21(b), issuers will be required to provide the separate shareholder vote on the frequency of the say-on-pay vote for the first annual or other such meeting of shareholders occurring on or after January 21, 2011. After reviewing the comment letters, we continue to believe that the say-on-pay vote and the frequency vote should be required of newly public companies in the proxy statement for such company's first annual meeting after the initial public offering. This will give shareholders the opportunity to express a view on these matters while the company is in the process of establishing policies that will apply as a public company and could benefit from understanding its shareholders' point of view.

2. Item 24 of Schedule 14A

In order to implement the requirements of Section 14A(a), we proposed new Item 24 to Schedule 14A, to briefly explain the general effect of the frequency vote, such as whether the vote is non-binding. We are adopting this amendment to Schedule 14A as proposed with a modification.

a. Proposed Amendments

In addition to disclosure regarding the vote on executive compensation, we proposed that issuers would be required to disclose in the proxy statement that they are providing a separate shareholder advisory vote on the frequency of the shareholder advisory vote on executive compensation. Proposed Item 24 of Schedule 14A would also require issuers to briefly explain the general effect of this vote, such as whether the vote is non-binding.

b. Comments on the Proposed Amendments

Commentators generally supported proposed Item 24 of Schedule 14A as it relates to the frequency of say-on-pay votes.[114] One commentator expressed the view that the proposed amendment is not needed as it will lead to boilerplate disclosure.[115] Some commentators also suggested that issuers should be required to disclose the current frequency of say-on-pay votes.[116]

c. Final Rule

After reviewing and considering the comments, we are adopting Item 24 of Schedule 14A as proposed with a modification. Issuers will be required to disclose in the proxy statement that they are providing a separate shareholder advisory vote on the frequency of say-on-pay votes. Item 24 of Schedule 14A will also require issuers to briefly explain the general effect of this vote, such as whether the vote is non-binding.[117] As noted above, this is similar to the approach taken by the Commission in connection with disclosure requirements about the shareholder advisory vote on executive compensation for companies subject to EESA.[118] Based on our experience with these votes, we believe that such requirements will lead to useful disclosure of information about the nature and effect of the vote for shareholders to consider, such as whether the vote is non-binding.

After reviewing comments, we are also adding a requirement to Item 24 for issuers to provide disclosure of the current frequency of say-on-pay votes and when the next scheduled say-on-pay vote will occur,[119] in their proxy materials. We believe this will provide useful information to shareholders about upcoming say-on-pay and frequency shareholder advisory votes.

3. Amendment to Rule 14a–4

In order to implement the requirements of Section 14A(a)(2), we also proposed amendments to Rule 14a–4. After considering comments, we are adopting the amendments to Rule 14a–4 as proposed, with slight modification.

[106] *See, e.g.,* letters from ABA, Pfizer, Society of Corp. Sec., and Sullivan.

[107] *See, e.g.,* letter from the ABA.

[108] *See, e.g.,* letters from Business Roundtable, FSR, Pfizer, PGGM, and Protective Life.

[109] *See, e.g.,* letters from AFSCME, CII, CalPERS, ICGN, Georg Merkl ("Merkl"), Public Citizen, and RAILPEN Investments and Universities Superannuation Scheme ("RAILPEN & USS").

[110] *See, e.g.,* letters from ABA, Compensia, Davis Polk, NACD, and Sullivan.

[111] As proposed, Rule 14a–21(b) would have required a frequency vote within the six-year period from the date of the most recent frequency vote.

[112] Exchange Act Section 14A(a)(2).

[113] See discussion in Section II.E below.

[114] *See, e.g.,* letters from CalPERS, ICGN, PGGM, and Protective Life.

[115] *See* letter from Society of Corp. Sec.

[116] *See, e.g.,* letters from ICGN and TIAA–CREF.

[117] As discussed in Section II.A.2.a, Section 14A(a) does not require additional disclosure with respect to the non-binding nature of the vote. We are requiring additional disclosure so that information about the advisory nature of the vote is available to shareholders before they vote.

[118] See Section II.A.2.a, above.

[119] Issuers should disclose the current frequency as determined by the board following a shareholder advisory vote. We would not expect disclosure of either the current frequency or when the next scheduled say-on-pay vote will occur in proxy materials for the meeting where an issuer initially conducts the say-on-pay and frequency votes.

a. Proposed Amendments

As noted in the Proposing Release, Section 14A(a)(2) requires a shareholder advisory vote on whether say-on-pay votes will occur every 1, 2, or 3 years. Thus, shareholders must be given four choices: Whether the shareholder vote on executive compensation will occur every 1, 2, or 3 years, or to abstain from voting on the matter. In our view, Section 14A(a)(2) does not allow for alternative formulations of the shareholder vote, such as proposals that would provide shareholders with two substantive choices (*e.g.,* to hold a separate shareholder vote on executive compensation every year or less frequently), or only one choice (*e.g.,* a company proposal to hold shareholder votes every two years). We noted in the Proposing Release that we would expect that the board of directors will include a recommendation as to how shareholders should vote on the frequency of shareholder votes on executive compensation.[120] However, the issuer must make clear in these circumstances that the proxy card provides for four choices (every 1, 2, or 3 years, or abstain) and that shareholders are not voting to approve or disapprove the issuer's recommendation. Accordingly, we proposed amendments to our proxy rules to reflect the statutory requirement that shareholders must be provided the opportunity to cast an advisory vote on whether the shareholder vote on executive compensation required by Section 14A(a)(1) of the Exchange Act will occur every 1, 2, or 3 years, or to abstain from voting on the matter.[121]

Specifically, we proposed amendments to Rule 14a–4 under the Exchange Act, which provides requirements as to the form of proxy that issuers are required to include with their proxy materials, to require that issuers present four choices to their shareholders. Absent amendment, Rule 14a–4 requires the form of proxy to provide means whereby the person solicited is afforded an opportunity to specify by boxes a choice between approval or disapproval of, or abstention with respect to each separate matter to be acted upon, other than elections to office.[122] We proposed amendments to revise this standard to permit proxy cards to reflect the choice of 1, 2, or 3 years, or abstain, for these votes.

b. Comments on the Proposed Amendments

Comments on the proposal were generally favorable. Many commentators expressed support for the proposed approach where shareholders are given four choices on the frequency vote.[123] Some commentators suggested alternative approaches including a vote where shareholders would rank each choice of frequency or vote separately for each of 1, 2, and 3 years,[124] a vote where management would choose 1, 2, or 3 years as the frequency and ask shareholders to approve or disapprove its choice,[125] and a two-step approach whereby shareholders would first vote whether or not they have a preference as to the frequency of say-on-pay votes and, if they do have a preference, subsequently vote on whether such votes should be conducted every 1, 2, or 3 years.[126]

In addition, we requested comment in the Proposing Release as to whether issuers, brokers, transfer agents, and data processing firms would be able to accommodate the four choices for a single line item on the proxy card. Commentators indicated that they would be ready for the vote with four choices on the proxy card by January 21, 2011.[127] One commentator recommended that we clarify that issuers may vote uninstructed shares in accordance with management's recommendations so long as they follow the requirements of Rule 14a–4,[128] while another suggested that the Commission extend the transition guidance permitting the presentation of three choices for the frequency vote for the entire 2011 proxy season and perhaps require the three-choice approach for all issuers for 2011 to allow for uniformity among different issuers.[129]

c. Final Rule

After considering the comments, we are adopting the rule substantially as proposed with some modifications. Specifically, we are adopting amendments to Rule 14a–4 under the Exchange Act, which provides requirements as to the form of proxy that issuers are required to include with their proxy materials, to require that issuers present four choices to their shareholders. Under existing Rule 14a–4, the form of proxy is required to provide means whereby the person solicited is afforded an opportunity to specify by boxes a choice between approval or disapproval of, or abstention with respect to each separate matter to be acted upon, other than elections to office. Absent an amendment, Rule 14a–4 would not permit proxy cards to reflect the choice of 1, 2, or 3 years, or abstain. The amendments revise the rule to permit proxy cards to reflect the choice of 1, 2, or 3 years, or abstain, for the frequency vote.

In response to comment, we note that issuers may vote uninstructed proxy cards in accordance with management's recommendation for the frequency vote only if the issuer follows the existing requirements of Rule 14a–4 to (1) include a recommendation for the frequency of say-on-pay votes in the proxy statement, (2) permit abstention on the proxy card, and (3) include language regarding how uninstructed shares will be voted in bold on the proxy card.

4. Amendment to Rule 14a–8

In connection with implementing the requirements of Section 14A(a)(2), we also proposed a note to Rule 14a–8(i)(10) relating to shareholder proposals. After considering the comments, we are adopting the amendment to Rule 14a–8 with some modifications.

a. Proposed Amendments

Our proposed amendment to Rule 14a–8 under the Exchange Act would add a note to Rule 14a–8(i)(10) to clarify the status of shareholder proposals that seek an advisory shareholder vote on executive compensation or that relate to the frequency of shareholder votes approving executive compensation. Rule 14a–8 provides eligible shareholders with an opportunity to include a proposal in an issuer's proxy materials for a vote at an annual or special meeting of shareholders. An issuer generally is required to include the proposal unless the shareholder has not complied with the rule's procedural requirements or the proposal falls within one of the rule's 13 substantive bases for exclusion.[130] One of the substantive bases for exclusion, Rule 14a–8(i)(10), provides that an issuer

[120] *See* Section II.B.3 of the Proposing Release.

[121] Because the shareholder vote on the frequency of voting on executive compensation is advisory, we do not believe that it is necessary to prescribe a standard for determining which frequency has been "adopted" by the shareholders.

[122] Rule 14a–4(b)(1).

[123] *See, e.g.,* letters from Calvert, COPERA, ICGN, Meridian, Merkl, PGGM, and Protective Life.

[124] *See* letter from Keith P. Bishop ("Bishop").

[125] *See* letter from UBC.

[126] *See* letter from Society of Corp. Sec.

[127] *See, e.g.,* letters from Broadridge Financial Solutions, Inc. ("Broadridge") and Proxytrust ("Proxytrust").

[128] *See* letter from Sullivan.

[129] *See* letter from ABA. For a discussion of transition matters, see Section II.F below.

[130] These substantive bases for exclusion are set forth in Rule 14a–8(i).

may exclude a shareholder proposal that has already been substantially implemented.

We proposed adding a note to Rule 14a–8(i)(10) to permit the exclusion of a shareholder proposal that would provide a say-on-pay vote or seeks future say-on-pay votes or that relates to the frequency of say-on-pay votes, provided the issuer has adopted a policy on the frequency of say-on-pay votes that is consistent with the plurality of votes cast in the most recent vote in accordance with Rule 14a–21(b). As noted in Section I above, a "say-on-pay" vote is defined as a separate resolution subject to shareholder vote to approve the compensation of executives, as disclosed pursuant to Item 402 of Regulation S–K, or any successor to Item 402.

As proposed, an issuer would be permitted to exclude shareholder proposals that propose a vote on the approval of executive compensation as disclosed pursuant to Item 402 of Regulation S–K or on the frequency of such votes, including those drafted as requests to amend the issuer's governing documents, so long as the issuer has adopted a policy on the frequency of say-on-pay votes that is consistent with the plurality of votes cast in the most recent vote required by Rule 14a–21(b) and provides a vote on frequency at least as often as required by Section 14A(a)(2).

b. Comments on the Proposed Amendments

Comments on the proposal were mixed. Many commentators supported the proposed amendment to permit exclusion of shareholder proposals on frequency and say-on-pay,[131] stating that the amendment would eliminate redundancy and reduce administrative burdens and costs.[132] Other commentators disagreed with the general approach,[133] stating that they believe it would be unwise as a matter of public policy and would inappropriately interpret substantial implementation because the note would permit exclusion of proposals requesting a frequency that the issuer has not implemented.[134] Other commentators asserted that an amendment is not required because issuers should be permitted to exclude any shareholder proposals on frequency as long as the issuer complies with Section 14A(a)(2).[135] Some commentators suggested that we should also permit issuers to exclude shareholder proposals on the frequency of say-on-pay votes when they adopt a policy to hold say-on-pay votes more frequently than the frequency that is consistent with the plurality of votes cast in the most recent shareholder vote[136] to prevent issuers being penalized for providing shareholders with more frequent say-on-pay votes.[137] Other commentators felt that issuers should not be required to adopt a particular policy on the frequency of say-on-pay votes in order to be permitted to exclude shareholder proposals on executive compensation,[138] noting that an issuer should be permitted to exclude shareholder proposals on frequency so long as the issuer provides a reasonable basis for the frequency chosen to prevent an annual re-visiting of the frequency vote by shareholders.[139]

In addition, some commentators stated that the proposed note to Rule 14a–8(i)(10) should incorporate a majority standard rather than the proposed plurality standard, so that issuers would need to adopt a policy consistent with the majority of votes cast in order to exclude a shareholder proposal as substantially implemented,[140] noting that the majority standard would be consistent with policies that boards should implement actions recommended by majority shareholder vote.[141] Some commentators also recommended that issuers should be permitted to exclude shareholder proposals for votes on executive compensation that are narrower in scope[142] than the say-on-pay vote required under Rule 14a–21(a).[143] These commentators expressed the concern that shareholders could undermine the non-binding nature of the frequency vote through more specific vote proposals.[144]

Finally, some commentators indicated that it would be inappropriate to permit companies to exclude shareholder proposals on frequency if there have been material changes in the company's compensation program since the prior frequency vote[145] because shareholders should be permitted the opportunity to revisit their decision on the frequency vote under such circumstances.[146] Other commentators noted that material changes to an issuer's compensation program should not limit the availability of Rule 14a–8(i)(10) because shareholders will understand that a company's compensation program is dynamic and factor this into their frequency voting decisions.[147] These commentators noted that the difficulty in determining whether changes are material would erode the benefit of the note to Rule 14a–8(i)(10), create uncertainty as to a company's ability to exclude shareholder proposals on frequency,[148] and burden the staff with analyzing materiality on a case-by-case basis.[149]

c. Final Rule

After reviewing the comments, we are adopting the amendment to Rule 14a–8(i)(10) with some modifications.

We continue to believe that under certain conditions, an issuer should be permitted to exclude subsequent shareholder proposals that seek a vote on the same matters as the shareholder advisory votes on say-on-pay and frequency required by Section 14A(a). Consequently, consistent with the proposal, we are adding a note to Rule 14a–8(i)(10) to permit the exclusion of a shareholder proposal that would provide a say-on-pay vote, seeks future say-on-pay votes, or relates to the frequency of say-on-pay votes in certain circumstances; however, in response to comments,[150] we are changing the threshold for exclusion from a plurality to a majority. Specifically, as adopted, the note to Rule 14a–8(i)(10) will permit exclusion of such a shareholder proposal if, in the most recent shareholder vote on frequency of say-on-pay votes, a single frequency (*i.e.,* one, two or three years) received the support of a majority of the votes cast and the issuer has adopted a policy on

[131] *See, e.g.,* letters from ABA, Business Roundtable, Center for Capital Markets Competitiveness of the U.S. Chamber of Commerce ("CCMC"), Eaton, FSR, ICGN, Pfizer, PGGM, and Protective Life.

[132] *See, e.g.,* letter from Business Roundtable.

[133] *See, e.g.,* letters from AFSCME, Calvert, Center on Exec. Comp., CII, Public Citizen, and UBC.

[134] *See, e.g.,* letter from AFSCME.

[135] *See* letter from UBC.

[136] *See, e.g.,* letters from ABA, Davis Polk, Meridian, Society of Corp. Sec., and Sullivan.

[137] *See* letter from Sullivan.

[138] *See, e.g.,* letters from Boeing and Center on Exec. Comp.

[139] *See* letter from Boeing.

[140] *See, e.g.,* letters from CalPERS, CII, and SBA of Florida.

[141] *See* letter from CII.

[142] An example would be a shareholder proposal for an advisory vote on the Chief Executive Officer's compensation as disclosed under Item 402 of Regulation S–K.

[143] *See, e.g.,* letters from Business Roundtable, Boeing, CCMC, Davis Polk, Pfizer, and Society of Corp. Sec.

[144] *See* letter from Boeing.

[145] *See, e.g.,* letters from Boston Common, Calvert, First Affirmative, ICGN, PIRC, PGGM, RAILPEN & USS, Social Investment, and Walden.

[146] *See* letter from RAILPEN & USS.

[147] *See, e.g.,* letters from ABA, Boeing, Frederic W. Cook & Co., Inc. ("Frederic Cook"), McGuireWoods, Pfizer, PM&P, and Protective Life.

[148] *See* letter from McGuireWoods.

[149] *See* letter from Frederic Cook.

[150] *See, e.g.,* letters from CalPERS, CII, and SBA of Florida.

the frequency of say-on-pay votes that is consistent with that choice.[151]

In light of the nature of the vote—with three substantive choices—it is possible that no single choice will receive a majority of votes and that, as a result, there may be issuers that may not be able to exclude subsequent shareholder proposals regarding say-on-pay matters even if they adopt a policy on frequency that is consistent with plurality of votes cast. We also recognize, however, that if no single frequency choice receives the support of a majority of votes cast, the choice preferred by the plurality may not represent the choice preferred by most of the company's shareholders. For example, if 30% of votes support annual voting, 30% support biennial voting, and 40% favor triennial voting, no frequency would have received a majority of votes cast; therefore, it is not clear that implementing the plurality choice would be favored by most of the company's shareholders. In that situation, if the company implemented triennial voting and the note to Rule 14a–8(i)(10) allowed exclusion of shareholder proposals seeking a different frequency, this could prevent shareholders from putting forth proposals that seek to request that the company implement a frequency that would be preferred by a majority of shareholders. After considering commentators' views, we are concerned that this approach would inappropriately restrict shareholder proposals on this topic, particularly in light of Section 14A(c)(4)'s directive that the shareholder advisory votes required by Sections 14A(a) and (b) may not be construed "to restrict or limit the ability of shareholders to make proposals for inclusion in proxy materials related to executive compensation."

On the other hand, if a majority of votes cast favors a given frequency and the issuer adopts a policy on frequency that is consistent with the choice of the majority of votes, then in our view, as a matter of policy it is appropriate for Rule 14a–8 to provide for exclusion of subsequent shareholder proposals that would provide a say-on-pay vote, seek future say-on-pay votes, or relate to the frequency of say-on-pay votes. We believe that, in these circumstances, additional shareholder proposals on frequency generally would unnecessarily burden the company and its shareholders given the company's adherence to the view favored by a majority of shareholder votes regarding the frequency of say-on-pay votes.[152] As described above, an issuer would not be permitted to exclude such shareholder proposals under the note if no frequency choice received a majority of the votes cast.

As a result of this amendment, an issuer will be permitted to exclude shareholder proposals that propose a vote on the frequency of such votes,[153] including those drafted as requests to amend the issuer's governing documents. For example, if in the first vote under Rule 14a–21(b) a majority of votes were cast for a two-year frequency for future shareholder votes on executive compensation, and the issuer adopts a policy to hold the vote every two years, a shareholder proposal seeking a different frequency could be excluded so long as the issuer seeks votes on executive compensation every two years.[154]

We also believe that a shareholder proposal that would provide an advisory vote or seek future advisory votes on executive compensation with substantially the same scope as the say-on-pay vote required by Rule 14a–21(a)—the approval of executive compensation as disclosed pursuant to Item 402 of Regulation S–K—should also be subject to exclusion under Rule 14a–8(i)(10) if the issuer adopts a policy on frequency that is consistent with the majority of votes cast. This is consistent with the proposal, although like additional frequency votes, the note to Rule 14a–8(i)(10) would condition exclusion on the company implementing the frequency favored by a majority of shareholders. In this circumstance, shareholders would be provided the opportunity to provide say-on-pay votes on the frequency preferred by a majority of shareholders when last polled, and we believe additional proposals on the same matter would impose unnecessary burdens on companies and shareholders.

We are also modifying the note slightly. To avoid confusion, we are removing the requirement that an issuer must provide "a vote on frequency at least as often as required by Section 14A(a)(2)." We believe this language is not necessary as issuers are already required to comply with Section 14A(a)(2) in any event. In addition, we are removing the language "as substantially implemented" from the note to avoid confusion.

5. Amendment to Form 8–K

We also proposed amendments to Form 10–Q and Form 10–K to require additional disclosure regarding the issuer's decision to adopt a policy on the frequency of say-on-pay votes following a shareholder advisory vote on frequency. After considering the comments, we are not adopting amendments to Form 10–Q and Form 10–K. Instead, we are adopting a new Form 8–K Item to require disclosure of the issuer's decision on the frequency of say-on-pay votes.

a. Proposed Amendments

Issuers are currently required to disclose the preliminary results of shareholder votes pursuant to Item 5.07 of Form 8–K within four business days following the day the shareholder meeting ends and final voting results within four business days of when they are known. This item will require issuers to report how shareholders voted in the say-on-pay vote and the frequency of shareholder votes on executive compensation.

We proposed amendments to Form 10–K and Form 10–Q to require additional disclosure regarding the issuer's decision in light of such vote as to how frequently the company will include those say-on-pay votes for the six subsequent years. Our proposed amendments to Item 9B of Form 10–K and new Item 5(c) of Part II of Form 10–Q would have required an issuer to disclose this decision in the Form 10–Q covering the quarterly period during which the shareholder advisory vote occurs, or in the Form 10–K if the shareholder advisory vote occurs during the issuer's fourth quarter. In light of the relevance of this decision to potential shareholder proposals on the topic, we proposed this disclosure to notify shareholders on a timely basis about the issuer's decision on how frequently it

[151] For purposes of this analysis, an abstention would not count as a vote cast. We are prescribing this voting standard solely for purposes of determining the scope of the exclusion under the note to Rule 14a–8(i)(10), and not for the purpose of determining whether a particular voting frequency should be considered to have been adopted or approved by shareholder vote as a matter of state law.

[152] We recognize that this approach is different from the traditional "substantially implemented" standard in Rule 14a–8(i)(10) since the frequency sought by a shareholder would be different from the frequency the issuer has implemented. We have revised the note to avoid confusion in that regard. A shareholder proposal seeking a frequency that is the same as that provided by the company would be excludable under the traditional "substantially implemented" standards in Rule 14a–8(i)(10) without regard to the new note, assuming there are no other differences that would lead to a different result.

[153] No-action requests to exclude shareholder proposals that seek shareholder advisory votes on different aspects of executive compensation will be evaluated on a case-by-case basis by the staff.

[154] Issuers seeking to exclude a shareholder proposal under the note to Rule 14a–8(i)(10) are required to follow the same shareholder proposal process with the staff of the Commission as would be required if the issuer intended to rely on any other substantive basis for exclusion under Rule 14a–8.

will provide the say-on-pay vote to shareholders.

b. Comments on the Proposed Amendments

Comments on the proposal were mixed. A number of commentators supported the amendments as proposed that would require disclosure of an issuer's decision as to the frequency of say-on-pay votes in the Form 10–Q or Form 10–K for the period during which the advisory vote occurs [155] as the requirement would allow shareholders to readily obtain an issuer's decision on the frequency of say-on-pay votes.[156] Some commentators questioned whether the Commission should require such disclosure of an issuer's determination regarding frequency following the results of a shareholder advisory vote at all,[157] given that the shareholder vote on the frequency of say-on-pay votes is only advisory.[158] Other commentators suggested that we should allow issuers additional time to consider the results of the shareholder vote [159] and to contact shareholders for additional feedback,[160] particularly if the shareholders do not express a clear preference on frequency. These commentators recommended that we instead require that disclosure about the issuer's decision be included in a later Form 10–Q or Form 10–K filing,[161] Form 8–K filing,[162] or on the issuer's Web site.[163] These commentators indicated that a requirement for a later filing would still permit shareholders adequate time to submit a shareholder proposal on the frequency of say-on-pay votes.[164]

Commentators also noted that Item 5.07 of Form 8–K currently requires disclosure of the number of votes cast "for, against or withheld" on matters submitted to a vote of shareholders, but that the item would not permit disclosure of the results of the frequency vote for "1 year, 2 years, 3 years, or abstain." [165] These commentators suggested that we amend Item 5.07 of Form 8–K to facilitate reporting the results of the frequency vote.[166]

c. Final Rule

After reviewing the comments on this issue, we have concluded that disclosure of the issuer's determination regarding frequency of say-on-pay votes should be required, but we are adopting the disclosure requirement through an amendment to Item 5.07 of Form 8–K in lieu of amendments to Form 10–Q and Form 10–K. We have considered the position of commentators who were concerned that the required timing of disclosure under our proposal would not permit sufficient time for issuers to fully consider the results of the vote, including through board deliberations and consultation with shareholders as described above, before the disclosure of the decision is required.[167] In light of this concern, we are adopting this disclosure requirement as a Form 8–K requirement due at a later date, in lieu of amending Form 10–Q and Form 10–K, to give issuers additional time to make their decisions.

Under our final rule, Item 5.07 of Form 8–K requires an issuer to disclose its decision regarding how frequently it will conduct shareholder advisory votes on executive compensation following each shareholder vote on the frequency of say-on-pay votes. To comply, an issuer will file an amendment to its prior Form 8–K filings under Item 5.07 that disclose the preliminary and final results of the shareholder vote on frequency. This amended Form 8–K will be due no later than 150 calendar days after the date of the end of the annual or other meeting in which the vote required by Rule 14a–21(b) took place, but in no event later than 60 calendar days prior to the deadline for the submission of shareholder proposals under Rule 14a–8 for the subsequent annual meeting, as disclosed in the issuer's proxy materials for the meeting at which the frequency vote occurred.[168] In the amended Item 5.07 Form 8–K, the issuer must disclose its determination regarding the frequency of say-on-pay votes.[169]

We believe the time period specified for filing the amended Item 5.07 Form 8–K should address commentators' requests that we revise the proposal to allow companies additional time to carefully consider the results of the frequency vote, including through board and committee deliberations and discussions with shareholders, before disclosure of the decision is required.[170] It also should provide enough time for shareholders to consider whether to submit a shareholder proposal on say-on-pay votes or on the frequency of say-on-pay votes once the disclosure is provided.

In addition, in response to comment,[171] we are adopting a technical amendment to Item 5.07(b) of Form 8–K to facilitate reporting of shareholder votes on frequency. Item 5.07 of Form 8–K generally requires an issuer to "state the number of votes cast for, against, or withheld, as well as the number of abstentions and broker non-votes as to each such matter * * *." The amendments we adopt today will clarify that, with respect to the vote on the frequency of say-on-pay votes, the issuer will be required to disclose the number of votes cast for each of 1 year, 2, years, and 3 years, as well as the number of abstentions.[172]

6. Effect of Shareholder Vote

Although the language in Section 951 of the Act indicates that the separate resolution subject to shareholder vote is "to determine" the frequency of the shareholder vote on executive compensation, in light of new Section 14A(c) of the Exchange Act, we continue to believe this shareholder vote, and all shareholder votes required by Section 951 of the Act, are intended to be non-binding on the issuer or the issuer's board of directors. New Section 14A(c) states that the shareholder votes referred to in Section 14A(a) and Section 14A(b) (which includes all votes

[155] *See, e.g.,* letters from CalPERS, ICGN, Meridian, PGGM, and SBA of Florida.

[156] *See* letter from SBA of Florida.

[157] *See, e.g.,* letters from Business Roundtable, Boeing, Center on Exec. Comp., CCMC, FSR, and Society of Corp. Sec.

[158] *See, e.g.,* letter from Society of Corp. Sec.

[159] *See, e.g.,* letters from Compensia, Davis Polk, Eaton, Frederic Cook, PM&P, and Protective Life.

[160] *See, e.g.,* letters from ABA, Boeing, TIAA–CREF, and Time Warner Inc. ("Time Warner").

[161] *See, e.g.,* letters from Eaton, Frederic Cook, Compensia, and PM&P.

[162] *See, e.g.,* letters from ABA and Davis Polk.

[163] *See* letter from Business Roundtable.

[164] *See* letter from ABA.

[165] *See, e.g.,* letter from Davis Polk.

[166] *See* letter from PIRC.

[167] *See, e.g.,* letters from ABA, Boeing, Compensia, Davis Polk, Eaton, Frederic Cook, PM&P, Protective Life, TIAA–CREF, and Time Warner.

[168] Item 5.07 is not among the list of items subject to the safe harbor from liability in Rules 13a–11 [17 CFR 240.13a–11] and 15d–11 [17 CFR 240.15d–11] under the Exchange Act. In addition, companies that fail to file a timely report required by Item 5.07 will lose their eligibility to file Form S–3 registration statements. We are not making a change to this as a result of our amendments to Item 5.07. We continue to believe that Item 5.07 does not require management to make rapid materiality and similar judgments within the compressed Form 8–K timeframe. *See Additional Form 8–K Disclosure Requirements and Acceleration of Filing Date*, Release No. 33–8400 (Mar. 16, 2004) [69 FR 15594] at Section II.E and *Proxy Disclosure Enhancements*, Release No. 33–9089 (Dec. 16, 2009) [74 FR 68334] at Section II.E.

[169] Item 5.07(d) of Form 8–K.

[170] In this regard, we note the recent guidance provided by the Division of Corporation Finance that Regulation FD [17 CFR 243.100 *et seq.*] does not prohibit directors from speaking privately with a shareholder or group of shareholders as described in that guidance. *See* Regulation FD CDIs, Question 101.11.

[171] *See, e.g.,* letters from Davis Polk and PIRC.

[172] We are adopting a conforming technical change to Instruction 1 to Item 5.07 to carve out Item 5.07(d) from the four-business day period for reporting the event. *See* Instruction 1 to Item 5.07 of Form 8–K.

under Section 951 of the Act) "shall not be binding on the issuer or the board of directors of an issuer."[173] Though we received a comment letter asserting that the shareholder vote on frequency is binding,[174] in our view the plain language of Exchange Act Section 14A(c) indicates that this vote is advisory. Accordingly, we are adopting new Item 24 of Schedule 14A to include language to require disclosure regarding the general effect of the shareholder advisory votes, such as whether the vote is non-binding.[175]

C. Issues Relating to Both Shareholder Votes Required by Section 14A(a)

1. Amendments to Rule 14a–6

We proposed amendments to Rule 14a–6 to add the say-on-pay and frequency of say-on-pay votes to the list of items that do not require the filing of proxy materials in preliminary form. After considering comments, we are adopting the proposed amendments to Rule 14a–6, with some modification.

a. Proposed Amendments

Rule 14a–6(a) generally requires issuers to file proxy statements in preliminary form at least ten calendar days before definitive proxy materials are first sent to shareholders, unless the items included for a shareholder vote in the proxy statement are limited to specified matters. During the time before final proxy materials are filed, our staff has the opportunity to comment on the disclosures and issuers are able to incorporate the staff's comments in their final proxy materials. Absent an amendment to Rule 14a–6(a), a proxy statement that includes a solicitation for either the shareholder vote on the approval of executive compensation or the approval of the frequency of the votes approving executive compensation required by Sections 14A(a)(1) and 14A(a)(2) would need to be filed in preliminary form. Because the shareholder vote on executive compensation and the shareholder vote on the frequency of such shareholder votes are required for all issuers, we view them as similar to the other items specified in Rule 14a–6(a) that do not require a preliminary filing. In the Proposing Release, we noted our view that a preliminary filing requirement for the shareholder votes on executive compensation and the frequency of such votes would impose unnecessary administrative burdens and preparation and processing costs associated with the filing and processing of proxy material that would unlikely be selected for review in preliminary form.[176]

We proposed amendments to Rule 14a–6(a) to add the shareholder votes on executive compensation and the frequency of shareholder votes on executive compensation required by Section 14A(a) to the list of items that do not trigger a preliminary filing.[177] As proposed, a proxy statement that includes a solicitation with respect to either of these shareholder votes would not trigger a requirement that the issuer file the proxy statement in preliminary form, so long as a preliminary filing would not otherwise be required under Rule 14a–6(a).

b. Comments on the Proposed Amendments

Comments on the proposal were favorable. While one commentator stated that say-on-pay votes and votes on the frequency of say-on-pay votes should trigger the requirement to file in preliminary form to provide the market and investors additional time to consider the executive compensation disclosures,[178] the preponderance of commentators agreed that no preliminary proxy should be required.[179] These commentators noted the similarity in proposals for all issuers and the likelihood that the administrative burdens would outweigh any benefits from a preliminary filing.[180] In addition, one commentator asserted that we should not require a preliminary proxy statement for shareholder advisory votes on the frequency of say-on-pay votes that are not required by Section 14A so that issuers would not be required to file in preliminary form as a result of including a frequency vote in their proxy materials voluntarily.[181] Other commentators suggested that no preliminary proxy statement should be required for any separate shareholder vote on executive compensation,[182] noting that it would be inappropriate to require a preliminary filing for proposals on more narrow aspects of compensation if a preliminary filing is not required for broader proposals.[183]

c. Final Rule

After considering the comments, we are adopting the amendments to Rule 14a–6(a) as proposed, with slight modifications. We are adopting amendments to Rule 14a–6(a) to add any shareholder advisory vote on executive compensation, including shareholder votes to approve executive compensation and the frequency of shareholder votes on executive compensation required by Section 14A(a), to the list of items that do not trigger a preliminary filing. As adopted, a proxy statement that includes a solicitation with respect to any advisory vote on executive compensation, including a say-on-pay vote or a vote on the frequency of say-on-pay votes, would not trigger a requirement that the issuer file the proxy statement in preliminary form, so long as any other matters to which the solicitation relates include only the other matters specified by Rule 14a–6(a). Finally, in a revision from the proposal, this amendment will also encompass an advisory vote on executive compensation, including a vote on the frequency of say-on-pay votes, that is not required by Section 14A. Upon review of the comments, we are persuaded by commentators' arguments that our preliminary proxy filing requirements should not differentiate between say-on-pay votes simply because, in one case, the issuer is required to include the proposal, and, in the other, the issuer chooses to do so.

2. Broker Discretionary Voting

As noted in the Proposing Release,[184] Section 957 of the Act amends Section 6(b) of the Exchange Act[185] to direct the national securities exchanges to change their rules to prohibit broker discretionary voting of uninstructed shares in certain matters, including

[173] Exchange Act Section 14A(c).

[174] *See* letter from Merkl.

[175] Even though each of the shareholder advisory votes required by Section 14A is non-binding pursuant to the rule of construction in Section 14A(c), as we noted in Note 69 of the Proposing Release, we believe these votes could play a role in an issuer's executive compensation decisions.

[176] *See* Section II.C.1 of the Proposing Release. *See also, Proxy Rules—Amendments to Eliminate Filing Requirements for Certain Preliminary Proxy Material; Amendments With Regard to Rule 14a–8, Shareholder Proposals*, Release No. 34–25217 (Dec. 21, 1987) [52 FR 48982].

[177] In the recent release relating to the similar shareholder votes for companies subject to EESA with outstanding indebtedness under the TARP program, we received comments regarding whether a preliminary proxy statement should be required for shareholder votes on executive compensation for TARP companies. While some commentators argued that a preliminary proxy statement should be required, other commentators argued persuasively that the burdens of such an approach outweighed the costs. As a result, we decided to eliminate the requirement for a preliminary proxy statement for shareholder votes on executive compensation for TARP companies. *See* TARP Adopting Release, *supra* note 18, at 75 FR 2791.

[178] *See* letter from Brian Foley ("Foley").

[179] *See, e.g.,* letters from Ameriprise Financial ("Ameriprise"), ABA, Business Roundtable, CalPERS, Center on Exec. Comp., Compensia, Davis Polk, FSR, ICGN, Pfizer, PGGM, PM&P, Protective Life, and Society of Corp. Sec.

[180] *See, e.g.,* letter from Compensia.

[181] *See* letter from Business Roundtable.

[182] *See* letters from ABA and ICGN.

[183] *See* letter from ABA.

[184] See Section II.C.2 of the Proposing Release.

[185] 15 U.S.C. 78f(b).

shareholder votes on executive compensation. The national securities exchanges have made substantial progress in amending their rules regarding broker discretionary voting on executive compensation matters to implement this requirement.[186] Under these amended exchange rules, for issuers with a class of securities listed on a national securities exchange, broker discretionary voting of uninstructed shares is not permitted for a shareholder vote on executive compensation or a shareholder vote on the frequency of the shareholder vote on executive compensation.[187]

3. Relationship to Shareholder Votes on Executive Compensation for TARP Companies

Issuers that have received financial assistance under the Troubled Asset Relief Program, or TARP, are required to conduct a separate annual shareholder vote to approve executive compensation during the period in which any obligation arising from the financial assistance provided under the TARP remains outstanding.[188]

Because the vote required to approve executive compensation pursuant to the Emergency Economic Stabilization Act of 2008, or EESA, is effectively the same vote that would be required under Section 14A(a)(1), as we indicated in the Proposing Release,[189] we believe that a shareholder vote to approve executive compensation under Rule 14a–20 for issuers with outstanding indebtedness under the TARP would satisfy Rule 14a–21(a). Consequently, we noted in the Proposing Release that we would not require an issuer that conducts an annual shareholder advisory vote to approve executive compensation pursuant to EESA to conduct a separate shareholder advisory vote on executive compensation under Section 14A(a)(1) until that issuer has repaid all indebtedness under the TARP. Such an issuer would be required to include a separate shareholder advisory vote on executive compensation pursuant to Section 14A(a)(1) and Rule 14a–21(a) for the first annual meeting of shareholders after the issuer has repaid all outstanding indebtedness under the TARP. Commentators on this issue generally expressed support for our proposed approach to companies with outstanding indebtedness under TARP,[190] and we have determined to implement this approach under the rules as adopted.

Even though issuers with outstanding indebtedness under the TARP have a separate statutory requirement to provide an annual shareholder vote on executive compensation so long as they are indebted under the TARP, absent exemptive relief these issuers would be required, pursuant to Section 14A(a)(2) of the Exchange Act, to provide a separate shareholder advisory vote on the frequency of shareholder votes on executive compensation for the first annual or other such meeting of shareholders on or after January 21, 2011. In our view, however, because such issuers have a requirement to conduct an annual shareholder advisory vote on executive compensation so long as they are indebted under the TARP, a shareholder advisory vote on the frequency of such votes while the issuer remains subject to a requirement to conduct such votes on an annual basis would not serve a useful purpose. We expressed these views in the Proposing Release[191] and, as noted above, commentators supported our views on this point.

We have considered, therefore, whether issuers with outstanding indebtedness under the TARP should be subject to the requirements of Section 14A(a)(2) of the Exchange Act. We do not believe it is necessary or appropriate in the public interest or consistent with the protection of investors to require an issuer to conduct a shareholder advisory vote on the frequency of the shareholder advisory vote on executive compensation when the issuer already is required to conduct advisory votes on executive compensation annually regardless of the outcome of such frequency vote. Because Section 14A(a)(2) would burden TARP issuers and their shareholders with an additional vote while providing little benefit to either the issuer or its shareholders, we continue to believe an exemption by rule is appropriate, pursuant to both the exemptive authority granted by Section 14A(e) of the Exchange Act[192] and the Commission's general exemptive authority pursuant to Section 36(a)(1) of the Exchange Act.[193] As a result, Rule 14a–21(b), as we are adopting it, exempts an issuer with outstanding indebtedness under the TARP from the requirements of Rule 14a–21(b) and Section 14A(a)(2) until the issuer has repaid all outstanding indebtedness under the TARP. Similar to the approach for shareholder advisory votes under Rule 14a–21(a), such an issuer would be required to include a separate shareholder advisory vote on the frequency of shareholder advisory votes on executive compensation pursuant to Section 14A(a)(2) and Rule 14a–21(b) for the first annual meeting of shareholders after the issuer has repaid all outstanding indebtedness under the TARP.

D. Disclosure of Golden Parachute Arrangements and Shareholder Approval of Golden Parachute Arrangements

1. General

Section 14A(b)(1) of the Exchange Act requires all persons making a proxy or consent solicitation seeking shareholder approval of an acquisition, merger, consolidation or proposed sale or disposition of all or substantially all of an issuer's assets to provide disclosure, in accordance with rules we promulgate, of any agreements or understandings that the soliciting person has with its named executive officers (or that it has with the named executive officers of the acquiring issuer) concerning compensation that is based on or otherwise relates to the

[186] *See, e.g., Notice of Filing and Order Granting Accelerated Approval of a Proposed Rule Change to Amend NYSE Rule 452 and Listed Company Manual Section 402.08 to Eliminate Broker Discretionary Voting on Executive Compensation Matters,* Release No. 34–62874, SR–NYSE–2010–59 (Sept. 9, 2010); *Notice of Filing and Order Granting Accelerated Approval of Proposed Rule Change to Prohibit Members from Voting Uninstructed Shares on Certain Matters,* Release No. 34–62992, SR–NASDAQ–2010–114 (Sept. 24, 2010).

[187] Broker discretionary voting in connection with merger or acquisition transactions also is not permitted under rules of the national securities exchanges. *See, e.g.,* NYSE Rule 452.

[188] Section 111(e) of the Emergency Economic Stabilization Act of 2008, 12 U.S.C. 5221. *See also* Rule 14a–20.

[189] *See* Section II.C.3 of the Proposing Release.

[190] *See, e.g.,* letters from ABA, CalPERS, COPERA, Davis Polk, FSR, PGGM, and RAILPEN & USS.

[191] *See* Section II.C.3 of the Proposing Release.

[192] Exchange Act Section 14A(e) provides that "the Commission may, by rule or order, exempt an issuer or class of issuers from the requirement" under Sections 14A(a) or 14A(b). Section 14A(e) further provides that "in determining whether to make an exemption under this subsection, the Commission shall take into account, among other considerations, whether the requirements under [Section 14A(a) and 14A(b)] disproportionately burdens small issuers." In adopting this exemption, the Commission considered whether the requirements of Section 14A(a) and (b) as applied to TARP recipients to conduct a shareholder advisory vote on the frequency of say-on-pay votes could disproportionately burden small issuers. As described further in Section II.E below, we have also considered whether the provision as a whole disproportionately burdens small issuers. We note, in addition, that to the extent a TARP recipient is a small issuer, it will be subject to the exemption.

[193] 15 U.S.C. 78mm(a)(1). Exchange Act Section 36(a)(1) provides that "the Commission, by rule, regulation, or order, may conditionally or unconditionally exempt any person, security, or transaction, or any class of persons, securities, or transactions, from any provision or provisions of this title or of any rule or regulation thereunder, to the extent that such exemption is necessary or appropriate in the public interest, and is consistent with the protection of investors."

merger transaction. In addition, Section 14A(b)(1) requires disclosure of any agreements or understandings that an acquiring issuer has with its named executive officers and that it has with the named executive officers of the target company in transactions in which the acquiring issuer is making a proxy or consent solicitation seeking shareholder approval of an acquisition, merger, consolidation or proposed sale or disposition of all or substantially all of an issuer's assets. Section 14A(b)(1) of the Exchange Act requires the disclosure to be in a "clear and simple form in accordance with regulations to be promulgated by the Commission" and to include "the aggregate total of all such compensation that may (and the conditions upon which it may) be paid or become payable to or on behalf of such executive officer." [194]

Under existing Commission rules, a target issuer soliciting shareholder approval of a merger is required to describe briefly any substantial interest, direct or indirect, by security holdings or otherwise, of any person who has been an executive officer or director since the beginning of the last fiscal year in any matter to be acted upon.[195] In response to this requirement, target issuers often include disclosure in their proxy statements about compensation arrangements that may be payable to a target issuer's executive officers and directors in connection with the transaction. In addition, under our existing rules, issuers are required to include in annual reports and annual meeting proxy statements detailed information in accordance with Item 402(j) of Regulation S–K about payments that may be made to named executive officers upon termination of employment or in connection with a change in control.[196] The Item 402(j) disclosure is provided based on year-end information and various assumptions, and generally does not reflect any actual termination or termination event.[197]

2. Item 402(t) of Regulation S–K

We proposed Item 402(t) of Regulation S–K to require disclosure of named executive officers' golden parachute arrangements in both tabular and narrative formats. This disclosure will be required in merger proxies and other disclosure documents for similar transactions as described in Section II.D.3 below. After considering the comments on this proposal, we are adopting Item 402(t) as proposed, with some modifications.

a. Proposed Amendments

We proposed Item 402(t) of Regulation S–K to require disclosure of named executive officers' golden parachute arrangements in both tabular and narrative formats. We based our proposals on Section 14A(b)(1)'s requirement that disclosure of the golden parachute compensation in any proxy or consent solicitation to approve an acquisition, merger, consolidation or proposed sale or disposition of all or substantially all assets be "in a clear and simple form in accordance with regulations to be promulgated by the Commission" and include "the aggregate total of all such compensation that may (and the conditions upon which it may) be paid or become payable to or on behalf of such executive officer." [198]

Consistent with Section 14A(b)(1) of the Exchange Act, agreements or understandings between a target issuer conducting a solicitation and its named executive officers would be subject to disclosure under proposed Item 402(t). In addition, because golden parachute compensation arrangements also may involve agreements or understandings between the acquiring issuer and the named executive officers of the target issuer, we proposed that Item 402(t) require disclosure of this compensation in addition to the disclosure mandated by Section 14A(b)(1). Specifically, to cover the full scope of potential golden parachute compensation applicable to the transaction, we proposed that Item 402(t) require disclosure of all golden parachute compensation relating to the merger among the target and acquiring issuers and the named executive officers of each.[199]

We did not propose to amend the requirements for golden parachutes disclosure in annual meeting proxy statements, although, under our proposal companies would be permitted to provide disclosure in annual meeting proxies in accordance with the new requirement.[200]

b. Comments on the Proposed Amendments

Comments on the proposal were generally favorable. We requested comment on a number of aspects of proposed Item 402(t), which we describe in more detail below.

i. General Comments on the Proposed Item 402(t) Table

We proposed that the Item 402(t) table would present quantitative disclosure of the individual elements of compensation that a named executive officer would receive that are based on or otherwise relate to the merger, acquisition, or similar transaction, and the total for each named executive officer.

Many commentators agreed that Item 402(t) as proposed would elicit disclosure of all elements of golden parachute compensation "in a clear and simple form" as required by Section 14A(b)(1).[201] In addition, some commentators suggested that Item 402(t) should be clarified to require disclosure of only compensation triggered by the subject transaction so that issuers are not required to disclose any golden parachute compensation that would not be triggered by the subject transaction.[202]

ii. Comments on the Elements of Compensation and Presentation of the Proposed Item 402(t) Table

As proposed, Item 402(t) would not have any *de minimis* exceptions for compensation below a certain dollar threshold and would not require disclosure of previously vested equity and pension benefits. Some commentators urged that Item 402(t) should have *de minimis* exceptions, like Item 402(j),[203] because, in their view, the exclusion of such immaterial amounts would not be inconsistent with Section 14A(b)(1)'s requirement to

[194] Exchange Act Section 14A(b)(1).

[195] Item 5 of Schedule 14A.

[196] *See* Item 402(j) of Regulation S–K [17 CFR 229.402(j)], Item 8 of Schedule 14A, and Item 11 of Form 10–K. Item 402(j) disclosure is required in both Annual Reports on Form 10–K and in annual meeting proxy statements, though such disclosure is typically provided in annual meeting proxy statements and incorporated into the Form 10–K by reference pursuant to General Instruction G(3) of Form 10–K. References to "annual meeting proxy statements" in this context are meant to encompass both locations for the disclosure.

[197] See Instruction 1 to Item 402(j), which requires quantitative disclosure applying the assumptions that the triggering event took place on the last business day of the issuer's last completed fiscal year, and the price per share of the issuer's securities is the closing market price as of that date. Where a triggering event has actually occurred for a named executive officer who was no longer serving as a named executive officer of the issuer at the end of the last completed fiscal year, Instruction 4 to Item 402(j) requires Item 402(j) disclosure for that named executive officer only for that triggering event.

[198] Exchange Act Section 14A(b)(1).

[199] However, because any agreements between a soliciting target company's named executive officers and the acquiring company are beyond the scope of the disclosure required by Section 14A(b)(1), we did not propose to subject such agreements to the Rule 14a–21(c) shareholder advisory vote required by Section 14A(b)(2) and Rule 14a–21(c). *See* discussion of Rule 14a–21(c) in Section II.D.4 below.

[200] *See* Sections II.D.2 and II.D.4 below.

[201] *See, e.g.,* letters from Davis Polk, PGGM, and WorldatWork.

[202] *See, e.g.,* letters from Davis Polk, Society of Corp. Sec., and Wachtell.

[203] *See, e.g.,* letters from Compensia, Davis Polk, McGuireWoods, PM&P, and Sullivan.

disclose the total amount of golden parachute compensation.[204] In addition, some commentators asserted that we should amend Item 402(j) rather than propose a new Item 402(t).[205]

Most commentators agreed with the proposed approach to omit previously vested equity and pension benefits from the table,[206] as including such amounts in the table could lead to confusion by overstating the total compensation.[207] Other commentators, however, recommended that such compensation be disclosed in the table [208] to make the compensation disclosure more comprehensive.[209]

A number of commentators also requested various other changes to the proposed table. Some commentators argued that issuers should have more flexibility in drafting the table to fit their individual circumstances,[210] or that issuers should be permitted to differentiate between cash severance compensation and cash amounts for outstanding awards that have been accelerated.[211] With respect to employment agreements, most commentators supported our proposed approach to exclude disclosure of employment agreements from the Item 402(t) table,[212] though some commentators argued that such employment agreements should be quantified and included in the tabular disclosure to provide more comprehensive disclosure.[213] A number of commentators supported the footnote identification of amounts of "single-trigger" and "double-trigger" [214] compensation elements,[215] with some commentators recommending that the disclosure be included in the main text rather than in footnotes if an issuer believes it would be useful to the presentation.[216] One commentator, however, indicated that identification of single-trigger and double-trigger elements should not be required as it believed this disclosure would not be useful to investors.[217]

We also requested comment with respect to the appropriate measurement for issuer stock price for tabular disclosure in proxy statements for mergers or similar transactions. A number of commentators agreed with our proposed approach to calculate such amounts based on the issuer's share price as of the latest practicable date,[218] though many other commentators suggested that the share price contemplated by the deal should be used, if available,[219] with an alternative to use the average closing price over the first five business days following public announcement of the transaction.[220] One commentator expressed a concern that the share price as of the latest practicable date could lead to potential gaming of the price by issuers.[221]

iii. Comments on Individuals Subject to Item 402(t) Disclosure

Some commentators indicated that requiring disclosure under Item 402(t) of a broader group of individuals than is required by Exchange Act Section 14A(b)(1) would be potentially confusing to investors [222] as such disclosure goes beyond the requirements of Section 14A and could lead to as many as three separate tables.[223] Different commentators supported disclosure of the broader group of individuals [224] in order to provide the full picture of compensation being received in connection with the transaction.[225]

Most commentators supported the proposal that issuers would not be required to include Item 402(t) information with respect to individuals who would have been among the most highly compensated executive officers but for the fact that they were not serving as an executive officer at the end of the last completed fiscal year.[226] One commentator, however, argued that issuers should be permitted to include disclosure of the compensation of such individuals to conform to the presentation of compensation in prior filings and that we should clarify that the named executive officers subject to Item 402(t) is determined in the same manner as under Item 5.02(e) of Form 8–K.[227]

iv. Comments on Item 402(t) Disclosure in Annual Meeting Proxy Statements

In the Proposing Release, we did not propose requiring Item 402(t) disclosure in annual meeting proxy statements. Most commentators agreed that the proposed Item 402(t) narrative and tabular disclosure should not be required in annual meeting proxy statements [228] given the costs and burdens this would impose on issuers.[229] However, other commentators recommended that such disclosure should be required in annual meeting proxy statements,[230] noting that such information plays a key part in shareholder evaluation of an issuer's compensation program.[231]

c. Final Rule

After considering comments, we are adopting Item 402(t) of Regulation S–K as proposed, with some modifications, to require disclosure of named executive officers' golden parachute arrangements in both tabular and narrative formats.

i. Item 402(t) Table and Narrative Requirements

We are adopting the following new table, as proposed:

[204] *See* letter from Compensia.

[205] *See, e.g.,* letters from Business Roundtable and Meridian.

[206] *See, e.g.,* letters from ABA, Center on Exec. Comp., Davis Polk, FSR, ICGN, NACD, Pfizer, PM&P, Protective Life, and WorldatWork.

[207] *See* letter from ABA.

[208] *See, e.g.,* letters from Barnard, Glass Lewis, PGGM, and Senator Levin.

[209] *See, e.g.,* letter from Glass Lewis.

[210] *See* letter from ABA.

[211] *See* letter from Towers Watson.

[212] *See, e.g.,* letters from ABA, Center on Exec. Comp., Compensia, Davis Polk, Frederic Cook, FSR, Hermes, and PGGM.

[213] *See, e.g.,* letters from Glass Lewis, NACD, and PIRC.

[214] A "double-trigger" arrangement requires that the executive's employment be terminated without cause or that the executive resign for good reason within a limited period of time after the change-in-control to trigger payment. A "single-trigger" arrangement does not require such a termination or resignation after the change-in-control to trigger payment.

[215] *See, e.g.,* letters from CalPERS, CII, FSR, Hermes, ICGN, and PGGM.

[216] *See, e.g.,* letters from ABA and NACD.

[217] *See* letter from Protective Life.

[218] *See, e.g.,* letters from ABA, Center on Exec. Comp., and ICGN.

[219] *See, e.g.,* letters from Davis Polk, PM&P, and Sullivan.

[220] *See* letter from PGGM.

[221] *See* letter from PGGM.

[222] *See, e.g.,* letters from Center on Exec. Comp., Davis Polk, FSR, NACD, Pfizer, PGGM, Protective Life, Towers Watson, Wachtell, Lipton, Rosen & Katz ("Wachtell"), and WorldatWork.

[223] *See* letter from Davis Polk.

[224] *See, e.g.,* letters from CalPERS, ICGN, PIRC, and Senator Carl Levin ("Senator Levin").

[225] *See* letter from PIRC.

[226] *See, e.g.,* letters from Davis Polk, ICGN, PGGM, and PM&P.

[227] *See* letter from ABA.

[228] *See, e.g.,* letters from ABA, Center for Exec. Comp., Compensia, Davis Polk, Frederic Cook, FSR, Hermes Equity Ownership Services ("Hermes"), ICGN, McGuireWoods, PGGM, PM&P, and WorldatWork.

[229] *See, e.g.,* letter from Frederic Cook.

[230] *See, e.g.,* letters from AFSCME, Protective Life, and Public Citizen.

[231] *See* letter from AFSCME.

GOLDEN PARACHUTE COMPENSATION

Name	Cash ($)	Equity ($)	Pension/ NQDC ($)	Perquisites/ benefits ($)	Tax reim-bursement ($)	Other ($)	Total ($)
(a)	(b)	(c)	(d)	(e)	(f)	(g)	(h)
PEO							
PFO							
A							
B							
C							

The table presents quantitative disclosure of the individual elements of compensation that an executive would receive that are based on or otherwise relate to the merger, acquisition, or similar transaction, and the total for each named executive officer.[232] As proposed and adopted, elements that will be separately quantified and included in the total will be any cash severance payment (*e.g.,* base salary, bonus, and pro-rata non-equity incentive plan [233] compensation payments) (column (b)); the dollar value of accelerated stock awards, in-the-money option awards for which vesting would be accelerated, and payments in cancellation of stock and option awards (column (c)); pension and nonqualified deferred compensation benefit enhancements (column (d)); perquisites and other personal benefits and health and welfare benefits (column (e)); and tax reimbursements (*e.g.,* Internal Revenue Code Section 280G tax gross-ups) (column (f)). Consistent with the proposal, we are adopting an "Other" column of the table for any additional elements of compensation not specifically includable in the other columns of the table (column (g)). This column, like the columns for the other elements, will require footnote identification of each separate form of compensation reported. The final column in the table requires disclosure, for each named executive officer, of the aggregate total of all such compensation (column (h)).[234] We are adopting the table as proposed, with a requirement for separate footnote identification of amounts attributable to "single-trigger" arrangements and amounts attributable to "double-trigger" arrangements, so that shareholders can readily discern these amounts.

As proposed and adopted, the tabular disclosure required by Item 402(t) requires quantification with respect to any agreements or understandings, whether written or unwritten, between each named executive officer and the acquiring company or the target company, concerning any type of compensation, whether present, deferred or contingent, that is based on or otherwise relates to an acquisition, merger, consolidation, sale or other disposition of all or substantially all assets. The table will quantify cash severance, equity awards that are accelerated or cashed out, pension and nonqualified deferred compensation enhancements, perquisites, and tax reimbursements. In addition, the table requires disclosure and quantification of the value of any other compensation related to the transaction.[235]

However, as adopted, Item 402(t) will require tabular and narrative disclosure in a proxy statement soliciting shareholder approval of a merger or similar transaction or a filing made with respect to a similar transaction only of compensation that is based on or otherwise relates to the subject transaction.[236] We agree with commentators that it would not be useful to shareholders to require disclosure of amounts that would not be paid or payable in connection with the transaction subject to shareholder approval.

To implement the statutory mandate to disclose the conditions upon which the compensation may be paid or become payable, as proposed and adopted, Item 402(t) [237] requires issuers to describe any material conditions or obligations applicable to the receipt of payment, including but not limited to non-compete, non-solicitation, non-disparagement or confidentiality agreements, their duration, and provisions regarding waiver or breach.[238] We are also adopting a requirement, as proposed, to provide a description of the specific circumstances that would trigger payment,[239] whether the payments would or could be lump sum, or annual, and their duration, and by whom the payments would be provided,[240] and any material factors regarding each agreement.[241] These narrative items are modeled on the narrative disclosure required with respect to termination and change-in-control agreements.[242]

ii. Elements of Compensation and Presentation of Item 402(t) Table

In response to commentators' requests for greater flexibility to facilitate clear presentation, we note that under our final rule issuers are permitted to add additional named executive officers, and additional columns or rows to the tabular disclosure, such as to disclose cash severance separately from other cash compensation or to distinguish "single-trigger" and "double-trigger" arrangements, so long as such disclosure is not misleading.

As noted in the Proposing Release,[243] we considered whether making the disclosure requirements in Item 402(j) applicable to transactions enumerated in Section 14A(b)(1), rather than adopting a new disclosure item for purposes of Section 14A(b)(1), would be an appropriate approach to satisfy the requirements of the Act. However, certain elements required by Section

[232] Item 402(t)(2) of Regulation S–K.

[233] As defined in Item 402(a)(6)(iii) of Regulation S–K.

[234] Exchange Act Section 14A(b)(1) requires disclosure of "the aggregate total of all such compensation that may (and the conditions upon which it may) be paid or become payable to or on behalf of such executive officer."

[235] Consistent with our proposals, we have adopted Instruction 3 to Item 402(t)(2) to provide, like Instruction 1 to Item 402(j), that in the event uncertainties exist as to the provision of payments and benefits, or the amounts involved, the issuer is required to make a reasonable estimate applicable to the payment or benefit and disclose material assumptions underlying such estimate in its disclosure. Unlike Item 402(j), Item 402(t) does not permit the disclosure of an estimated range of payments.

[236] Instruction 1 to Item 402(t)(2).

[237] Item 402(t)(3) of Regulation S–K.

[238] Item 402(t)(3)(iii) of Regulation S–K.

[239] Item 402(t)(3)(i) of Regulation S–K.

[240] Item 402(t)(3)(ii) of Regulation S–K.

[241] Item 402(t)(3) of Regulation S–K. Such material factors would include, for example, provisions regarding modifications of outstanding options to extend the vesting period or the post-termination exercise period, or to lower the exercise price.

[242] Item 402(j) of Regulation S–K.

[243] *See* Section II.D.2 of the Proposing Release.

14A(b)(1) are not included in Item 402(j). Specifically, Item 402(j) does not require disclosure about arrangements that do not discriminate in scope, terms or operation in favor of executive officers and that are available generally to all salaried employees,[244] permits exclusion of *de minimis* perquisites and other personal benefits,[245] and does not require presentation of an aggregate total of all compensation that is based on or otherwise relates to a transaction.[246]

Despite the views of some commentators, we continue to believe that Item 402(t) should not permit exclusion of *de minimis* perquisites and other personal benefits because exclusion of these amounts would be inconsistent with Section 14A(b)(1), which requires disclosure of "the aggregate total of all such compensation that may [* * *] be paid or become payable [* * *]." Moreover, we continue to believe that the Section 14A(b)(1) requirement to disclose the information "in a clear and simple form" is best satisfied through the use of tabular disclosure, which Item 402(j) does not require.

Item 402(t), like Item 402(j),[247] does not require separate disclosure or quantification with respect to compensation disclosed in the Pension Benefits Table and Nonqualified Deferred Compensation Table. Item 402(t), as proposed and adopted, also does not require disclosure or quantification of previously vested equity awards because these award amounts are vested without regard to the transaction. We agree with the views expressed by some commentators that previously vested equity awards are not compensation "that is based on or otherwise relates to" the transaction. Similarly, after reviewing the comments, we continue to believe that we should not require tabular disclosure and quantification of compensation from *bona fide* post-transaction employment agreements to be entered into in connection with the merger or acquisition transaction. We agree with the views expressed by many commentators that future employment arrangements are not compensation "that is based on or otherwise relates to" the transaction.[248]

Under the final rule, where Item 402(t) disclosure is included in an annual meeting proxy statement,[249] the price per share amount will be calculated based on the closing market price per share of the issuer's securities on the last business day of the issuer's last completed fiscal year, as proposed,[250] consistent with quantification standards used in Item 402(j). However, in response to comments, we have modified how the issuer stock price will be measured for calculating dollar amounts for the tabular disclosure required by Item 402(t) in connection with a transactional filing. In a proxy statement soliciting shareholder approval of a merger or similar transaction or a filing made with respect to a similar transaction, Item 402(t)'s tabular quantification of dollar amounts based on issuer stock price will be based on the consideration per share, if such value is a fixed dollar amount, or otherwise on the average closing price per share over the first five business days following the first public announcement of the transaction.[251]

iii. Individuals Subject to Item 402(t) Disclosure

We continue to believe that Item 402(t) disclosure should cover a broader group of individuals than is required by Section 14A(b). Because compensation arrangements may involve agreements or understandings between the acquiring issuer and the named executive officers of the target issuer, Item 402(t), as proposed and adopted, requires disclosure of the full scope of golden parachute compensation applicable to the transaction. We agree with commentators and continue to believe that shareholders may find disclosure about these arrangements that are not otherwise required to be disclosed by Section 14A(b) informative to their voting decisions.

As both proposed and adopted, we have included an instruction providing that Item 402(t) disclosure need not be provided for persons who are named executive officers because they would have been among the most highly compensated executive officers but for the fact that they were not serving as an executive officer at the end of the last completed fiscal year.[252] However, in response to comments, we are clarifying that where Item 402(t) disclosure is provided in a proxy statement soliciting shareholder approval of a merger or similar transaction or a filing made with respect to a similar transaction, this instruction will be applied with respect to the named executive officers for whom disclosure was required in the issuer's most recent filing requiring Summary Compensation Table disclosure.[253]

iv. Item 402(t) Disclosure in Annual Meeting Proxy Statements

We are not requiring Item 402(t) disclosure in annual meeting proxy statements. We agree with the views expressed by most commentators that the proposed Item 402(t) narrative and tabular disclosure should not be required in annual meeting proxy statements given the costs and burdens this would impose on issuers. We believe that the requirements of Item 402(j) provide sufficient information to shareholders in that context, and note that issuers may also include disclosure pursuant to Item 402(t) voluntarily if they believe it would permit shareholders to gain a better understanding of their compensation programs.

An issuer seeking to satisfy the exception from the separate merger proxy shareholder vote under Section 14A(b)(2) and Rule 14a–21(c) by including Item 402(t) disclosure in an annual meeting proxy statement soliciting the shareholder vote required by Section 14A(a)(1) and Rule 14a–21(a)[254] will be able to satisfy Item 402(j) disclosure requirements with respect to a change-in-control of the issuer by providing the disclosure required by Item 402(t).[255] The issuer

[244] Instruction 5 to Item 402(j).

[245] *See* Instruction 2 to Item 402(j), which permits exclusion of perquisites and other personal benefits or property if the aggregate amount of such compensation will be less than $10,000.

[246] As proposed, we are adopting conforming changes to Item 402(a)(6)(ii) [17 CFR 229.402(a)(6)(ii)] and Item 402(m)(5)(ii) [17 CFR 229.402(m)(5)(ii)] of Regulation S–K to clarify that information regarding group life, health, hospitalization, or medical reimbursement plans that do not discriminate in scope, terms or operation, in favor of executive officers or directors of the company and that are generally available to all salaried employees must be included in disclosure pursuant to proposed Item 402(t).

[247] *See* Instruction 3 to Item 402(j).

[248] Information regarding such future employment agreements is subject to disclosure pursuant to Item 5(a) and Item 5(b)(xii) of Schedule 14A to the extent that such agreements constitute a "substantial interest" in the matter to be acted upon.

[249] A company may choose to include the disclosure in the annual meeting proxy statement in order for the Section 14A(a)(1) shareholder vote to satisfy the exception from the merger proxy separate vote. See Section II.D.4 below.

[250] Instruction 2 to Item 402(t)(2).

[251] Instruction 1 to Item 402(t)(2).

[252] Instruction 1 to Item 402(t), which requires Item 402(t) disclosure for individuals covered by Items 402(a)(3)(i), (ii) and (iii), and for smaller reporting companies, the individuals covered by Items 402(m)(2)(i) and (ii). Item 402(t) disclosure will not be required for individuals for whom Item 402(t) disclosure otherwise is required by Item 402(a)(3)(iv), and for smaller reporting companies, by Item 402(m)(2)(iii).

[253] Instruction 1 to Item 402(t)(2) and Instruction 2 to Item 1011(b). This is similar to the approach used in Instruction 4 to Item 5.02 of Form 8–K.

[254] This exception and the comments we received on the exception are discussed in Section II.D.4 below.

[255] We note also that one example of material information to be addressed in CD&A is the basis for selecting particular termination or change-in-

Continued

must still include in an annual meeting proxy statement disclosure in accordance with Item 402(j) about payments that may be made to named executive officers upon termination of employment.

3. Amendments to Schedule 14A, Schedule 14C, Schedule 14D–9, Schedule 13E–3, Schedule TO, and Item 1011 of Regulation M–A

We proposed amendments to require that the disclosure set forth in Item 402(t) of Regulation S–K be included in merger proxies as well as filings for other transactions not referenced in the Act. After considering the comments received, we are adopting the amendments to Schedule 14A, Schedule 14C, Schedule 14D–9, Schedule 13E–3, and Item 1011 of Regulation M–A as proposed with slight modifications to Item 1011 of Regulation M–A. We are also adopting an amendment to Schedule TO to clarify that the Item 402(t) disclosure is not required in third-party bidders' tender offer statements, so long as the transactions are not also Rule 13e–3 going-private transactions.

a. Proposed Amendments

We proposed amendments to Items 5(a) and (b) of Schedule 14A under the Exchange Act, as well as conforming changes to Item 3 of Schedule 14C, Item 1011(b) of Regulation M–A, Item 15 of Schedule 13E–3 and Item 8 of Schedule 14D–9. These proposals were intended to implement the disclosure requirements in Section 14A(b)(1) as well as to extend the new disclosure requirements to similar transactions by requiring that the disclosure set forth in Item 402(t) of Regulation S–K be included in any proxy or consent solicitation material seeking shareholder approval of an acquisition, merger, consolidation, or proposed sale or other distribution of all or substantially all the assets of the issuer. Our proposals would require such disclosure not only in a proxy or consent solicitation relating to such a transaction, as required by the Act, but also in the following:

- Information statements filed pursuant to Regulation 14C;
- Proxy or consent solicitations that do not contain merger proposals but require disclosure of information under Item 14 of Schedule 14A pursuant to Note A of Schedule 14A;
- Registration statements on Forms S–4 and F–4 containing disclosure relating to mergers and similar transactions;
- Going private transactions on Schedule 13E–3; and
- Third-party tender offers on Schedule TO and Schedule 14D–9 solicitation/recommendation statements.

We also proposed amendments to Item 1011(b) of Regulation M–A that would require the bidder [256] in a third-party tender offer to provide information in its Schedule TO about a target's golden parachute arrangements only to the extent the bidder has made a reasonable inquiry about the golden parachute arrangements and has knowledge of such arrangements. In addition, we proposed exceptions to both the disclosure requirement under Item 1011(b) for both bidders and targets in third-party tender offers and filing persons in Rule 13e–3 going-private transactions where the target or subject company is a foreign private issuer, and to the disclosure obligation under Item 402(t) with respect to agreements and understandings with senior management of foreign private issuers where the target or acquirer is a foreign private issuer.

b. Comments on the Proposed Amendments

Comments on the proposal were generally favorable. A number of commentators expressed support for our proposed approach to require disclosure of golden parachute arrangements in connection with other transaction not specifically referenced in the Act.[257] One commentator objected that the proposal goes beyond the scope of the statute by requiring disclosure of golden parachute compensation in connection with tender and exchange offers.[258] One commentator also questioned whether such disclosure should be required in third-party tender offers, given the difficulty bidders may face in obtaining accurate information regarding a target company's golden parachute arrangements.[259] Commentators also supported excluding foreign private issuers from Item 402(t) disclosure requirements for bidders and target companies in third-party tender offers and filing persons in Rule 13e–3 going-private transactions.[260]

c. Final Rule

After considering the comments, we are adopting the amendments to Schedule 14A, Schedule 14C, Schedule 14D–9, Schedule 13E–3, and Item 1011 of Regulation M–A as proposed, with slight modifications to Item 1011 of Regulation M–A. We are also adopting an amendment to Schedule TO to provide that bidders in third-party tender offers are not required to provide the disclosure required by Item 1011(b) of Regulation M–A.

Issuers could structure transactions in a manner that avoids implicating Section 14(a) of the Exchange Act (*e.g.,* tender offers and certain Rule 13e–3 going-private transactions), while still effectively seeking the consent of shareholders with respect to their investment decision (*e.g.,* whether or not to tender their shares or approve a going-private transaction, in instances where such going-private transactions are not subject to Regulation 14A). For these reasons, we continue to believe that requiring Item 402(t) disclosure in all such transactions furthers the purposes of Section 14A(b) of the Exchange Act and would minimize the regulatory disparity that might otherwise result from treating such transactions differently. Thus, we are adopting amendments that would require the Item 402(t) disclosure in various transactions, whether a merger, acquisition, a Rule 13e–3 going-private transaction or a tender offer.[261]

In addition, we note that acquiring companies may solicit proxies to approve the issuance of shares or a reverse stock split in order to conduct a merger transaction, and that such proxy statements are required to include disclosure of information required under Item 14 of Schedule 14A pursuant to Note A of Schedule 14A. Thus, we are also adopting amendments that would require the Item 402(t) disclosure in those proxy statements that are required to include disclosure of information required under Item 14 of Schedule 14A pursuant to Note A of Schedule 14A.[262] The shareholder advisory vote required by Section 14A(b)(2), however, will not be extended to transactions beyond those specified in that section.

We have revised the final rule in response to comments to provide that

control events as triggering payment (*e.g.,* the rationale for providing a single trigger for payment in the event of a change-in-control). *See* Item 402(b)(2)(xi) of Regulation S–K.

[256] "Bidder" is defined in Rule 14d–1(g)(2) [17 CFR 240.14d–1(g)(2)].

[257] *See, e.g.,* letters from ICGN and PGGM.

[258] *See* letter from Wachtell.

[259] *See* letter from ABA.

[260] *See, e.g.,* letters from ABA, ICGN, and PGGM.

[261] As adopted, companies filing solicitation/recommendation statements on Schedule 14D–9 in connection with third-party tender offers will be obligated to provide this additional disclosure. *See* Item 8 of Schedule 14D–9. However, as explained below, bidders filing offer statements on Schedule TO will not have a similar obligation. *See* Item 11 of Schedule TO.

[262] *See* Item 5(a)(5) and Item 5(b)(3) of Schedule 14A, which will require acquiring companies to include the Item 402(t) disclosure with respect to each named executive officer of both the acquiring issuer and the target issuer.

bidders in third-party tender offers will not be required to comply with Item 1011(b), which calls for Item 402(t) disclosure. We are persuaded that bidders may face difficulties in obtaining the information necessary to provide such disclosure [263] and that it is not necessary to require a bidder to provide this information since the target companies will be required to provide the Item 402(t) golden parachute compensation disclosure in Schedule 14D–9 filed by the tenth business day from the date the tender offers are first published, sent or given to security holders.[264] We believe this revision to the proposal will alleviate a potential burden that bidders in third-party tender offers may encounter while still accomplishing our goal of minimizing the regulatory disparity that might otherwise result from treating third-party tender offers differently than other transactions described in this section by retaining the disclosure requirement in Schedule 14D–9. However, we did not adopt a similar revision to the proposed changes to Schedule 13E–3; therefore, the disclosure of golden parachute arrangements will be required in third-party tender offers that are also Rule 13e–3 going-private transactions.[265] In light of the revision to the proposal, we are not adopting the instruction to Item 1011(b) of Regulation M–A that would have allowed bidders to provide the disclosure only to the extent the information was known after making a reasonable inquiry. Therefore, Item 1011(b), as adopted, does not include the proposed instruction.

In addition, we are adopting as proposed an exception to the disclosure requirement under Item 1011(b) for targets in third-party tender offers and filing persons in Rule 13e–3 going-private transactions where the target or subject company is a foreign private issuer. Consistent with the proposal, we are also adopting an exception to the disclosure obligation under Item 402(t) with respect to agreements and understandings with senior management of foreign private issuers where the target or acquirer is a foreign private issuer.[266] We agree with commentators and believe such accommodations are appropriate in light of our long-standing accommodation to foreign private issuers regarding compensation disclosure.[267]

4. Rule 14a–21(c)

Section 14A(b)(2) generally requires a separate shareholder advisory vote on golden parachute compensation arrangements required to be disclosed under Section 14A(b)(1) in connection with mergers and similar transactions. A separate shareholder advisory vote would not be required on golden parachute compensation if disclosure of that compensation had been included in the executive compensation disclosure that was subject to a prior advisory vote of shareholders under Section 14A(a)(1) of the Exchange Act.

We proposed Rule 14a–21(c) to implement these requirements. We are adopting this rule substantially as proposed with some minor changes in response to comments.

a. Proposed Rule

Proposed Rule 14a–21(c) would require issuers to conduct a separate shareholder advisory vote in proxy statements for meetings at which shareholders are asked to approve an acquisition, merger, consolidation, or proposed sale or other disposition of all or substantially all assets, consistent with Section 14A(b)(2). This shareholder advisory vote would be required only with respect to the golden parachute agreements or understandings required to be disclosed by Section 14A(b)(1), as disclosed pursuant to proposed Item 402(t) of Regulation S–K. We proposed Rule 14a–21(c) to require a shareholder advisory vote only on the golden parachute compensation agreements or understandings for which Section 14A(b)(1) requires disclosure and Section 14A(b)(2) requires a shareholder vote. Consistent with Section 14A(b)(2), as proposed, issuers would not be required to include in the merger proxy a separate shareholder vote on golden parachute compensation disclosed in accordance with Item 402(t) of Regulation S–K if Item 402(t) disclosure of that compensation had been included in the executive compensation disclosure that was subject to a prior vote of shareholders under Section 14A(a)(1) of the Exchange Act and Rule 14a–21(a).

b. Comments on the Proposed Amendments

Comments on the proposal were generally positive. As noted above, some commentators indicated that requiring disclosure under Item 402(t) of a broader group of individuals than would be covered by the Rule 14a–21(c) shareholder advisory vote would be potentially confusing to investors [268] as such disclosure goes beyond the requirements of Section 14A and could lead to as many as three separate tables.[269]

Most commentators agreed with our proposed approach that if golden parachute arrangements were modified or amended subsequent to being subject to the annual shareholder vote under Rule 14a–21(a), a separate shareholder vote in the merger proxy should be required to cover only the changes to such arrangements,[270] given that full disclosure of the full set of arrangements will also be provided.[271] Some commentators, however, believed that in this circumstance the subsequent vote should cover the entire set of golden parachute arrangements, not just the changes, so that shareholders have the opportunity to vote on the full complement of compensation that would be payable.[272]

In addition, some commentators recommended that certain changes to golden parachute arrangements that were altered or amended subsequent to being subject to the shareholder advisory vote under Rule 14a–21(a) should be exempt from a separate shareholder advisory vote in a merger proxy. In their view, there should be an exemption for certain routine, non-substantive changes, such as where the same compensation arrangements apply to new named executive officers who were not included in the prior disclosure that was subject to the shareholder vote,[273] subsequent grants in the ordinary course of additional awards subject to the same acceleration terms that applied to awards covered by a previous vote,[274] routine changes in salary subsequent to the prior vote,[275] and changes that result in a reduction in compensation value.[276] Other

[263] *See* letter from ABA.

[264] We are adopting an amendment to Schedule TO to avoid imposing on bidders the obligation to provide such disclosure. See Item 11 of Schedule TO.

[265] *See* Item 15 of Schedule 13E–3.

[266] Instruction 2 to Item 402(t).

[267] *See, e.g.,* Item 402(a)(1) of Regulation S–K, and Items 6.B and 6.E.2 of Form 20–F [17 CFR 249.220f].

[268] *See, e.g.,* letters from Center on Exec. Comp., Davis Polk, FSR, NACD, Pfizer, PGGM, Protective Life, Towers Watson, Wachtell, Lipton, Rosen & Katz ("Wachtell"), and WorldatWork.

[269] *See* letter from Davis Polk.

[270] *See, e.g.,* letters from ABA, Frederic Cook, McGuireWoods, NACD, PGGM, Protective Life, and WorldatWork.

[271] *See, e.g.,* letter from ABA.

[272] *See, e.g.,* letter from CII.

[273] *See, e.g.,* letters from McGuireWoods, PM&P, Protective Life, Steve Quinlivan ("Quinlivan"), and Sullivan.

[274] *See, e.g.,* letters from Business Roundtable, Compensia, FSR, McGuireWoods, PM&P, Protective Life, Sullivan, and Wachtell.

[275] *See* letter from McGuireWoods.

[276] *See, e.g.,* letters from Frederic Cook, Meridian, and Protective Life.

commentators stated that there should be no exceptions and that a new golden parachute vote should be required if there have been any changes since the arrangements were subject to the Rule 14a–21(a) shareholder advisory vote.[277]

c. Final Rule

After considering the comments, we are adopting Rule 14a–21(c) as proposed, with some modifications. Consistent with the proposal, our rule does not require issuers to use any specific language or form of resolution to be voted on by shareholders. In addition, we note that, as provided in Section 14A(c), this shareholder vote will not be binding on the issuer or its board of directors.

i. Scope of Rule 14a–21(c) Shareholder Advisory Vote

Under Rule 14a–21(c), issuers will be required to provide a separate shareholder advisory vote in proxy statements for meetings at which shareholders are asked to approve an acquisition, merger, consolidation, or proposed sale or other disposition of all or substantially all assets, consistent with Section 14A(b)(2). However, issuers are not required to provide a separate shareholder advisory vote in proxy statements for meetings at which shareholders are asked to approve other proposals, such as an increase in authorized shares or a reverse stock split, which may be necessary for the issuer to effectuate a transaction. A vote under Rule 14a–21(c) is required only if the shareholders are voting to approve the transaction and the transaction and golden parachute arrangements come within those covered by Section 14A(b). Consistent with the proposal, this advisory vote will be required only with respect to the golden parachute agreements or understandings required to be disclosed by Section 14A(b)(1), as disclosed pursuant to proposed Item 402(t) of Regulation S–K.

Section 14A(b)(1) requires disclosure of any agreements or understandings between the soliciting person and any named executive officer of the issuer or any named executive officers of the acquiring issuer, if the soliciting person is not the acquiring issuer. When a target issuer conducts a proxy or consent solicitation to approve a merger or similar transaction, golden parachute compensation agreements or understandings between the acquiring issuer and the named executive officers of the target issuer are not within the scope of disclosure required by Section 14A(b)(1), and thus a shareholder vote to approve arrangements between the soliciting target issuer's named executive officers and the acquiring issuer is not required by Exchange Act Section 14A(b)(2). Consequently, consistent with the proposal, Rule 14a–21(c) as adopted requires a shareholder advisory vote only on the golden parachute compensation agreements or understandings for which Section 14A(b)(1) requires disclosure and Section 14A(b)(2) requires a shareholder vote. As described in Section II.D.2.c.iii above, however, disclosure of all golden parachute arrangements will be required, even though a vote on the arrangements will not be required.

ii. Exceptions to Rule 14a–21(c) Shareholder Advisory Vote

Consistent with Section 14A(b)(2) and our proposal, issuers will not be required to include in the merger proxy a separate shareholder vote on the golden parachute compensation disclosed under Item 402(t) of Regulation S–K if Item 402(t) disclosure of that compensation had been included in the executive compensation disclosure that was subject to a prior vote of shareholders under Section 14A(a)(1) of the Exchange Act and Rule 14a–21(a). In this regard, we note that Section 14A(b)(2) requires only that the golden parachute arrangements have been subject to a prior shareholder vote under Section 14A(a)(1); such arrangements need not have been approved by shareholders.

For issuers to take advantage of this exception, however, the executive compensation disclosure subject to the prior shareholder vote must have included Item 402(t) disclosure of the same golden parachute arrangements. Even if the annual meeting proxy statement provided some disclosure with respect to golden parachute arrangements,[278] the annual meeting proxy statement must include the disclosure required by Item 402(t) in order for the annual meeting shareholder vote under Section 14A(a)(1) and Rule 14a–21(a) to satisfy the exception from the merger proxy separate shareholder vote under Section 14A(b)(2) and Rule 14a–21(c). Consequently, we would expect that some issuers may voluntarily include Item 402(t) disclosure with their other executive compensation disclosure in annual meeting proxy statements soliciting the shareholder vote required by Section 14A(a)(1) and Rule 14a–21(a) so that this exception would be available to the issuer for a potential subsequent merger or acquisition transaction. We also expect that some issuers may choose to include the new disclosure for other reasons, such as investor interest in the information.

The exception will be available only to the extent the same golden parachute arrangements previously subject to an annual meeting shareholder vote remain in effect, and the terms of those arrangements have not been modified subsequent to the Section 14A(a)(1) shareholder vote. As proposed and adopted, if the disclosure pursuant to Item 402(t) has been updated to change only the value of the items in the Golden Parachute Compensation Table to reflect price movements in the issuer's securities, no new shareholder advisory vote under Section 14A(b)(1) will be required. New golden parachute arrangements, and any revisions to golden parachute arrangements that were subject to a prior Section 14A(a)(1) shareholder vote will be subject to the separate merger proxy shareholder vote requirement of Section 14A(b)(2) and Rule 14a–21(c).[279]

Additionally, we agree with certain commentators[280] that changes that result only in a reduction in value of the total compensation payable should not require a new shareholder vote. If the shareholders have had an opportunity to vote on a more highly valued compensation package, then we do not believe issuers should be required to provide a separate vote on a change that results only in a compensation package that has been reduced in value.

We believe that the other examples of changes cited by commentators, including changes in compensation because of a new named executive officer, additional grants of equity compensation in the ordinary course, and increases in salary, are significant changes to the golden parachute compensation disclosure and, consistent with Section 14A(b)(2), should be subject to a shareholder vote. Because a shareholder vote would already have been obtained on portions of the arrangements, however, only the new arrangements and revised terms of the arrangements previously subject to a Section 14A(a)(1) shareholder vote will be subject to the merger proxy separate

[277] *See, e.g.,* letters from Glass Lewis and PGGM.

[278] See CD&A and Item 402(j) of Regulation S–K, and for smaller reporting companies see Item 402(q)(2) of Regulation S–K for the disclosure requirements applicable to annual meeting proxy statements.

[279] For example, we would view any change that would result in an IRC Section 280G tax gross-up becoming payable as a change in terms triggering such a separate vote, even if such tax gross-up becomes payable only because of an increase in the issuer's share price.

[280] *See, e.g.,* letters from Frederic Cook, Meridian, and Protective Life.

shareholder vote under Section 14A(b)(2) and Rule 14a–21(c).

Consistent with the proposal, issuers providing for a shareholder vote on new arrangements or revised terms will need to provide two separate tables under Item 402(t) of Regulation S–K in merger proxy statements.[281] One table will disclose all golden parachute compensation, including both arrangements and amounts previously disclosed and subject to a say-on-pay vote under Section 14A(a)(1) and Rule 14a–21(a) and the new arrangements or revised terms. The second table will disclose only the new arrangements or revised terms subject to the vote, so that shareholders can clearly see what is subject to the shareholder vote under Section 14A(b)(2) and Rule 14a–21(c). Similarly, in cases where Item 402(t) requires disclosure of arrangements between an acquiring company and the named executive officers of the soliciting target company, issuers will need to clarify whether these agreements are included in the shareholder advisory vote by providing a separate table of all agreements and understandings subject to the shareholder advisory vote required by Section 14A(b)(2) and Rule 14a–21(c), if different from the full scope of golden parachute compensation subject to Item 402(t) disclosure.[282]

E. Treatment of Smaller Reporting Companies

Section 951 of the Act establishes a new Section 14A(e) of the Exchange Act, which provides that we may, by rule or order, exempt an issuer or class of issuers from the requirements of Section 14A(a) and (b). In determining whether to make an exemption under this subsection, we are directed to take into account, among other considerations, whether the requirements of Sections 14A(a) and 14A(b) disproportionately burden small issuers.

In the Proposing Release, we did not propose to exempt small issuers or smaller reporting companies[283] from the requirements of Sections 14A(a) and 14A(b). Comments on this issue were mixed. Many commentators agreed that the requirements of Section 14A should be applied to all issuers and that there should be no exemptions for smaller reporting companies,[284] while a number of other commentators asserted that smaller reporting companies should be exempt from the requirements of Exchange Act Section 14A and our proposed rules.[285] Among those opposed to applying the requirements to smaller reporting companies, in addition to stating that these requirements would be a burden to smaller reporting companies,[286] some commentators asserted that smaller reporting companies may feel compelled to include additional disclosure beyond the scaled requirements otherwise applicable to smaller reporting companies, including a CD&A, because of such votes,[287] which would impose significant burdens on these issuers. One commentator urged that, if we do not exempt smaller reporting companies, we should at least delay implementation of the proposed rules for smaller reporting companies so that smaller companies would have the opportunity to observe how larger companies conduct the vote and respond to the disclosure requirements.[288]

After reviewing and considering these comments, we are adopting a temporary exemption for smaller reporting companies so that these issuers will not be required to conduct either a shareholder advisory vote on executive compensation or a shareholder advisory vote on the frequency of say-on-pay votes until the first annual or other meeting of shareholders occurring on or after January 21, 2013.[289] We do not believe that smaller reporting companies should be permanently exempt from the say-on-pay vote, frequency of say-on-pay votes and golden parachute disclosure and vote because we believe investors have the same interest in voting on the compensation of smaller reporting companies and in clear and simple disclosure of golden parachute compensation in connection with mergers and similar transactions as they have for other issuers. However, after reviewing comments on the potential burdens on smaller reporting companies, we believe it is appropriate to provide additional time before smaller reporting companies are required to conduct the shareholder advisory votes on executive compensation and the frequency of say-on-pay votes.

We believe that a delayed effective date for the say-on-pay and frequency votes for smaller reporting companies should allow those companies to observe how the rules operate for other companies and should allow them to better prepare for implementation of the rules. We also believe that delayed implementation for these companies will allow us to evaluate the implementation of the adopted rules by larger companies and provide us with the additional opportunity to consider whether adjustments to the rule would be appropriate for smaller reporting companies before the rule becomes applicable to them. We believe a temporary exemption by rule is appropriate, under the exemptive authority granted by Section 14A(e) of the Exchange Act[290] and also under the Commission's general exemptive authority pursuant to Section 36(a)(1) of the Exchange Act, in the public interest and consistent with the protection of investors.[291]

This temporary exemption for smaller reporting companies does not apply to the requirements of Section 14A(b)(2) and Rule 14a–21(c) to provide a shareholder advisory vote on golden parachute compensation in connection with mergers or other extraordinary transactions. We view the temporary exemption as a transition matter that will facilitate eventual compliance with the regular, periodic say-on-pay vote requirement by smaller reporting

[281] *See* Instruction 6 to Item 402(t)(2) of Regulation S–K.

[282] Instruction 7 to Item 402(t)(2). As discussed above, such agreements are not required to be subject to the Rule 14a–21(c) shareholder advisory vote, but issuers may voluntarily subject them to such a vote.

[283] "Smaller reporting company" is defined in Rule 12b–2 under the Exchange Act.

[284] *See, e.g.,* letters from AFSCME, Boston Common, CalPERS, Calvert, CII, First Affirmative, Glass Lewis, ICGN, Merkl, PGGM, Public Citizen, RAILPEN & USS, SBA of Florida, Senator Levin, Social Investment, and Walden.

[285] *See, e.g.,* letters from American Bankers Association ("Am. Bankers"), Independent Community Bankers of America ("ICBA"), NACD, Society of Corp. Sec., and Virginia Bankers Association ("VBA").

[286] *See, e.g.,* letters from ABA, Am. Bankers, and VBA.

[287] *See, e.g.,* letters from ABA and Society of Corp. Sec.

[288] *See* letter from ABA.

[289] Rules 14a–21(a) and (b).

[290] Exchange Act Section 14A(e) provides that "the Commission may, by rule or order, exempt an issuer or class of issuers from the requirement" under Sections 14A(a) or 14A(b). Section 14A(e) further provides that "in determining whether to make an exemption under this subsection, the Commission shall take into account, among other considerations, whether the requirements under [Section 14A(a) and 14A(b)] disproportionately burdens small issuers." In considering whether to provide an exemption, the Commission considered whether the requirements of Section 14A(a) and (b) as applied to smaller reporting companies to conduct a shareholder advisory vote on executive compensation and a shareholder advisory vote on the frequency of say-on-pay votes could disproportionately burden small issuers.

[291] 15 U.S.C. 78 mm(a)(1). Exchange Act Section 36(a)(1) provides that "the Commission, by rule, regulation, or order, may conditionally or unconditionally exempt any person, security, or transaction, or any class of persons, securities, or transactions, from any provision or provisions of this title or of any rule or regulation thereunder, to the extent that such exemption is necessary or appropriate in the public interest, and is consistent with the protection of investors."

companies. We do not believe similar considerations support an exemption for the shareholder advisory vote on golden parachute arrangements in light of the extraordinary nature of the transactions involved.

We have also crafted our amendments to minimize the costs for smaller reporting companies, while providing shareholders the opportunity to express their views on the companies' compensation arrangements. For example, once they fully apply to smaller reporting companies, our amendments will provide shareholders of those companies the same voting rights with respect to executive compensation as apply to shareholders of other companies subject to the proxy rules. We do not believe that Section 14A and our final rules, especially given the temporary exemption, would unduly burden smaller reporting companies. For example, our final rule does not alter the existing scaled disclosure requirements set forth in Item 402 of Regulation S–K for smaller reporting companies, which recognize that the compensation arrangements of smaller reporting companies typically are less complex than those of other public companies.[292] Under the rules we adopt today, we do not alter the provision in our rules that smaller reporting companies are not required to provide a CD&A. Therefore, the amendment to Item 402(b) of Regulation S–K will not apply to smaller reporting companies, as such companies are not required to provide a CD&A.

Our amendments will, however, require quantification of golden parachute arrangements in merger proxies. Smaller reporting companies are not required to provide this quantification under current Item 402(q) in annual meeting proxy statements, and are not required to do so under our new rules unless they seek to qualify for the exception for a shareholder advisory vote on golden parachute compensation in a later merger transaction. Even though our rules impose additional disclosure requirements relating to the shareholder advisory votes required by Section 14A, we do not believe our rules will impose a significant additional cost or disproportionate burden upon smaller reporting companies. As noted above, smaller reporting companies tend to have less complex compensation arrangements[293] so the additional disclosures should not add significantly to their disclosure burden. As a result, we do not believe the rules we adopt today place a disproportionate burden on smaller reporting companies.

F. Transition Matters

As noted above in Section I, Section 14A(a)(3) requires that both the initial shareholder vote on executive compensation and the initial vote on the frequency of votes on executive compensation be included in proxy statements relating to an issuer's first annual or other meeting of the shareholders occurring on or after January 21, 2011. Because Section 14A(a) applies to shareholder meetings taking place on or after January 21, 2011, any proxy statements, whether in preliminary or definitive form, even if filed prior to this date, for meetings taking place on or after January 21, 2011, must include the separate resolutions for shareholders to approve executive compensation and the frequency of say-on-pay votes required by Section 14A(a) without regard to whether our rules to implement Section 14A(a) have become effective by that time. To facilitate compliance with the new statute, we addressed certain first year transition issues in the Proposing Release. We are now extending those transition positions as described below.

Before effectiveness of the amendment to Rule 14a–6(a) adopted in this release, Rule 14a–6 will continue to require the filing of a preliminary proxy statement at least ten days before the proxy is sent or mailed to shareholders unless the meeting relates only to the matters specified by Rule 14a–6(a). Until the rules we are adopting to implement Exchange Act Section 14A become effective, we will not object if issuers do not file proxy material in preliminary form if the only matters that would require a filing in preliminary form are the say-on-pay vote and frequency of say-on-pay vote required by Section 14A(a).

Before the amendment to Rule 14a–4 adopted in this release becomes effective, Rule 14a–4 provides that persons solicited are to be afforded the choice between approval or disapproval of, or abstention with respect to, each matter to be voted on, other than elections of directors. Until effectiveness of the amendment to Rule 14a–4 adopted in this release, we will not object if the form of proxy for a shareholder vote on the frequency of say-on-pay votes provides means whereby the person solicited is afforded an opportunity to specify by boxes a choice among 1, 2 or 3 years, or abstain. In addition, we understand that, although some commentators indicated they are prepared for the four-choice frequency vote, the systems of other proxy service providers are currently set up to register at most three votes—for, against, or abstain—and these providers may have short-term difficulty in programming their systems to enable shareholders to vote among four choices. As a result, because the preparedness of these providers may vary significantly on a firm-by-firm basis, for any proxy materials filed for meetings to be held on or before December 31, 2011, we will not object if the form of proxy for a shareholder vote on the frequency of say-on-pay votes provides means whereby the person solicited is afforded an opportunity to specify by boxes a choice among 1, 2 or 3 years, and there is no discretionary authority to vote proxies on the frequency of say-on-pay votes matter in the event the person solicited does not select a choice among 1, 2 or 3 years.[294]

Issuers with outstanding indebtedness under the TARP are already required to conduct an annual shareholder advisory vote on executive compensation until the issuer has repaid all outstanding indebtedness under the TARP. Because such issuers are subject to an annual requirement to provide a say-on-pay vote, a requirement to provide a vote on the frequency of such votes would impose unnecessary burdens on issuers and shareholders, and our final rules provide an exemption from such requirement. Until the rules we are adopting to implement Exchange Act Section 14A become effective, we will not object if an issuer with outstanding indebtedness under the TARP does not include a resolution for a shareholder advisory vote on the frequency of say-on-pay votes in its proxy statement for its annual meeting, provided it fully complies with its say-on-pay voting obligations under EESA Section 111(e).

Finally, as we discussed above, we are adopting a temporary exemption for smaller reporting companies to defer application of the requirements of Section 14A(a)(1) and (a)(2) and Rule 14a–21(a) and (b) to conduct shareholder advisory votes on executive compensation and the frequency of such votes. Until the rules we are adopting to implement Exchange Act Section 14A

[292] *See Executive Compensation and Related Person Disclosure,* Release No. 33–8732A (Aug. 29, 2006) [71 FR 53158] (hereinafter, the "2006 Executive Compensation Release") at Section II.D.1. The scaled compensation disclosure requirements for smaller reporting companies are set forth in Item 402(1) [17 CFR 229.402(l)] through (r) [17 CFR 229.402(r)] of Regulation S–K.

[293] *See* 2006 Executive Compensation Release, *supra* note 292, at Section II.D.1.

[294] *See Shareholder Communications, Shareholder Participation in the Corporate Electoral Process and Corporate Governance Generally,* Release No. 34–16356 (Nov. 21, 1979) [44 FR 68770].

become effective, we will not object if a smaller reporting company does not include a resolution for a shareholder advisory vote on say-on-pay or the frequency of say-on-pay votes in its proxy statement for its annual meeting. As with other issuers, smaller reporting companies are required to conduct the shareholder advisory vote on golden parachute compensation upon effectiveness of Rule 14a–21(c).

III. Paperwork Reduction Act

A. Background

Certain provisions of the final amendments contain "collection of information" requirements within the meaning of the Paperwork Reduction Act of 1995 ("PRA").[295] We published a notice requesting comment on the collection of information requirements in the proposing release for the rule amendments, and we submitted these requirements to the Office of Management and Budget ("OMB") for review in accordance with the PRA.[296] The title for the collection of information is:

(1) "Regulation 14A and Schedule 14A" (OMB Control No. 3235–0059);

(2) "Regulation 14C and Schedule 14C" (OMB Control No. 3235–0057);

(3) "Form 8–K" (OMB Control No. 3235–0060);

(4) "Form 10" (OMB Control No. 3235–0064);

(5) "Regulation S–K" (OMB Control No. 3235–0071);[297]

(6) "Schedule 14D–9" (OMB Control No. 3235–0102);

(7) "Schedule 13E–3" (OMB Control No. 3235–0007);

(8) "Schedule TO" (OMB Control No. 3235–0515);

(9) "Form S–1" (OMB Control No. 3235–0065);

(10) "Form S–4" (OMB Control No. 3235–0324);

(11) "Form S–11" (OMB Control No. 3235–0067);

(12) "Form F–4" (OMB Control No. 3235–0325); and

(13) "Form N–2" (OMB Control No. 3235–0026).

The regulations, schedules, and forms were adopted under the Securities Act and the Exchange Act, except for Form N–2, which we adopted pursuant to the Securities Act and the Investment Company Act. The regulations, forms, and schedules set forth the disclosure requirements for periodic reports, current reports, registration statements and proxy and information statements filed by companies to help shareholders make informed voting decisions. The hours and costs associated with preparing, filing and sending the form or schedule constitute reporting and cost burdens imposed by each collection of 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.

B. Summary of the Final Rules

As discussed in more detail above, we are adopting new Rule 14a–21 under the Exchange Act and new Item 24 of Schedule 14A. Rule 14a–21 will implement the requirements of Section 14A of the Exchange Act to provide separate shareholder advisory votes on executive compensation, the frequency of shareholder votes on executive compensation, and, in connection with merger and similar transactions, golden parachute compensation arrangements. New Item 24 of Schedule 14A will require disclosure in proxy statements with respect to each of these shareholder votes. New Rule 14a–21 and new Item 24 of Schedule 14A will increase existing disclosure burdens for proxy statements by requiring:

- New disclosure about the requirement to provide separate shareholder votes on executive compensation, the frequency of shareholder votes on executive compensation and golden parachute compensation arrangements in connection with merger transactions; and
- New disclosure of the general effect of the shareholder advisory votes, such as whether such votes are non-binding.

As discussed in more detail above, we are also adopting amendments to Item 402(b) of Regulation S–K. The amendments to Item 402(b) of Regulation S–K may increase existing disclosure burdens for proxy statements by requiring:

- New disclosure of whether, and if so, how the issuer has considered the results of the most recent shareholder vote on executive compensation required by Section 14A of the Exchange Act in determining compensation policies and decisions, and, if so, how that consideration has affected the issuer's compensation decisions and policies.

As discussed in more detail above, we are also adopting new Item 402(t) of Regulation S–K and amendments to Item 1011(b) of Regulation M–A, Item 5 of Schedule 14A, Item 3 of Schedule 14C, Item 15 of Schedule 13E–3, Item 11 of Schedule TO, and Item 8 of Schedule 14D–9. These amendments, other than the amendment to Schedule TO, will increase existing disclosure burdens for proxy statements, registration statements on Form S–4 and F–4, solicitation/recommendation statements on Schedule 14D–9, and going-private schedules by requiring:

- New tabular and narrative disclosure of understandings and agreements of named executive officers with acquiring and target companies in connection with merger, acquisition, Rule 13e–3 going-private transactions, and tender offers,[298] and disclosure of the aggregate total of all compensation that may be paid or become payable to each named executive officer.

As discussed in more detail above, we are adopting amendments to Form 8–K. The amendments to Form 8–K will increase existing disclosure burdens for current reports on Form 8–K by requiring:

- New disclosure of the issuer's decision of how frequently to provide a separate shareholder vote on executive compensation in light of a shareholder advisory vote on the frequency of shareholder votes on executive compensation conducted pursuant to Section 14A(a)(2) of the Exchange Act.

Together, new Rule 14a–21 and new Item 24 of Schedule 14A and the amendments to Item 5 of Schedule 14A, Item 3 of Schedule 14C, Item 402 of Regulation S–K, Item 1011 of Regulation M–A, Item 15 of Schedule 13E–3, Item 11 of Schedule TO, and Item 8 of Schedule 14D–9 will implement and supplement the requirements under Section 14A of the Exchange Act and also will provide additional meaningful disclosure regarding golden parachute arrangements and issuers' consideration of the shareholder votes and the effect of such votes on issuers' compensation policies and decisions. We believe these changes will result in more meaningful disclosure for investors making voting or investment decisions.

We are adopting an amendment to Rule 14a–4, which relates to the form of proxy that issuers are required to include with their proxy materials, to require that issuers present four choices to their shareholders in connection with the advisory vote on frequency. We are also adopting an amendment to Rule

[295] 44 U.S.C. 3501 *et seq.*

[296] 44 U.S.C. 3507(d) and 5 CFR 1320.11.

[297] The paperwork burden from Regulation S–K is imposed through the forms that are subject to the disclosures in Regulation S–K and is reflected in the analysis of those forms. To avoid a Paperwork Reduction Act inventory reflecting duplicative burdens, for administrative convenience we estimate the burdens imposed by Regulation S–K to be a total of one hour.

[298] Companies filing solicitation/recommendation statements on Schedule 14D–9 in connection with third-party tender offers will be obligated to provide this additional disclosure. However, bidders filing tender offer statements on Schedule TO will not have a similar obligation.

14a–6 to add the shareholder votes on executive compensation and the frequency of shareholder votes on executive compensation required by Section 14A(a), as well as any shareholder advisory vote on executive compensation, to the list of items that do not trigger the filing of a preliminary proxy statement. In addition, we are adopting an amendment to Rule 14a–8, adding a note to Rule 14a–8(i)(10) to clarify the status of shareholder proposals relating to the approval of executive compensation or the frequency of shareholder votes approving executive compensation. Finally, we are adopting conforming amendments to Item 402(a) and Item 402(m) of Regulation S–K, clarifying that the disclosure required by proposed Item 402(t) includes information regarding group life, health, hospitalization, or medical reimbursement plans that do not discriminate in scope, terms or operation, in favor of executive officers or directors of the registrant and that are available generally to all salaried employees. Pursuant to these conforming amendments, issuers may continue to omit such information in connection with disclosure required by other portions of Item 402 of Regulation S–K. The amendments to Rule 14a–4, Rule 14a–6, Rule 14a–8 under the Exchange Act and Item 402(a) and Item 402(m) of Regulation S–K will not increase any existing disclosure burden. We believe these amendments will merely clarify existing and new statutory requirements or reduce burdens otherwise arising from our proposals. As a result, these amendments will not affect any existing disclosure burden.

Compliance with the proposed amendments by affected U.S. issuers will be mandatory. Responses to the information collections will not be kept confidential and there would be no mandatory retention period for the information disclosed.

C. Summary of Comment Letters and Revisions to Proposals

In the Proposing Release, we requested comment on the PRA analysis. We did not receive any comments that addressed our overall burden estimates for the proposed amendments, though our analysis was cited by one commentator who discussed our cost-benefit analysis.[299]

We have made few substantive modifications to the proposed amendments. We have adopted an amendment to Form 8–K to require the disclosure we had proposed to require in Form 10–Q or Form 10–K. Therefore, we have adjusted our estimates to reflect no changes to Forms 10–Q and 10–K and to estimate the increased burdens for Form 8–K.

We have also revised our amendments with respect to Schedule TO to eliminate the proposed requirement for bidders in third-party tender offers to provide Item 402(t) disclosure. We have adjusted our estimates to reflect no changes to Schedule TO, as any increased burden will be reflected in Schedule 13E–3 because Item 402(t) disclosure will be required in any tender offer that is also a Rule 13e–3 going-private transaction.

D. Revisions to PRA Reporting and Cost Burden Estimates

We anticipate that the disclosure amendments will increase the burdens and costs for companies that would be subject to the proposed amendments. New Section 14A of the Exchange Act, as created by Section 951 of the Act, has already increased the burdens and costs for issuers by requiring separate shareholder votes on executive compensation and the frequency of shareholder votes on executive compensation. Section 14A also requires additional disclosure of golden parachute arrangements in proxy solicitations to approve merger transactions and a separate shareholder vote to approve such arrangements in certain circumstances. Our amendments address the Act's requirements in the context of disclosure under the Federal proxy rules, Regulation S–K and related forms and schedules, thereby creating only an incremental increase in the burdens and costs for such issuers. The amendments specify how issuers are to comply with Section 14A of the Exchange Act and require new disclosure with respect to comparable transactions.

For purposes of the PRA, in the Proposing Release we estimated the annual incremental paperwork burden for all companies to prepare the disclosure that would be required under our proposals to be approximately 25,192 hours of company personnel time and a cost of approximately $8,141,200 for the services of outside professionals. These estimates included the time and the cost of data gathering systems and disclosure controls and procedures, the time and cost of preparing and reviewing disclosure by in-house and outside counsel and executive officers, and the time and cost of filing documents and retaining records. In deriving our estimates, we recognize that the burdens will likely vary among individual companies based on a number of factors, including the size and complexity of their organizations, the nature and complexity of their golden parachute compensation arrangements, and the nature of their operations. We believe that some companies will experience costs in excess of this average in the first year of compliance with proposals and some companies may experience less than the average costs. As discussed above, as a result of changes to our proposed rules, we are slightly reducing the total PRA burden and cost estimates that we originally submitted to the OMB in connection with the proposed amendments. We estimate the annual incremental paperwork burden for all companies to prepare the disclosure that would be required under our rule amendments to be approximately 24,942 hours of company personnel time and a cost of approximately $7,841,200 for the services of outside professionals.

We derived our new burden hour and cost estimates by estimating the average number of hours it would take an issuer to prepare and review the proposed disclosure requirements. These estimates represent the average burden for all companies, both large and small. Our estimates have been adjusted to reflect the fact that some of the amendments will be required in some but not all of the above listed documents depending upon the circumstances, and would not apply to all companies.

With respect to reporting companies, the disclosure required by new Item 402(t) of Regulation S–K will be required in merger proxy and information statements, Forms S–4 and F–4, Schedule 13E–3 and certain solicitation/recommendation statements. The disclosure required by new Item 402(t) may also be included in annual meeting proxy statements on a voluntary basis.

The disclosure required by our amendments to Item 402(b) of Regulation S–K will be required in proxy and information statements as well as Forms 10, 10–K, S–1, S–4, S–11, and N–2. The proposed amendments to CD&A will not be applicable to smaller reporting companies because under current CD&A reporting requirements these companies are not required to provide CD&A in their Commission filings. Based on the number of proxy filings that were received in the 2009 fiscal year, we estimate that approximately 1,200 domestic companies are smaller reporting companies that have a public float of less than $75 million.

[299] *See* letter from CCMC.

In the Proposing Release, we based our annual burden estimates on other assumptions. We have made some small adjustments to these estimates to reflect the revisions we made to the amendments. First, we continue to assume that the burden hours of the amendments will be comparable to the burden hours related to similar disclosure requirements under current reporting requirements, such as the disclosure required by Item 402(j). Second, we continue to assume that substantially all of the burdens associated with the amendments to Rule 14a–21 and Item 24 will be associated with Schedule 14A as this will be the primary disclosure document in which these items will be prepared and presented. In the case of our proposed amendments to Item 402(b) and Item 402(t) of Regulation S–K, we continue to assume that the burdens associated with the amendments will be associated with various disclosure documents as these items will be included in a number of forms and statements. We have noted an additional 1 hour for the amendments to Form 8–K, and we are no longer proposing any amendments that would alter the disclosure burden of Form 10–Q and Form 10–K.

For each reporting company, we estimate that the amendments will impose on average the following incremental burden hours:

- 2 hours for the amendments to CD&A.
- 1 hour for the amendments to Item 24 of Schedule 14A.
- 1 hour for the amendments to Form 8–K.
- 20 hours for new Item 402(t) of Regulation S–K.

1. Annual Meeting Proxy Statements

For purposes of the PRA, in the case of reporting companies, we estimate the annual incremental paperwork burden for annual meeting proxy statements under the amendments will be approximately 1 hour per form for companies that are smaller reporting companies, and 3 hours per form for companies that are non-accelerated filers (and not smaller reporting companies), accelerated filers, or large accelerated filers.[300] The estimated burden is smaller for smaller reporting companies as such issuers are not required to include a CD&A.

2. Exchange Act Current Reports

For purposes of the PRA, we estimate the annual incremental paperwork burden for Form 8–K under the amendments will be approximately 1 hour per form. Our estimates below also account for the fact that each issuer will only be required to include additional disclosure in one amended Form 8–K each year the issuer conducts a shareholder advisory vote on frequency.

3. Securities Act Registration Statements and Exchange Act Registration Statements

For purposes of the PRA, in the case of reporting companies, we estimate the annual incremental paperwork burden for Securities Act and Exchange Act registration statements under the amendments is approximately 2 hours per form, which represents the additional burden associated with our amendments to CD&A.[301] In making our estimates, we note that the additional burdens in CD&A only apply to issuers who have conducted a prior shareholder advisory vote and would not apply, for example, to issuers making an initial filing on Form S–1 or Form S–11.

4. Merger Proxies, Tender Offer Documents and Schedule 13E–3

For purposes of the PRA, in the case of reporting companies, we estimate the annual incremental paperwork burden for merger proxy statements, and registration statements on Form S–4 and F–4 to be 21 hours per form, as these forms will be required to include additional disclosures under Item 24 of Schedule 14A and Item 402(t) of Regulation S–K. We estimate the annual incremental paperwork burden for merger information statements, and tender offer solicitation/recommendation statements and Schedules 13E–3 to be 20 hours per form, as these forms will be required to include Item 402(t) disclosure but will not be required to include additional disclosure under Item 24 of Schedule 14A.

The tables below illustrate the total annual compliance burden of the collection of information in hours and in cost under the proposed amendments for current reports; proxy and information statements; Form 10; registration statements on Forms S–1, S–4, F–4, S–11, and N–2; and Regulation S–K.[302] The burden estimates were calculated by multiplying the estimated number of responses by the estimated average amount of time it would take an issuer to prepare and review the proposed disclosure requirements. For the Exchange Act report on Form 8–K, and the proxy statements we estimate that 75% of the burden of preparation is carried by the company internally and that 25% of the burden of preparation is carried by outside professionals retained by the issuer at an average cost of $400 per hour.

For registration statements on Forms S–1, S–4, F–4, S–11, and N–2, and the Exchange Act registration statement on Form 10, we estimate that 25% of the burden of preparation is carried by the issuer internally and that 75% of the burden of preparation is carried by outside professionals retained by the issuer at an average cost of $400 per hour. There is no change to the estimated burden of the collections of information under Regulation S–K because the burdens that this regulation imposes are reflected in our revised estimated for the forms. The portion of the burden carried by outside professionals is reflected as a cost, while the portion of the burden carried by the issuer internally is reflected in hours.

[300] Our estimate for annual proxy statements is based upon an estimated burden over a six-year period during which the shareholder advisory votes required by Section 14A(a) would not occur annually. We used a six-year period because issuers will conduct at least two shareholder advisory votes on executive compensation and at least one shareholder advisory vote on the frequency of such votes in this time period. We then estimated an average annual burden based on the average burden over the six-year period.

[301] We have assumed that the annual incremental paperwork burden under the proposed amendments to Item 402(b) of Regulation S–K would be included in the annual meeting proxy statement.

[302] Figures in both tables have been rounded to the nearest whole number.

TABLE 1—INCREMENTAL PAPERWORK BURDEN UNDER THE AMENDMENTS FOR CURRENT REPORTS; PROXY AND INFORMATION STATEMENTS

	Number of responses [303] (A)	Incremental burden hours/ form (B)	Total incremental burden hours (C)=(A)*(B)	75% Company (D)=(C)*0.75	25% Professional (E)=(C)*0.25	Professional costs (F)=(E)*$400
8–K [304]	7,212	1	7,212	5,409	1,803	$721,200
Form 10 [305]	9	2	18	4	14	5,600
DEF 14A [306]	7,212					
Accel. Filers	6,112	3	18,336	13,752	4,584	1,833,600
SRC Filers	1,100	1	1,100	825	275	110,000
DEF 14C	582					
Accel. Filers	482	2	964	723	241	96,400
SRC Filers	100	0	0	0	0	0
Reg. S–K	N/A	N/A	N/A	N/A	N/A	N/A
Total			27,630	20,713		2,766,800

TABLE 2—INCREMENTAL PAPERWORK BURDEN UNDER THE AMENDMENTS FOR REGISTRATION STATEMENTS, MERGER PROXY AND INFORMATION STATEMENTS, TENDER OFFER DOCUMENTS AND SCHEDULES 13E–3

	Number of responses [307] (A)	Incremental burden hours/ form (B)	Total incremental burden hours (C)=(A)*(B)	25% Company (D)=(C)*0.25	75% Professional (E)=(C)*0.75	Professional costs (F)=(E)*$400
Form S–1 [308]	485	2	970	243	727	$290,800
Form S–11	22	2	44	11	33	13,200
Form S–4 [309]	499	21	10,479	2,620	7,859	3,143,600
Form F–4	27	21	567	142	425	170,000
DEFM 14A	137	21	2,877	719	2,158	863,200
DEFM 14C [310]	14	20	280	70	210	84,000
Schedule 14D–9	77	20	1,540	385	1,155	462,000
Schedule 13E–3	5	20	100	25	75	30,000
Form N–2 [311]	29	2	58	14	44	17,600
Reg. S–K	N/A	N/A	N/A	N/A	N/A	N/A
Total			16,915	4,229		5,074,400

IV. Cost-Benefit Analysis

A. Introduction

We are adopting amendments to implement and supplement the

[303] The number of responses reflected in the table equals the actual number of forms and schedules filed with the Commission during the 2009 calendar year, adjusted to reflect the estimated number of forms and schedules that would be required to include additional disclosure under our rules as proposed. As explained below in notes 304 through 306, we have reduced the number of estimated filings to reflect that the additional disclosure requirements will only apply to a smaller number of the forms filed.

[304] We calculated the burden hours for Form 8–K based on the number of proxy statements filed with the Commission during the 2009 calendar year. We assumed that there would be an aggregate equal number of Forms 8–K to disclose the issuer's plans with respect to the frequency vote as the number of proxy statements.

[305] The burden allocation for Form 10 uses a 25% internal to 75% outside professional allocation. We have reduced the number of estimated Form 10 filings to reflect that approximately 95% of these forms would not require additional disclosure, as new disclosure required under Item 402 will only relate to issuers in spin-off transactions that are disclosing compensation of public parent companies that have conducted a prior shareholder vote on executive compensation.

[306] The estimates for Schedule 14A and Schedule 14C are separated to reflect our estimate of the burden hours and costs related to the proposed amendments to CD&A which will be applicable to companies that are large accelerated filers, accelerated filers, and non-accelerated filers (that are not smaller reporting companies), but will not be applicable to smaller reporting companies.

[307] The number of responses reflected in the table equals the actual number of forms and schedules filed with the Commission during the 2009 calendar year, adjusted to reflect the estimated number of forms and schedules that would be required to include additional disclosure under our rules as proposed. As explained below in notes 308 through 311, we have reduced the number of estimated filings to reflect that the additional disclosure requirements will only apply to a smaller number of the forms filed.

[308] We have reduced the number of estimated Form S–1 and Form S–11 filings to reflect that approximately 60% of these forms will not require additional disclosure, as new disclosure required under Item 402 will only relate to issuers who are already public companies and have conducted a prior shareholder vote on executive compensation.

[309] We have reduced the number of estimated Form S–4 and Form F–4 filings to reflect an approximate 75% of these forms which will not relate to mergers or similar transactions but will be other transactions (*e.g.,* holding company formations and financings) to which the amended rules will not apply.

[310] We have reduced the number of estimated DEFM 14C filings to reflect an approximate 15% of these forms, which will not relate to merger transactions but will involve dissolutions and similar transactions.

[311] We have reduced the number of estimated Form N–2 filings to reflect that 29 filings were made by business development companies during calendar year 2009, because only business

provisions of the Dodd-Frank Act relating to shareholder approval of executive compensation and disclosure and shareholder approval of golden parachute compensation arrangements. Section 951 of the Dodd-Frank Act amends the Exchange Act by adding new Section 14A. New Section 14A(a)(1) requires companies to conduct a separate shareholder advisory vote to approve the compensation of executives. Section 14A(a)(2) requires companies to conduct a separate shareholder advisory vote to determine how often an issuer will conduct a shareholder advisory vote on executive compensation. In addition, Section 14A(b) requires companies soliciting votes to approve merger or acquisition transactions to provide disclosure of certain "golden parachute" compensation arrangements and, when such arrangements have not been included in the shareholder advisory vote on executive compensation, to conduct a separate shareholder advisory vote to approve the golden parachute compensation arrangements.[312]

We are adopting new Rule 14a–21 to implement Section 14A(a)(1) by providing separate shareholder advisory votes to approve executive compensation, to approve the frequency of such votes on executive compensation, and to approve golden parachute compensation arrangements at shareholder meetings at which shareholders are asked to approve merger transactions. In addition to the votes required by Section 14A, we are also adopting a new Item 24 of Schedule 14A to elicit disclosure, similar to our approach with respect to TARP companies providing shareholder advisory votes on executive compensation, regarding the effect of the shareholder votes required by Rule 14a–21, including whether the votes are non-binding.

New Item 402(t) of Regulation S–K implements and supplements the statutory requirement in Section 14A(b)(1) to promulgate rules for the clear and simple disclosure of golden parachute compensation arrangements that the soliciting person has with its named executive officers (if the acquiring issuer is not the soliciting person) or that it has with the named executive officers of the acquiring issuer that relate to the merger transaction. In addition, Item 402(t), will supplement the requirements of Section 14A(b)(1) by requiring disclosure of golden parachute compensation arrangements between the acquiring company and the named executive officers of the target company if the target company is the soliciting person.

Our amendments to Item 5 of Schedule 14A and Item 3 of Schedule 14C will require disclosure regarding golden parachute compensation arrangements in accordance with Section 14A(b)(1) of the Exchange Act. We are also adopting amendments to require that additional disclosure regarding golden parachute compensation arrangements be included in connection with other transactions. We are adopting amendments to Regulation M–A, Schedule 14D–9, and Schedule 13E–3 that will require additional disclosure regarding golden parachute compensation arrangements in connection with Rule 13e–3 going-private transactions and tender offers.[313]

We are also adopting amendments to Item 402 of Regulation S–K to require additional Compensation Discussion and Analysis disclosure about the issuer's response to the shareholder vote on executive compensation and to provide additional disclosure about golden parachute compensation arrangements. We are also adopting amendments to Form 8–K to require disclosure regarding the issuer's action as a result of the shareholder advisory vote on the frequency of shareholder votes on executive compensation.

We are adopting an amendment to Rule 14a–4, which relates to the form of proxy that issuers are required to include with their proxy materials, to require that issuers present four choices to their shareholders in connection with the advisory vote on frequency. We are also adopting an amendment to Rule 14a–6 to add the shareholder votes on executive compensation and the frequency of shareholder votes on executive compensation required by Section 14A(a), as well as any shareholder advisory vote on executive compensation, to the list of items that do not trigger the filing of a preliminary proxy statement. In addition, we are adopting an amendment to Rule 14a–8, adding a note to Rule 14a–8(i)(10) to clarify the status of shareholder proposals relating to the approval of executive compensation or the frequency of shareholder votes approving executive compensation.

The rules we are adopting, which implement the relevant provisions of the Dodd-Frank Act, will directly affect most public companies as well as potential private acquirers. Our amended rules implement the shareholder advisory vote requirements of Section 14A, promulgate rules for additional disclosure in accordance with Section 14A(b)(1), and provide for additional disclosure, not required by Section 14A, relating to the shareholder advisory votes. In addition, our amended rules expand the required disclosure of Section 14A(b)(1) to require disclosure of arrangements between additional parties, namely agreements between the acquiring company and named executive officers of the target company, and require disclosure with respect to additional transactions, including certain tender offers and Rule 13e–3 going-private transactions. As discussed below, the enhanced disclosure required by our amended rules regarding the shareholder approval of executive compensation and companies' responses to shareholder votes will provide shareholders and investors with timely information about such votes that is consistent with the information required to be provided under the Act and that enhance the operation of our rules pursuant to the Act. The enhanced disclosure regarding golden parachute compensation will provide a more complete picture of the compensation to shareholders as they consider voting and investment decisions relating to mergers and similar transactions.

We are sensitive to the costs and benefits imposed by the rule and form amendments we are adopting. The discussion below focuses on the costs and benefits of the amendments made by the Commission to implement the Act within its permitted discretion, rather than the costs and benefits of the Act itself.

B. Comments on the Cost-Benefit Analysis

In the Proposing Release, we requested qualitative and quantitative feedback on the nature of the benefits and costs described and any benefits and costs we may have overlooked. We received one comment letter relating to the cost-benefit analysis in the Proposing Release.[314] The commentator asserted that we had underestimated the costs and burdens involved because we did not take into account the following additional categories of costs: Costs

development companies will be subject to the amended disclosure required under Item 402 on Form N–2.

[312] According to the Dodd-Frank Wall Street Reform and Consumer Protection Act Conference Report at page 872, Section 951 is "designed to address shareholder rights and executive compensation practices."

[313] Companies filing solicitation/recommendation statements on Schedule 14D–9 in connection with third-party tender offers will be obligated to provide this additional disclosure. However, bidders filing tender offer statements on Schedule TO will not have a similar obligation.

[314] *See* letter from CCMC.

associated with proxy advisory firms and the potential for companies to retain additional consulting services relating to their compensation decisions and say-on-pay votes, additional costs associated with submitting no-action letter requests under Rule 14a–8, and increased costs due to increased demand for proxy solicitation and other shareholder communications services.[315]

C. Benefits

The amended rules we are adopting today are intended to implement and supplement the requirements of Section 14A of the Exchange Act as set forth in Section 951 of the Dodd-Frank Act. Our amended rules not only implement the shareholder advisory votes required by Section 14A, but also require additional disclosure addressing whether, and if so, how issuers have considered these required shareholder advisory votes, and if so, how such votes have affected the companies' compensation policies and decisions.

We believe the enhanced disclosures about the results of the shareholder advisory vote on the frequency of the approval of executive compensation will provide timely information to shareholders about the issuer's plans for future shareholder advisory votes. The enhanced disclosure and amendments to the CD&A requirements in Item 402(b) of Regulation S–K about whether, and if so, how an issuer has considered the results of a shareholder vote to approve executive compensation and, if so, how that consideration has affected its compensation policies and decisions will benefit shareholders and other market participants by providing potentially useful information for voting and investment decisions.

Our amended rules will also specify how the shareholder advisory votes required by Section 14A(a) relate to existing shareholder advisory votes required for issuers with outstanding indebtedness under TARP. In our view, because of the similarity of the separate annual say-on-pay vote requirements, a company with indebtedness under TARP need only provide one annual shareholder advisory vote. As we have discussed above, we have indicated that the annual shareholder advisory vote under EESA would fulfill the requirements for the shareholder vote pursuant to Section 14A(a)(1) and Rule 14a–21(a). We believe this benefits such companies by reducing confusion and burdens of the two requirements by specifying that two separate annual shareholder votes are not required. In addition, because issuers with indebtedness under TARP must conduct an annual shareholder advisory vote on executive compensation, we have adopted an exemption from the frequency vote required by Section 14A(a)(2) and Rule 14a–21(b) until the issuer repays all indebtedness under TARP. We believe this benefits such issuers and their shareholders by avoiding the cost and confusion of conducting a vote on the frequency of a shareholder advisory vote when the frequency of such a vote is mandated by another requirement.

After reviewing the comments we have received, we are also adopting a temporary exemption for smaller reporting companies that will delay the implementation of the shareholder advisory votes on say-on-pay and frequency required by Section 14A(a) and Rule 14a–21(a) and (b) for a two-year period. We believe that a delayed effective date for the say-on-pay and frequency votes will benefit smaller reporting companies by allowing these companies to observe how the rules operate for other companies by preparing them for implementation of the rules. We believe that delayed implementation for these companies will also allow us to evaluate the implementation of the adopted rules by larger companies and provide us with the additional opportunity to consider whether adjustments to the rule would be appropriate for smaller reporting companies before the rule becomes applicable to them.

In these amended rules, we also provide guidance for issuers and shareholders regarding the interaction of the shareholder advisory votes required by Section 14A and shareholder proposals under Rule 14a–8 by adding a note to Rule 14a–8(i)(10). The note we are adopting will reduce potential confusion among shareholders and issuers with respect to what may be excluded under our rules in light of the new requirements under Section 14A, while preserving the ability of shareholders to make proposals relating to executive compensation.

New Item 402(t) of Regulation S–K will require narrative and tabular disclosure of golden parachute compensation arrangements in the clear and simple form required by Section 14A(b)(1) of the Exchange Act. Because Section 14A(b)(1) requires that disclosure not only be in a clear and simple form, but also that it include an aggregate total of all golden parachute compensation for each named executive officer, we have adopted Item 402(t) to require that such disclosure appear in a table. The tabular format is designed to provide investors with clear disclosure about golden parachute compensation that is comparable across different issuers and transactions and make the information more accessible. In addition to the tabular disclosure, we are also adopting amendments to require narrative disclosure to provide additional context and disclosure not suitable to the tabular format. Our approach is similar to the existing approach to executive compensation disclosure in Item 402 of Regulation S–K and provides a focused manner in which to present and quantify golden parachute compensation. Narrative disclosure supplements the tables by providing additional context and discussion of the numbers presented in the table. We believe that the combination of narrative and tabular disclosure will provide the clearest picture of the full scope of golden parachute compensation in the clear and simple format required by Section 14A(b)(1).

Because Section 14A(b)(1)'s disclosure requirements are limited to agreements or understandings between the person conducting the solicitation and any named executive officers of the issuer or any named executive officers of the acquiring issuer if the person conducting the solicitation is not the acquiring issuer, we have formulated Item 402(t) to require disclosure, in addition to the disclosure mandated by Section 14A(b)(1), of agreements or understandings between the acquiring company and the named executive officers of the target company. Item 402(t) requires disclosure of all golden parachute compensation relating to the merger among the target and acquiring companies and the named executive officers of each in order to cover the full scope of golden parachute compensation applicable to the transaction. By providing disclosure of the full scope of golden parachute compensation, we believe issuers will provide more detailed, comprehensive, and useful information to shareholders to consider when making their voting or investment decisions.

Likewise, additional disclosure on golden parachute compensation, without regard to whether the transaction is structured as a merger, a tender offer,[316] or a Rule 13e–3 going-private transaction that is not subject to Regulation 14A, will benefit

[315] *See* letter from CCMC. See also Section IV.D below for additional discussion.

[316] Companies filing solicitation/recommendation statements on Schedule 14D–9 in connection with third-party tender offers will be obligated to provide this additional disclosure. However, bidders filing tender offer statements on Schedule TO will not have a similar obligation.

shareholders and other market participants by allowing them to timely and more accurately assess the transaction and evaluate with greater acuity the golden parachute compensation that named executive officers could expect to receive and the related potential interests such officers might have in pursuing and/or supporting a change in control transaction. While our existing disclosure requirements include much of this disclosure, the specificity and narrative and tabular format of Item 402(t) will allow for a clear presentation of the full scope of the information. Furthermore, by standardizing disclosure of golden parachute compensation arrangements across different transaction structures, our amended rules will enable shareholders to compare more easily such compensation among various types of change in control transactions and structures. In addition, our amended rules will also enable the shareholders of the acquirer to timely and more accurately assess the cost of the acquisition transaction in proxy statements for which additional disclosure is required pursuant to Note A of Schedule 14A where acquirer shareholders do not vote on the merger transaction but vote to approve another proposal such as the issuance of shares or a stock split.

We have adopted such disclosure requirements in both tabular and narrative formats, with disclosure of aggregate total compensation, in accordance with the requirement of Section 14A(b)(1) that such disclosure be in a clear and simple form. To the extent investors expect to see information about all of the economic benefits that may accrue to an executive in one location of the proxy statement (including golden parachute arrangements and other compensation, such as future employment contracts), the benefit of this disclosure may be limited since the information about other executive compensation that may be disclosed in proxy materials does not need to be included in tabular format pursuant to Item 402(t) of Regulation S–K.

Our amended rules will also benefit issuers by specifying how they must comply with the requirements of Exchange Act Section 14A in the context of the Federal proxy rules. The amended rules will eliminate uncertainty that may exist among issuers and other market participants, if we did not propose any rules, regarding what is necessary under the Commission's proxy rules when conducting a shareholder vote required under Exchange Act Section 14A. The amended rules specify how the statutory requirements operate in connection with the Federal proxy rules and accordingly, we believe the amended rules promote better compliance with the requirements of Exchange Act Section 14A and reduce the amount of management time and financial resources necessary to ensure that issuers comply with their obligations under both Exchange Act Section 14A and the Federal proxy rules. This will benefit issuers, their shareholders and other market participants.

D. Costs

We recognize that the amendments we are adopting will impose new disclosure requirements on companies and are likely to result in costs related to information collection.[317] The amendments we are adopting that require the disclosure of executive compensation in a tabular format are likely to result in certain costs. We expect these costs, however, to be limited since much of the compensation required to be disclosed under our amended rules is currently required to be disclosed in narrative format in the existing disclosure regime.

Our analysis of the costs of the amendments we are adopting today relates to the incremental direct and indirect costs arising from the requirements in our rule amendments. The analysis below does not reflect any additional direct or indirect costs arising from new Exchange Act Section 14A, including the shareholder advisory votes on say-on-pay, frequency, and golden parachute compensation, and any likely additional costs which would be incurred because of these votes. As noted above, one commentator asserted that we had underestimated the costs and burdens involved because we did not take into account the following additional categories of costs: Costs associated with proxy advisory firms and the potential for companies to retain additional consulting services relating to their compensation decisions and say-on-pay votes, additional costs associated with submitting no-action letter requests under Rule 14a–8, and increased costs due to increased demand for proxy solicitation and other shareholder communications services.[318] We do not believe the additional costs described by the commentator will arise as a result of our amendments today as these items relate to increased costs resulting from the requirements of Section 14A, including the say-on-pay vote, the frequency vote, and the shareholder advisory vote on golden parachute compensation. With respect to costs associated with submitting no-action letter requests and Rule 14a–8, we note that Section 14A(c)(4) specifically provides that the Section 14A shareholder advisory votes may not be construed "to restrict or limit the ability of shareholders to make proposals for inclusion in proxy materials related to executive compensation."[319] Although our new rules include a note advising of one circumstance when a shareholder proposal may be excluded, the rules do not impose any new obligations with respect to Rule 14a–8.

We are adopting new Item 402(t) to implement the requirement of Section 14A(b)(1) of the Exchange Act that we promulgate rules for disclosure of golden parachute compensation arrangements in a clear and simple form, which we believe is best provided in both narrative and tabular format. In addition to the required disclosure under Section 14A(b)(1), we are also expanding the disclosure to cover agreements between the acquiring company and the named executive officers of a target company in a merger or similar transaction. Though this additional disclosure will result in certain additional costs for issuers preparing a merger proxy, we believe that the additional disclosure is appropriate in order to provide shareholders information about the full scope of golden parachute compensation applicable to the transaction. If the disclosure provided by the issuer is not presented in a clear manner, the disclosure of golden parachute compensation for both target and acquirer executives in target and acquirer proxy statements may be confusing to investors. In addition, because parties often have to rely on each other for the other side's information, this reliance may add to

[317] We estimate the annual incremental paperwork burden for all companies to prepare the disclosure that would be required under both Exchange Act Section 14A and our rule amendments to be approximately 24,942 hours of company personnel time and a cost of approximately $7,841,200 for the services of outside professionals. As noted above in the Comments on the Cost-Benefit Analysis section, we received one comment letter relating to the cost-benefit analysis that asserted that the PRA numbers cited in the Proposing Release underestimated the costs and burdens involved. *See* letter from CCMC. We acknowledge that the PRA estimates do not reflect the full magnitude of the economic costs involved, but are estimates of the collection of information burden and cost for the limited purpose of the PRA. In addition to costs arising from our rule amendments, the PRA estimates include collection of information-related costs arising from new Exchange Act Section 14A.

[318] *See* letter from CCMC.

[319] Exchange Act Section 14A(c)(4).

the costs of mergers that are ultimately born by shareholders. There may also be certain indirect costs to issuers and shareholders as a result of our rule amendments, as the additional disclosure of golden parachute compensation may result in increased transactional expenses in the form of additional advisers and consultants, increased time to prepare disclosure documents, and increased time and expense to negotiate compensation arrangements.

Furthermore, companies engaging in or subject to a Rule 13e–3 going-private transaction and companies preparing solicitation/recommendation statements given their status as targets in third-party tender offers may face increased costs because of the required disclosure of golden parachute compensation arrangements, including the required table and aggregate totals. In addition, companies soliciting proxies or consents for transactions for which additional disclosure is required pursuant to Note A of Schedule 14A may face increased costs as well due to the additional disclosure requirements of Item 5 of Schedule 14A. We have adopted these disclosure requirements that go beyond the requirements of Section 14A(b)(1) because we believe the rules will reduce the regulatory disparity that might otherwise result from treating such transactions differently from mergers. In response to commentators, however, we have eliminated the proposed requirement for bidders in third-party tender offers to provide Item 402(t) disclosure. We believe this change is appropriate given that target companies that are the subject of third-party tender offers will provide the 402(t) disclosure in their Schedules 14D–9 within ten days after the commencement of the offers. We also believe this change addresses the concern expressed by one of the commentators that third-party bidders, particularly in non-negotiated transactions, may not have access to reliable information about the golden parachute arrangements between target companies and their named executive officers. By retaining the disclosure requirement in Schedule 14D–9, we are still able to minimize the regulatory disparity that might otherwise result from treating third-party tender offers differently than other transactions.

As noted above, there may also be additional indirect costs relating to such increased disclosure, as well as costs associated with obtaining compensation information from the other parties involved in a transaction in order to fulfill the issuer's disclosure obligations.

The expanded Compensation Discussion and Analysis disclosure may also result in costs associated with drafting disclosure that addresses whether, and if so, how the results of a shareholder vote on executive compensation were considered in determining the issuer's compensation policies and decisions and any resultant effect on those compensation policies and decisions. Similarly, the revisions to the current reporting requirements on Form 8–K may result in costs associated with assessing the results of a shareholder vote on the frequency of shareholder votes to approve executive compensation and drafting the additional disclosure regarding the company's plans to conduct votes in the future. Some of these costs could include the cost of hiring additional advisors, such as attorneys, to assist in the analysis and drafting.

We believe that these costs will not be unduly burdensome given that much of the disclosure is covered by our pre-existing disclosure requirements, even though we are adopting rules that require that such disclosure be included in both narrative and tabular format. The amendments we adopt exceed the pre-existing narrative requirements, as we are adopting tabular disclosure with an aggregate total and no *de minimis* threshold for perquisites. We expect that there will be incremental costs associated with drafting the additional disclosure, but that much of the information would be readily obtainable by the parties given existing disclosure requirements and as part of the due diligence process prior to drafting the transaction documents.

In addition to the direct costs associated with the required disclosure, the amended rules might create additional indirect costs for private companies that may be engaged in takeovers of public companies. We do not expect, however, the specific and detailed disclosure and the shareholder advisory vote regarding golden parachutes to diminish the number of takeover transactions.

The note to Rule 14a–8(i)(10) we are adopting may also impose certain costs on shareholders as it would permit issuers to exclude certain shareholder proposals that would otherwise not be excludable under our rules. In addition, our rule amendments may impose certain indirect costs on shareholders who might pursue alternative means to communicate their positions regarding the frequency of say-on-pay votes. We do not believe that the rules we are adopting today would impose any additional direct or indirect costs on issuers because of shareholder proposals. Any such costs would result from the shareholder advisory votes required by Section 14A.

V. Consideration of Impact on the Economy, Burden on Competition, and Promotion of Efficiency, Competition and Capital Formation

Section 23(a)(2) of the Exchange Act [320] also requires us, when adopting rules under the Exchange Act, to consider the impact that any new rule would have on competition. Section 23(a)(2) prohibits us from adopting any rule that would impose a burden on competition not necessary or appropriate in furtherance of the purposes of the Exchange Act. In addition, Section 2(b) [321] of the Securities Act and Section 3(f) [322] of the Exchange Act require us, when engaging in rulemaking where we are required to consider or determine whether an action is necessary or appropriate in the public interest, to also consider whether the action will promote efficiency, competition, and capital formation.

The amendments we are adopting will implement the Section 14A requirement for shareholder advisory votes to approve executive compensation, the frequency of such votes, and golden parachute compensation arrangements in connection with merger and similar transactions. We also adopting certain additional disclosure requirements to provide investors with additional information about these required votes and to apply the required disclosure from Section 14A(b)(1) to certain other agreements and transaction structures. We do not believe that the additional disclosure we are adopting will impose a burden on competition.

The amendments we are adopting will not only implement the requirements of Section 14A of the Exchange Act, but will also help ensure that shareholders receive disclosure regarding the required votes, the nature of an issuer's responsibilities to hold the votes under Section 14A, and the issuer's consideration of the results of the votes and the effect of such consideration on the issuer's compensation policies and decisions. The amendments will also enhance the transparency of a company's compensation policies. As discussed in greater detail above, we believe these benefits will be achieved without imposing any significant additional burdens on issuers. As a result, the amendments we are adopting should improve the ability of investors to make informed voting and investment decisions, and, therefore lead to

[320] 15 U.S.C. 78w(a)(2).

[321] 15 U.S.C. 77b(b).

[322] 15 U.S.C. 78c(f).

increased efficiency and competitiveness of the U.S. capital markets.

We believe the amendments we are adopting will also benefit issuers and their shareholders by specifying in a clear and concise fashion how issuers must comply with the Dodd-Frank Act requirements, in the context of the Federal proxy rules and our disclosure rules. By specifying how issuers must comply with the shareholder advisory votes and enhanced disclosure requirements from Section 14A, our rules will allow for more consistent disclosure from all entities and clearer disclosure for shareholders. By reducing uncertainty and promoting efficient presentation of information, our rules will permit issuers to more efficiently plan and draft disclosure documents, including annual meeting proxy statements, merger proxies, and tender offer and going-private documents.

Our rules will also provide additional time before smaller reporting companies are required to conduct the shareholder advisory votes on executive compensation and the frequency of say-on-pay votes. We believe that a delayed effective date for smaller reporting companies should allow those companies to observe how the rules operate for other companies and will increase efficiency by allowing them to better prepare for implementation of the rules. We also believe that delayed implementation for these companies will allow us to evaluate the implementation of the adopted rules by larger companies and provide us with the additional opportunity to consider whether adjustments to the rule would be appropriate for smaller reporting companies before the rules become applicable to them.

Our rules will require enhanced disclosure of golden parachute compensation arrangements in merger and similar transactions, regardless of how such transactions are structured. We believe the uniformity of our disclosure requirements across different types of transactions will help competition as issuers will be able to structure such transactions as they see fit, without the additional disclosure required by Section 14A(b) weighing in favor of a particular transaction structure. Though our amended rules will create additional, incremental disclosure burdens, we believe that the rules we are amending will enhance capital formation by allowing for clearer disclosure, more informed voting decisions by investors, and consistency across different types of transactions.

VI. Final Regulatory Flexibility Act Analysis

This Final Regulatory Flexibility Analysis (FRFA) has been prepared in accordance with the Regulatory Flexibility Act.[323] This FRFA relates to revisions to the rules under the Exchange Act regarding the proxy solicitation process and related executive compensation disclosures.

A. Reasons for, and Objectives of, the Proposed Action

The rule amendments are designed to implement the requirements of Section 951 of the Dodd-Frank Act, enhance the disclosure relating to the shareholder advisory votes required by Exchange Act Section 14A, and specify how our proxy rules will apply to such votes. Specifically, we are adopting amendments to the proxy rules to require shareholder advisory votes to approve executive compensation, to approve the frequency of shareholder votes to approve executive compensation, and to approve golden parachute compensation arrangements in connection with merger transactions. The amendments also require enhanced disclosure regarding an issuer's consideration of these votes and the impact of such consideration on an issuer's compensation policies and decisions.

B. Legal Basis

We are adopting the amendments pursuant to Section 951 of the Dodd-Frank Wall Street Reform and Consumer Protection Act, Sections 3(b), 6, 7, 10, and 19(a) of the Securities Act of 1933, as amended, and Sections 13, 14(a), 14A, 23(a), and 36 of the Securities Exchange Act of 1934, as amended.

C. Significant Issues Raised by Public Comments

In the Proposing Release, we requested comment on any aspect of the IRFA, including the number of small entities that would be affected by the proposed amendments, the nature of the impact, how to quantify the number of small entities that would be affected, and how to quantify the impact of the proposed amendments. We did not receive comments specifically addressing the IRFA. However, several commentators addressed aspects of the proposed rule amendments that could potentially affect small entities. In particular, some commentators believed that smaller companies should be exempted from all or part of the amendments.[324] Although we are not adopting a complete exemption from the amendments, we have made revisions to the amendments to phase-in the requirements for a shareholder advisory vote on executive compensation and a shareholder advisory vote on the frequency of say-on-pay votes for two full years to give smaller reporting companies more time to prepare for implementation of the rules and so that they can observe how larger companies conduct the votes. Smaller reporting companies will be required to conduct shareholder advisory votes on golden parachute compensation as required by Rule 14a–21(c) without a two-year delay.

D. Small Entities Subject to the Final Amendments

The amendments will affect some companies that are small entities. The Regulatory Flexibility Act defines "small entity" to mean "small business," "small organization," or "small governmental jurisdiction."[325] The Commission's rules define "small business" and "small organization" for purposes of the Regulatory Flexibility Act for each of the types of entities regulated by the Commission. Securities Act Rule 157[326] and Exchange Act Rule 0–10(a)[327] define a company, other than an investment company, to be a "small business" or "small organization" if it has total assets of $5 million or less on the last day of its most recent fiscal year. We estimate that there are approximately 1,210 companies, other than investment companies, that may be considered small entities. The proposed amendments would affect small entities that have a class of securities that are registered under Section 12 of the Exchange Act. An investment company, including a business development company,[328] is considered to be a "small business" if it, together with other investment companies in the same group of related investment companies, has net assets of $50 million or less as of the end of its most recent fiscal year.[329] We believe that certain of the amendments would affect small entities that are business development companies that have a class of securities registered under Section 12 of the Exchange Act. We estimate that there

[323] 5 U.S.C. 601.

[324] *See, e.g.,* letters from Am. Bankers, ICBA, NACD, Society of Corp. Sec., and VBA.

[325] 5 U.S.C. 601(6).

[326] 17 CFR 230.157.

[327] 17 CFR 240.0–10(a).

[328] Business development companies are a category of closed-end investment companies that are not required to register under the Investment Company Act [15 U.S.C. 80a–2(a)(48)].

[329] 17 CFR 270.0–10(a).

are approximately 31 business development companies that may be considered small entities.

E. Reporting, Recordkeeping, and Other Compliance Requirements

The disclosure amendments are designed to enhance the disclosure regarding the shareholder advisory votes required by Section 14A of the Exchange Act and provide additional disclosure about golden parachute compensation arrangements. These amendments would require small entities to provide:

- Disclosure of the shareholder advisory votes required by Section 14A and the effects of such votes, including whether they are non-binding;
- Disclosure of golden parachute arrangements described by Section 14A(b)(1) of the Exchange Act in merger proxies, and additional disclosure not required by Section 14A(b)(1) in connection with tender offers and going private transactions; and
- Disclosure of the issuer's decision in light of the shareholder vote on the frequency of shareholder votes to approve executive compensation required by Section 14A(a)(2) of the Exchange Act as to how frequently the issuer will include a shareholder vote on the compensation of executives.

F. Duplicative, Overlapping, or Conflicting Federal Rules

We believe the amendments would not duplicate, overlap, or conflict with other Federal rules.

G. Significant Alternatives

The Regulatory Flexibility Act directs us to consider alternatives that would accomplish our stated objectives, while minimizing any significant adverse impact on small entities. In connection with the disclosure amendments, we considered the following alternatives:

- Establishing different compliance or reporting requirements or timetables that take into account the resources available to small entities;
- Clarifying, consolidating, or simplifying compliance and reporting requirements under the rules for small entities;
- Use of performance rather than design standards; and
- Exempting small entities from all or part of the requirements.

Currently, small entities that are smaller reporting companies under Exchange Act Rule 12b–12 are subject to some different compliance or reporting requirements under Regulation S–K and the amendments will not affect these requirements.[330] Under Regulation S–K, smaller reporting companies are permitted to provide abbreviated compensation disclosure with respect to the principal executive officer and two most highly compensated executive officers for the last two completed fiscal years. Specifically, smaller reporting companies may provide the executive compensation disclosure specified in Items 402(l) through (r) of Regulation S–K, rather than the corresponding disclosure specified in Items 402(a) through (k) of Regulation S–K. Items 402(l) through (r) do not require smaller reporting companies to provide CD&A. Other than the amendments to CD&A, the remaining disclosure requirements apply to smaller reporting companies to the same extent as larger issuers, following the two-year phase-in period for say-on-pay votes and votes on the frequency of say-on-pay votes.

As noted above, the amendments to CD&A do not apply to smaller reporting companies. We are not expanding the existing scaled disclosure requirements under Item 402 of Regulation S–K, or establishing additional different compliance requirements or an exemption from coverage of the proposed amendments for smaller reporting companies. The amendments will provide investors with enhanced disclosure regarding the shareholder votes required by Section 14A of the Exchange Act and the issuers' consideration of the votes.

We are adopting amendments to Item 5 of Schedule 14A, as well as other forms and schedules, to implement and supplement the requirement of Section 14A(b)(1) to provide disclosure of golden parachute compensation arrangements in a clear and simple form. Under the amendments, all companies will be subject to the same golden parachute disclosure requirements. As amended, Schedule 14A will require the disclosure pursuant to Item 402(t) of Regulation S–K with respect to golden parachute compensation arrangements for merger proxies. Though much of the disclosure required by our amendment to Item 5 of Schedule 14A is currently required for all issuers, regardless of size, under our amended rules such disclosure will be required to be included in a tabular format pursuant to Item 402(t) of Regulation S–K, which will include an aggregate total and specific quantification of various compensation elements. All companies, regardless of size, will also be subject to these additional disclosure requirements in connection with other transactions not required by Section 14A(b)(1), including certain tender offers and Rule 13e–3 going-private transactions.

In addition, our amendments will require clear and straightforward disclosure of issuer's responses to shareholder advisory votes, and of golden parachute compensation arrangements in connection with mergers and similar transactions. We have used design rather than performance standards in connection with the amendments because, based on our past experience, we believe the amendments will be more useful to investors if there are specific disclosure requirements. The amendments are intended to result in more comprehensive and clear disclosure. In addition, the specific disclosure requirements in the amendments will promote consistent and comparable disclosure among all companies.

[330] Rule 12b–2 excludes business development companies from the definition of "smaller reporting companies."

VII. Statutory Authority and Text of the Amendments

The amendments described in this release are being adopted under the authority set forth in Section 951 of the Dodd-Frank Wall Street Reform and Consumer Protection Act, Sections 3(b), 6, 7, 10, and 19(a) of the Securities Act of 1933, as amended, and Sections 13, 14(a), 14A, 23(a), and 36 of the Securities Exchange Act of 1934, as amended.

List of Subjects in 17 CFR Parts 229, 240 and 249

Reporting and recordkeeping requirements, Securities.

Text of the Amendments

For the reasons set out in the preamble, the Commission amends title 17, chapter II, of the Code of Federal Regulations as follows:

PART 229—STANDARD INSTRUCTIONS FOR FILING FORMS UNDER SECURITIES ACT OF 1933, SECURITIES EXCHANGE ACT OF 1934 AND ENERGY POLICY AND CONSERVATION ACT OF 1975—REGULATION S–K

■ 1. The general authority citation for part 229 is revised to read as follows:

Authority: 15 U.S.C. 77e, 77f, 77g, 77h, 77j, 77k, 77s, 77z–2, 77z–3, 77aa(25), 77aa(26), 77ddd, 77eee, 77ggg, 77hhh, 777iii, 77jjj, 77nnn, 77sss, 78c, 78i, 78j, 78*l,* 78m, 78n, 78n–1, 78o, 78u–5, 78w, 78*ll,* 78mm, 80a–8, 80a–9, 80a–20, 80a–29, 80a–30, 80a–31(c), 80a–37, 80a–38(a), 80a–39, 80b–11, and 7201 *et seq.;* and 18 U.S.C. 1350, unless otherwise noted.

* * * * *

■ 2. Amend § 229.402 by:
■ a. Revising the last sentence of paragraph (a)(6)(ii);
■ b. Removing "and" at the end of paragraph (b)(1)(v);
■ c. Removing the period and adding in its place "; and" at the end of paragraph (b)(1)(vi);
■ d. Adding paragraph (b)(1)(vii);
■ e. Revising the last sentence of paragraph (m)(5)(ii); and
■ f. Adding paragraph (t).

The revisions read as follows:

§ 229.402 (Item 402) Executive compensation.

(a) * * *

(6) * * *

(ii) * * * Except with respect to the disclosure required by paragraph (t) of this Item, registrants may omit information regarding group life, health, hospitalization, or medical reimbursement plans that do not discriminate in scope, terms or operation, in favor of executive officers or directors of the registrant and that are available generally to all salaried employees.

* * * * *

(b) * * *

(1) * * *

(vii) Whether and, if so, how the registrant has considered the results of the most recent shareholder advisory vote on executive compensation required by section 14A of the Exchange Act (15 U.S.C. 78n–1) or § 240.14a–20 of this chapter in determining compensation policies and decisions and, if so, how that consideration has affected the registrant's executive compensation decisions and policies.

* * * * *

(m) * * *

(5) * * *

(ii) * * * Except with respect to disclosure required by paragraph (t) of this Item, smaller reporting companies may omit information regarding group life, health, hospitalization, or medical reimbursement plans that do not discriminate in scope, terms or operation, in favor of executive officers or directors of the smaller reporting company and that are available generally to all salaried employees.

* * * * *

(t) *Golden Parachute Compensation.* (1) In connection with any proxy or consent solicitation material providing the disclosure required by section 14A(b)(1) of the Exchange Act (15 U.S.C. 78n–1(b)(1)) or any proxy or consent solicitation that includes disclosure under Item 14 of Schedule 14A (§ 240.14a–101) pursuant to Note A of Schedule 14A, with respect to each named executive officer of the acquiring company and the target company, provide the information specified in paragraphs (t)(2) and (3) of this section regarding any agreement or understanding, whether written or unwritten, between such named executive officer and the acquiring company or target company, concerning any type of compensation, whether present, deferred or contingent, that is based on or otherwise relates to an acquisition, merger, consolidation, sale or other disposition of all or substantially all assets of the issuer, as follows:

GOLDEN PARACHUTE COMPENSATION

Name (a)	Cash ($) (b)	Equity ($) (c)	Pension/ NQDC ($) (d)	Perquisites/ benefits ($) (e)	Tax reimbursement ($) (f)	Other ($) (g)	Total ($) (h)
PEO							
PFO							
A							
B							
C							

(2) The table shall include, for each named executive officer:

(i) The name of the named executive officer (column (a));

(ii) The aggregate dollar value of any cash severance payments, including but not limited to payments of base salary, bonus, and pro-rated non-equity incentive compensation plan payments (column (b));

(iii) The aggregate dollar value of:

(A) Stock awards for which vesting would be accelerated;

(B) In-the-money option awards for which vesting would be accelerated; and

(C) Payments in cancellation of stock and option awards (column (c));

(iv) The aggregate dollar value of pension and nonqualified deferred compensation benefit enhancements (column (d));

(v) The aggregate dollar value of perquisites and other personal benefits or property, and health care and welfare benefits (column (e));

(vi) The aggregate dollar value of any tax reimbursements (column (f));

(vii) The aggregate dollar value of any other compensation that is based on or otherwise relates to the transaction not properly reported in columns (b) through (f) (column (g)); and

(viii) The aggregate dollar value of the sum of all amounts reported in columns (b) through (g) (column (h)).

Instructions to Item 402(t)(2).

1. If this disclosure is included in a proxy or consent solicitation seeking approval of an acquisition, merger, consolidation, or proposed sale or other disposition of all or substantially all the assets of the registrant, or in a proxy or consent solicitation that includes disclosure under Item 14 of Schedule 14A (§ 240.14a–101) pursuant to Note A of Schedule 14A, the disclosure provided by this table shall be quantified assuming that the triggering event took place on the latest practicable date, and that the price per share of the registrant's securities shall be determined as follows: If the shareholders are to receive a fixed dollar amount, the price per share shall be that fixed dollar amount, and if such value is not a fixed dollar amount, the price per share shall be the average closing market price of the registrant's securities over the first five business days following the first public announcement of the transaction. Compute the dollar value of in-the-money option awards for which vesting would be accelerated by determining the difference between this price and the exercise or base price of the options. Include only compensation that is based on or otherwise relates to the subject transaction. Apply Instruction 1 to Item 402(t) with respect to those executive officers for whom disclosure was required in the issuer's most recent filing with the Commission

under the Securities Act (15 U.S.C. 77a *et seq.*) or Exchange Act (15 U.S.C. 78a *et seq.*) that required disclosure pursuant to Item 402(c).

2. If this disclosure is included in a proxy solicitation for the annual meeting at which directors are elected for purposes of subjecting the disclosed agreements or understandings to a shareholder vote under section 14A(a)(1) of the Exchange Act (15 U.S.C. 78n–1(a)(1)), the disclosure provided by this table shall be quantified assuming that the triggering event took place on the last business day of the registrant's last completed fiscal year, and the price per share of the registrant's securities is the closing market price as of that date. Compute the dollar value of in-the-money option awards for which vesting would be accelerated by determining the difference between this price and the exercise or base price of the options.

3. In the event that uncertainties exist as to the provision of payments and benefits or the amounts involved, the registrant is required to make a reasonable estimate applicable to the payment or benefit and disclose material assumptions underlying such estimates in its disclosure. In such event, the disclosure would require forward-looking information as appropriate.

4. For each of columns (b) through (g), include a footnote quantifying each separate form of compensation included in the aggregate total reported. Include the value of all perquisites and other personal benefits or property. Individual perquisites and personal benefits shall be identified and quantified as required by Instruction 4 to Item 402(c)(2)(ix) of this section. For purposes of quantifying health care benefits, the registrant must use the assumptions used for financial reporting purposes under generally accepted accounting principles.

5. For each of columns (b) through (h), include a footnote quantifying the amount payable attributable to a double-trigger arrangement (*i.e.,* amounts triggered by a change-in-control for which payment is conditioned upon the executive officer's termination without cause or resignation for good reason within a limited time period following the change-in-control), specifying the time-frame in which such termination or resignation must occur in order for the amount to become payable, and the amount payable attributable to a single-trigger arrangement (*i.e.,* amounts triggered by a change-in-control for which payment is not conditioned upon such a termination or resignation of the executive officer).

6. A registrant conducting a shareholder advisory vote pursuant to § 240.14a–21(c) of this chapter to cover new arrangements and understandings, and/or revised terms of agreements and understandings that were previously subject to a shareholder advisory vote pursuant to § 240.14a–21(a) of this chapter, shall provide two separate tables. One table shall disclose all golden parachute compensation, including both the arrangements and amounts previously disclosed and subject to a shareholder advisory vote under section 14A(a)(1) of the Exchange Act (15 U.S.C. 78n–1(a)(1)) and § 240.14a–21(a) of this chapter and the new arrangements and understandings and/or revised terms of agreements and understandings that were previously subject to a shareholder advisory vote. The second table shall disclose only the new arrangements and/or revised terms subject to the separate shareholder vote under section 14A(b)(2) of the Exchange Act and § 240.14a–21(c) of this chapter.

7. In cases where this Item 402(t)(2) requires disclosure of arrangements between an acquiring company and the named executive officers of the soliciting target company, the registrant shall clarify whether these agreements are included in the separate shareholder advisory vote pursuant to § 240.14a–21(c) of this chapter by providing a separate table of all agreements and understandings subject to the shareholder advisory vote required by section 14A(b)(2) of the Exchange Act (15 U.S.C. 78n–1(b)(2)) and § 240.14a–21(c) of this chapter, if different from the full scope of golden parachute compensation subject to Item 402(t) disclosure.

(3) Provide a succinct narrative description of any material factors necessary to an understanding of each such contract, agreement, plan or arrangement and the payments quantified in the tabular disclosure required by this paragraph. Such factors shall include, but not be limited to a description of:

(i) The specific circumstances that would trigger payment(s);

(ii) Whether the payments would or could be lump sum, or annual, disclosing the duration, and by whom they would be provided; and

(iii) Any material conditions or obligations applicable to the receipt of payment or benefits, including but not limited to non-compete, non-solicitation, non-disparagement or confidentiality agreements, including the duration of such agreements and provisions regarding waiver or breach of such agreements.

Instructions to Item 402(t).

1. A registrant that does not qualify as a "smaller reporting company," as defined by § 229.10(f)(1) of this chapter, must provide the information required by this Item 402(t) with respect to the individuals covered by Items 402(a)(3)(i), (ii) and (iii) of this section. A registrant that qualifies as a "smaller reporting company," as defined by § 229.10(f)(1) of this chapter, must provide the information required by this Item 402(t) with respect to the individuals covered by Items 402(m)(2)(i) and (ii) of this section.

2. The obligation to provide the information in this Item 402(t) shall not apply to agreements and understandings described in paragraph (t)(1) of this section with senior management of foreign private issuers, as defined in § 240.3b–4 of this chapter.

■ 3. Amend § 229.1011 by redesignating paragraph (b) as paragraph (c) and adding new paragraph (b) to read as follows:

§ 229.1011 (Item 1011) Additional information.

* * * * *

(b) Furnish the information required by Item 402(t)(2) and (3) of this part (§ 229.402(t)(2) and (3)) and in the tabular format set forth in Item 402(t)(1) of this part (§ 229.402(t)(1)) with respect to each named executive officer

(1) Of the subject company in a Rule 13e–3 transaction; or

(2) Of the issuer whose securities are the subject of a third-party tender offer, regarding any agreement or understanding, whether written or unwritten, between such named executive officer and the subject company, issuer, bidder, or the acquiring company, as applicable, concerning any type of compensation, whether present, deferred or contingent, that is based upon or otherwise relates to the Rule 13e–3 transaction or third-party tender offer.

Instructions to Item 1011(b).

1. The obligation to provide the information in paragraph (b) of this section shall not apply where the issuer whose securities are the subject of the Rule 13e–3 transaction or tender offer is a foreign private issuer, as defined in § 240.3b–4 of this chapter.

2. For purposes of Instruction 1 to Item 402(t)(2) of this part: If the disclosure is included in a Schedule 13E–3 (§ 240.13e–100 of this chapter) or Schedule 14D–9 (§ 240.14d–101 of this chapter), the disclosure provided by this table shall be quantified assuming that the triggering event took place on the latest practicable date and that the price per share of the securities of the subject

company in a Rule 13e–3 transaction, or of the issuer whose securities are the subject of the third-party tender offer, shall be determined as follows: If the shareholders are to receive a fixed dollar amount, the price per share shall be that fixed dollar amount, and if such value is not a fixed dollar amount, the price per share shall be the average closing market price of such securities over the first five business days following the first public announcement of the transaction. Compute the dollar value of in-the-money option awards for which vesting would be accelerated by determining the difference between this price and the exercise or base price of the options. Include only compensation that is based on or otherwise relates to the subject transaction. Apply Instruction 1 to Item 402(t) with respect to those executive officers for whom disclosure was required in the most recent filing by the subject company in a Rule 13e–3 transaction or by the issuer whose securities are the subject of a third-party tender offer, with the Commission under the Securities Act (15 U.S.C. 77a *et seq.*) or Exchange Act (15 U.S.C. 78a *et seq.*) that required disclosure pursuant to Item 402(c).

* * * * *

PART 240—GENERAL RULES AND REGULATIONS, SECURITIES EXCHANGE ACT OF 1934

■ 4. The general authority citation for part 240 is revised to read as follows:

Authority: 15 U.S.C. 77c, 77d, 77g, 77j, 77s, 77z–2, 77z–3, 77eee, 77ggg, 77nnn, 77sss, 77ttt, 78c, 78d, 78e, 78f, 78g, 78i, 78j, 78j–1, 78k, 78k–1, 78*l,* 78m, 78n, 78n–1, 78o, 78o–4, 78p, 78q, 78s, 78u–5, 78w, 78x, 78*ll,* 78mm, 80a–20, 80a–23, 80a–29, 80a–37, 80b–3, 80b–4, 80b–11, and 7201 *et seq.,* 18 U.S.C. 1350, and 12 U.S.C. 5221(e)(3), unless otherwise noted.

* * * * *

■ 5. Amend § 240.13e–100 by revising Item 15 to read as follows:

* * * * *

§ 240.13e–100 Schedule 13E–3, Transaction statement under section 13(e) of the Securities Exchange Act of 1934 and Rule 13e–3 (§ 240.13e–3) thereunder.

* * * * *

Item 15. Additional Information

Furnish the information required by Item 1011(b) and (c) of Regulation M–A (§ 229.1011(b) and (c) of this chapter).

* * * * *

■ 6. Amend § 240.14a–4 by:

■ a. Adding the phrase "and votes to determine the frequency of shareholder votes on executive compensation pursuant to § 240.14a–21(b) of this chapter" at the end of the first sentence of paragraph (b)(1);

■ b. Adding paragraph (b)(3).

The addition reads as follows:

§ 240.14a–4 Requirements as to proxy.

* * * * *

(b) * * *

(3) A form of proxy which provides for a shareholder vote on the frequency of shareholder votes to approve the compensation of executives required by section 14A(a)(2) of the Securities Exchange Act of 1934 (15 U.S.C. 78n–1(a)(2)) shall provide means whereby the person solicited is afforded an opportunity to specify by boxes a choice among 1, 2 or 3 years, or abstain.

* * * * *

■ 7. Amend § 240.14a–6 by:

■ a. Revising paragraph (a)(7); and

■ b. Adding the phrase "to paragraph (a)" following the words "Note 1", "Note 2", "Note 3" and "Note 4".

The revision reads as follows:

§ 240.14a–6 Filing requirements.

(a) * * *

(7) A vote to approve the compensation of executives as required pursuant to section 14A(a)(1) of the Securities Exchange Act of 1934 (15 U.S.C. 78n–1(a)(1)) and § 240.14a–21(a) of this chapter, or pursuant to section 111(e)(1) of the Emergency Economic Stabilization Act of 2008 (12 U.S.C. 5221(e)(1)) and § 240.14a–20 of this chapter, a vote to determine the frequency of shareholder votes to approve the compensation of executives as required pursuant to Section 14A(a)(2) of the Securities Exchange Act of 1934 (15 U.S.C. 78n–1(a)(2)) and § 240.14a–21(b) of this chapter, or any other shareholder advisory vote on executive compensation.

* * * * *

■ 8. Amend § 240.14a–8 by adding *Note to paragraph (i)(10)* to read as follows:

§ 240.14a–8 Shareholder proposals.

* * * * *

(i) * * *

(10) * * *

Note to paragraph (i)(10): A company may exclude a shareholder proposal that would provide an advisory vote or seek future advisory votes to approve the compensation of executives as disclosed pursuant to Item 402 of Regulation S–K (§ 229.402 of this chapter) or any successor to Item 402 (a "say-on-pay vote") or that relates to the frequency of say-on-pay votes, provided that in the most recent shareholder vote required by § 240.14a–21(b) of this chapter a single year (*i.e.,* one, two, or three years) received approval of a majority of votes cast on the matter and the company has adopted a policy on the frequency of say-on-pay votes that is consistent with the choice of the majority of votes cast in the most recent shareholder vote required by § 240.14a–21(b) of this chapter.

* * * * *

■ 9. Add § 240.14a–21 to read as follows:

§ 240.14a–21 Shareholder approval of executive compensation, frequency of votes for approval of executive compensation and shareholder approval of golden parachute compensation.

(a) If a solicitation is made by a registrant and the solicitation relates to an annual or other meeting of shareholders at which directors will be elected and for which the rules of the Commission require executive compensation disclosure pursuant to Item 402 of Regulation S–K (§ 229.402 of this chapter), the registrant shall, for the first annual or other meeting of shareholders on or after January 21, 2011, or for the first annual or other meeting of shareholders on or after January 21, 2013 if the registrant is a smaller reporting company, and thereafter no later than the annual or other meeting of shareholders held in the third calendar year after the immediately preceding vote under this subsection, include a separate resolution subject to shareholder advisory vote to approve the compensation of its named executive officers, as disclosed pursuant to Item 402 of Regulation S–K.

Instruction to paragraph (a):

The registrant's resolution shall indicate that the shareholder advisory vote under this subsection is to approve the compensation of the registrant's named executive officers as disclosed pursuant to Item 402 of Regulation S–K (§ 229.402 of this chapter). The following is a non-exclusive example of a resolution that would satisfy the requirements of this subsection: "RESOLVED, that the compensation paid to the company's named executive officers, as disclosed pursuant to Item 402 of Regulation S–K, including the Compensation Discussion and Analysis, compensation tables and narrative discussion is hereby APPROVED."

(b) If a solicitation is made by a registrant and the solicitation relates to an annual or other meeting of shareholders at which directors will be elected and for which the rules of the Commission require executive compensation disclosure pursuant to Item 402 of Regulation S–K (§ 229.402 of this chapter), the registrant shall, for the first annual or other meeting of shareholders on or after January 21, 2011, or for the first annual or other

meeting of shareholders on or after January 21, 2013 if the registrant is a smaller reporting company, and thereafter no later than the annual or other meeting of shareholders held in the sixth calendar year after the immediately preceding vote under this subsection, include a separate resolution subject to shareholder advisory vote as to whether the shareholder vote required by paragraph (a) of this section should occur every 1, 2 or 3 years. Registrants required to provide a separate shareholder vote pursuant to § 240.14a–20 of this chapter shall include the separate resolution required by this section for the first annual or other meeting of shareholders after the registrant has repaid all obligations arising from financial assistance provided under the TARP, as defined in section 3(8) of the Emergency Economic Stabilization Act of 2008 (12 U.S.C. 5202(8)), and thereafter no later than the annual or other meeting of shareholders held in the sixth calendar year after the immediately preceding vote under this subsection.

(c) If a solicitation is made by a registrant for a meeting of shareholders at which shareholders are asked to approve an acquisition, merger, consolidation or proposed sale or other disposition of all or substantially all the assets of the registrant, the registrant shall include a separate resolution subject to shareholder advisory vote to approve any agreements or understandings and compensation disclosed pursuant to Item 402(t) of Regulation S–K (§ 229.402(t) of this chapter), unless such agreements or understandings have been subject to a shareholder advisory vote under paragraph (a) of this section. Consistent with section 14A(b) of the Exchange Act (15 U.S.C. 78n–1(b)), any agreements or understandings between an acquiring company and the named executive officers of the registrant, where the registrant is not the acquiring company, are not required to be subject to the separate shareholder advisory vote under this paragraph.

Instructions to § 240.14a–21:

1. Disclosure relating to the compensation of directors required by Item 402(k) (§ 229.402(k) of this chapter) and Item 402(r) of Regulation S–K (§ 229.402(r) of this chapter) is not subject to the shareholder vote required by paragraph (a) of this section. If a registrant includes disclosure pursuant to Item 402(s) of Regulation S–K (§ 229.402(s) of this chapter) about the registrant's compensation policies and practices as they relate to risk management and risk-taking incentives, these policies and practices would not be subject to the shareholder vote required by paragraph (a) of this section. To the extent that risk considerations are a material aspect of the registrant's compensation policies or decisions for named executive officers, the registrant is required to discuss them as part of its Compensation Discussion and Analysis under § 229.402(b) of this chapter, and therefore such disclosure would be considered by shareholders when voting on executive compensation.

2. If a registrant includes disclosure of golden parachute compensation arrangements pursuant to Item 402(t) (§ 229.402(t) of this chapter) in an annual meeting proxy statement, such disclosure would be subject to the shareholder advisory vote required by paragraph (a) of this section.

3. Registrants that are smaller reporting companies entitled to provide scaled disclosure in accordance with Item 402(*l*) of Regulation S–K (§ 229.402(*l*) of this chapter) are not required to include a Compensation Discussion and Analysis in their proxy statements in order to comply with this section. For smaller reporting companies, the vote required by paragraph (a) of this section must be to approve the compensation of the named executive officers as disclosed pursuant to Item 402(m) through (q) of Regulation S–K (§ 229.402(m) through (q) of this chapter).

■ 10. Amend § 240.14a–101 by:

■ a. Removing the dash that appears before paragraph (a) of Item 5 and adding in its place an open parenthesis;

■ b. Adding paragraph (a)(5) of Item 5;

■ c. Adding the phrase "to paragraph (a)" following the word "Instruction" that follows new paragraph (a)(5) of Item 5;

■ d. Adding paragraph (b)(3) of Item 5;

■ e. Adding the phrase "to paragraph (b)" following the word "Instruction" that follows new paragraph (b)(3) of Item 5;

■ f. Adding Item 24.

The additions read as follows:

§ 240.14a–101 Schedule 14A. Information required in proxy statement.

SCHEDULE 14A. INFORMATION

* * * * *

Item 5. Interest of Certain Persons in Matters to Be Acted Upon.

(a) * * *

(5) If the solicitation is made on behalf of the registrant, furnish the information required by Item 402(t) of Regulation S–K (§ 229.402(t) of this chapter).

* * * * *

(b) * * *

(3) If the solicitation is made on behalf of the registrant, furnish the information required by Item 402(t) of Regulation S–K (§ 229.402(t) of this chapter).

* * * * *

Item 24. Shareholder Approval of Executive Compensation. Registrants required to provide any of the separate shareholder votes pursuant to § 240.14a–21 of this chapter shall disclose that they are providing each such vote as required pursuant to section 14A of the Securities Exchange Act (15 U.S.C. 78n–1), briefly explain the general effect of each vote, such as whether each such vote is non-binding, and, when applicable, disclose the current frequency of shareholder advisory votes on executive compensation required by Rule 14a–21(a) and when the next such shareholder advisory vote will occur.

■ 11. Amend § 240.14c–101 by adding paragraph (c) of Item 3 to read as follows:

§ 240.14c–101 Schedule 14C. Information required in information statement.

SCHEDULE 14C. INFORMATION

* * * * *

Item 3. * * *

(c) Furnish the information required by Item 402(t) of Regulation S–K (§ 229.402(t) of this chapter).

* * * * *

■ 12. Amend § 240.14d–100 by revising Item 11 to read as follows:

§ 240.14d–100 Tender offer statement pursuant to section 14(d)(1) of the Securities Exchange Act of 1934.

* * * * *

Item 11. Additional Information.

Furnish the information required by Item 1011(a) and (c) of Regulation M–A (§ 229.1011 of this chapter).

* * * * *

■ 13. Amend § 240.14d–101 by amending Item 8 to add the words "and (c)" after "Item 1011(b)".

PART 249—FORMS, SECURITIES EXCHANGE ACT OF 1934

■ 14. The general authority citation for part 249 continues to read as follows:

Authority: 15 U.S.C. 78a *et seq.* and 7201 *et seq.;* and 18 U.S.C. 1350, unless otherwise noted.

* * * * *

■ 15. Amend Form 8–K (referenced in § 249.308), Item 5.07, by revising paragraph (b), adding paragraph (d), and revising Instruction 1 to read as follows:

Note: The text of Form 8–K does not, and this amendment will not, appear in the Code of Federal Regulations.

Form 8–K

* * * * *

Item 5.07. Submission of Matters to a Vote of Security Holders

* * * * *

(b) If the meeting involved the election of directors, the name of each director elected at the meeting, as well as a brief description of each other matter voted upon at the meeting; and state the number of votes cast for, against or withheld, as well as the number of abstentions and broker non-votes as to each such matter, including a separate tabulation with respect to each nominee for office. For the vote on the frequency of shareholder advisory votes on executive compensation required by section 14A(a)(2) of the Securities Exchange Act of 1934 (15 U.S.C. 78n–1) and § 240.14a–21(b), state the number of votes cast for each of 1 year, 2 years, and 3 years, as well as the number of abstentions.

* * * * *

(d) No later than one hundred fifty calendar days after the end of the annual or other meeting of shareholders at which shareholders voted on the frequency of shareholder votes on the compensation of executives as required by section 14A(a)(2) of the Securities Exchange Act of 1934 (15 U.S.C. 78n–1), but in no event later than sixty calendar days prior to the deadline for submission of shareholder proposals under § 240.14a–8, as disclosed in the registrant's most recent proxy statement for an annual or other meeting of shareholders relating to the election of directors at which shareholders voted on the frequency of shareholder votes on the compensation of executives as required by section 14A(a)(2) of the Securities Exchange Act of 1934 (15 U.S.C. 78n–1(a)(2)), by amendment to the most recent Form 8–K filed pursuant to (b) of this Item, disclose the company's decision in light of such vote as to how frequently the company will include a shareholder vote on the compensation of executives in its proxy materials until the next required vote on the frequency of shareholder votes on the compensation of executives.

* * * * *

Instruction 1 to Item 5.07. The four business day period for reporting the event under this Item 5.07, other than with respect to Item 5.07(d), shall begin to run on the day on which the meeting ended. * * *

* * * * *

By the Commission.

Dated: January 25, 2011.

Elizabeth M. Murphy,

Secretary.

[FR Doc. 2011–1971 Filed 2–1–11; 8:45 am]

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This is a continuing list of public bills from the current session of Congress which have become Federal laws. It may be used in conjunction with "P L U S" (Public Laws Update Service) on 202–741–6043. This list is also available online at *http://www.archives.gov/federal-register/laws.html*.

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To amend the Federal Water Pollution Control Act to clarify Federal responsibility for stormwater pollution. (Jan. 4, 2011; 124 Stat. 4128)

S. 3592/P.L. 111–379
To designate the facility of the United States Postal Service located at 100 Commerce Drive in Tyrone, Georgia, as the "First Lieutenant Robert Wilson Collins Post Office Building". (Jan. 4, 2011; 124 Stat. 4130)

S. 3874/P.L. 111–380
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S. 3903/P.L. 111–381
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S. 4036/P.L. 111–382
To clarify the National Credit Union Administration authority to make stabilization fund expenditures without borrowing from the Treasury. (Jan. 4, 2011; 124 Stat. 4134)

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